Naveen

From: "msfh-india-medco-assist" <msfh-india-medco-assist@field.amsterdam.msf.org>
To: <mirashiva@yahoo.com>; <prasanna_aid@yahoo.com>; <naveen@sochara.org>; <gopa.kumar@centad.org>; <drdabade@gmail.com>; <sahajbrc@icenet.co.in>; <bodhi_fha@dataone.in>; "Anurag Bhargava" <madhurag_bhargava@rediffmail.com>; "sahajbrc" <sahaj2006@dataone.in>; "Anant Phadke" <amol_p@vsnl.com>; <pc@lawyerscollective.org>; "Kajal Bhardwaj" <k0b0@yahoo.com>; "aidslaw" <aidslaw@lawyerscollective.org>; "Y K SAPRU" <yksapru@cpaaindia.org>; "Loone Gante" <loon_gangte@yahoo.com>; "chan park" <chansoobak@yahoo.com>; "dr. sathyamala" <csathyamala@gmail.com>
Cc: <Ellen.T.HOEN@paris.msf.org>; "Fernando PASCUAL" <Fernando.PASCUAL@geneva.msf.org>; <pascale.boulet@geneva.msf.org>; "MSFH-India-Hom" <msfh-india-hom@field.amsterdam.msf.org>; "Ramya Sheshadri" <biotechramya@gmail.com>; "prafulla saligram" <prapulli@gmail.com>; "Julie George" <george.julie@gmail.com>; <rattan_mnp@yahoo.co.in>; <ncpplus2003@yahoo.com>; <kkabraham@inpplus.net>; "Bappaditya Mukherjee" <bappaditya_mukherjee@yahoo.co.in>; "SAATHII" <saathii@yahoo.com>; "vinod" <vinudirect@gmail.com>; <daisy@inpplus.net>; "msfh-india-medco-assist" <msfh-india-medco-assist@field.amsterdam.msf.org>; <priya.pillai@centad.org>
Sent: 08 March 2007 12:04
Attach: attachments.zip
Subject: draft agenda stakeholders meeting, 12 & 13 march, mumbai

Dear mr. sapru, anant, chinu, mira, dr. sathya, prasanna, dr.dabade, abraham, loon and others,

many of you have requested a copy of the agenda. i am attaching the draft agenda. I hope that this meeting brings together for the first time many from all those organisations (and individuals) in india who are deeply connected by their work on access to treatment. the coming month is a crucial time with the novartis case, moxifloxacin opposition coming up. the ministry of chemicals and fertilizers is drafting a new pharma policy, proposing a unified regulatory authority and also finalising recommendations on data exclusivity.

ministry of health officials who understood the link between intellectual propoerty laws & prices and who were proposing a meeting on price control have been transferred. minstry of commerce is quitely rewriting the mashelkar report.

keeping in mind all this and many other developments that I may not be aware of i hope this meeting is the first among others to discuss concerns and issues related to affordable prices of medicines.

hope to see you all at the meeting,

the venue of the meeting is West End Hotel located in new marine lines, opposite bombay hospital.

Warm Regards,

Leena Menghaney
Campaign for Access to Essential Medicines
Medecins Sans Frontieres
C 106 Defence Colony
New Delhi 110 014
Tel: +91 9811365412, +91 1124332419

Draft Agenda

Stakeholders workshop on Pre-grant Patent Oppositions and other issues related to drug regulation and prices

12 & 13th March 2007, West End Hotel, Mumbai
Terrace Hall, West End Hotel

Objective of the meeting is to bring together stakeholders involved in research, advocacy, legal, technical and communication work related to access to treatment issues in India. Key stakeholders are health movement experts, patient groups, legal and community based organisations. Some of the issues of concern are related to law reform and implementation of the product patent regime with respect to its impact on the production of essential drugs by India for its people and patients in other developing countries. Advocacy and communication strategies focusing on bringing about mobilization and raising public debate around these issues are key to the success of this workshop.

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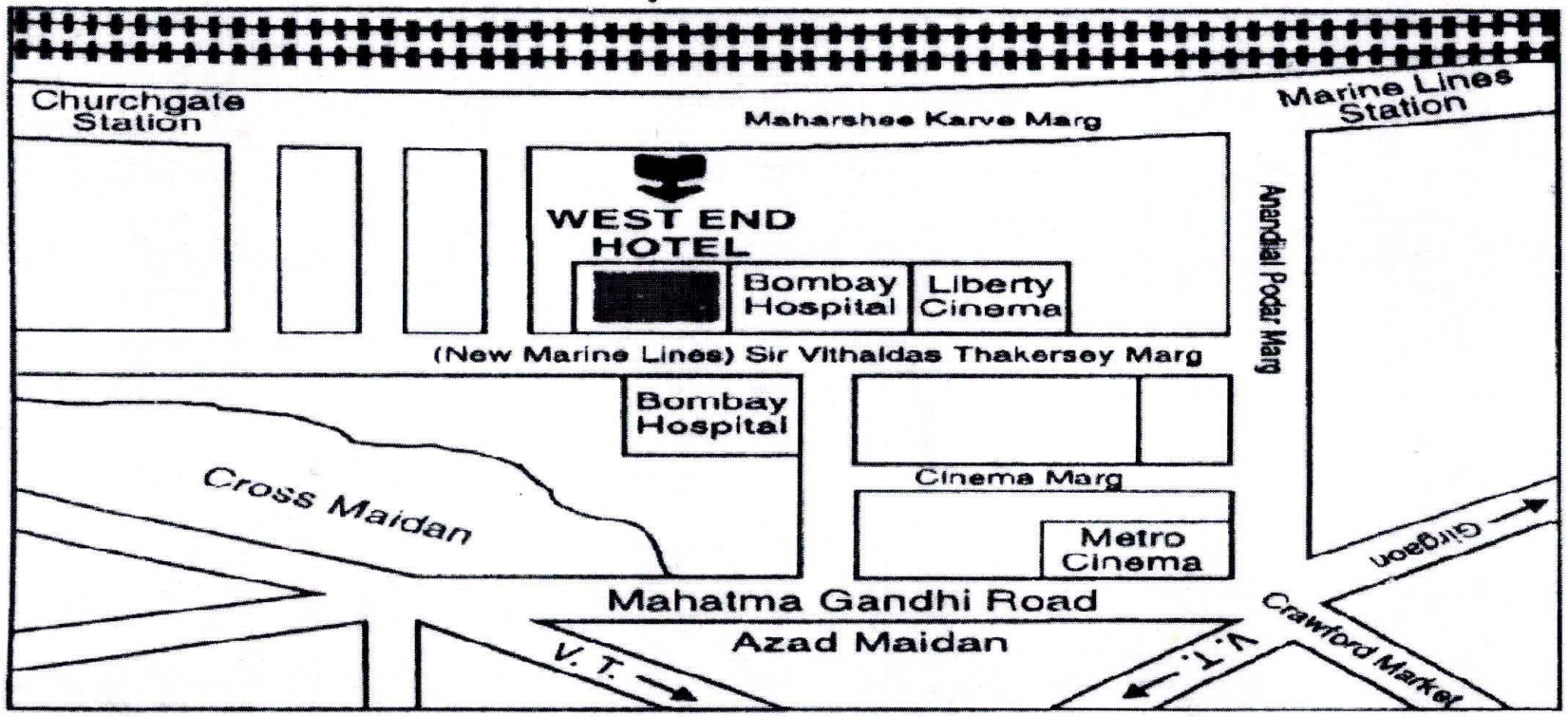
From: "msfh-india-medco-assist" <msfh-india-medco-assist@field.amsterdam.msf.org>
To: "Bappaditya Mukherjee" <bappaditya_mukherjee@yahoo.co.in>; <csathyamala@gmail.com>; "Gopa Kumar" <gopa.kumar@centad.org>; <ncpplus2003@yahoo.com>; <kkabraham@inpplus.net>; "MSFH-India-Hom" <msfh-india-hom@field.amsterdam.msf.org>; "Kausalya" <kousalya@pwnplus.org>; "Loone Gante" <loon_gangte@yahoo.com>; "DNP+" <dnpplus@yahoo.co.in>; <mirashiva@yahoo.com>; <upnpplus@yahoo.co.in>; "Naveen_CHC" <naveen@sochara.org>; <priya.pillai@centad.org>; <rattan_mnp@yahoo.co.in>; <reenageorge@vsnl.com>; "siddharth narrain" <siddharth.narrain@gmail.com>; "Subhadip Roy" <subhadip_roy_04@yahoo.com>; "vinod" <vinudirect@gmail.com>
Cc: "msfh-india-medco-assist" <msfh-india-medco-assist@field.amsterdam.msf.org>; "Mai DO" <Mai.DO@paris.msf.org>
Sent: Thursday, March 08, 2007 1:02 PM
Subject: Staekholders Workshop in Mumbai, Directions to the venue

> Dear all,
>
> The venue for the 12 & 13th March Stakeholders Workshop on pre-grant patent
> oppositions is the West End Hotel, New Marine Lines, Mumbai. It is opposite
> to the Bombay Hospital and adjacent to the Liberty Cinema. Contact No. of
> the hotel is 022-22039121. For further details please see attached map. Taxi
> to the venue from the airport will cost approximately about Rs. 300.
>
> Please feel free to contact us for any other assistance, 09871800723.
>
> Saral Kumar
> Project Assistant
> Campaign for Access to Essential Medicines
> Medecins Sans Frontieres - Holland (in India)
> Tel: +91 11 24337225, + 91 1151552413
> Fax: +91 11 24336834
> E-mail: msfh-india-medco-assist@field.amsterdam.msf.org

West End Hotel

45, New Marine Lines, Mumbai - 400 020
Tel. : 2203 9121
Fax : 91-22-2205 7506
E-mail : westhotel@hathway.com • Website : www.westendhotelmumbai.com



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----- Original Message -----
From: msfh-india-medco-assist
To: sahajbrc@yahoo.com ; sahajbrc@icenet.co.in ; Prasanna Saligram ; Naveen_CHC ; Anurag Bhargava ; dr. sathyamala ; amol_p@gmail.com
Sent: Tuesday, February 27, 2007 7:14 PM
Subject: Stakeholders Workshop on Pre-grant Oppositions, 12 & 13 March 07

dear AIDAN - dr. dabade, chinu, anurag, dr. sathya, anant, prasanna, naveen

In the last two years much work related to patent oppositions (technical, legal, advocacy, communication) has been undertaken by public interest organisations in India. along the way expertise and information has been built which needs to be shared. many pertinent queries come up repeatedly which also require discussion and understanding.

While many of us work in close alliance with each other, developments on patent oppositions (from identifying patent applications, filing, patent office hearings, the novartis case) have increased the need to meet and plan technical/legal work, advocacy and strategy on the same.

in this regard, the campaign for access to essential medicines seeks to hold a Stakeholders Workshop on Pre-grant Oppositions, on 12 & 13 March 07 in Mumbai (West End Hotel). we request you to block the dates. a background document is copied below and the agenda will below.

On cofirmation, we will make the necessary travel arrangements for participants. Accomodation is being arranged in the West End Hotel.

Please do get back to me,

Leena Menghaney
Campaign for Access to Essential Medicines
Medecins Sans Frontieres
C 106 Defence Colony
New Delhi 110 014
Tel: +91 9811365412, +91 1124332419

As decided in the Annual meet of AIDAN held in Bangalore (Dec'06), (On behalf of AIDAN) I am working ~ Lawyer's Collective in Bangalore on filing the pre-grant opposition for Moxifloxacin. We have already brought out a FAQ, and draft petition is ready. The opposition will be filed in Delhi, after this meeting.

Naveen
28/2/07

Background Note for Stakeholders Workshop on Pre-grant Oppositions, 12 & 13 March 07

Two years ago in March 2005, Indian Parliament approved the country's new Patent Act, thereby allowing pharmaceutical products (medicines) to be patented in India. This new law put some serious constraints on local production of drugs (generic competition) but also had some potentially important features.

The Indian Patent Act, if rigorously interpreted, provides several grounds for rejecting a patent, for instance if the pharmaceutical substance claimed is only a new form of a known substance - a unique provision which attempts to prevent the common practice of "ever greening" of patents and minor incremental changes to known substances. The law also provides for formal proceedings for anyone to object to a patent before it is granted.

Public interest groups realizing the potential of these provisions started to compile information on essential drugs on which patent applications were pending. Organizations like the Lawyers Collective, Alternative Law Forum and the Access Campaign (MSF) also came forward with legal aid and technical support for the drafting and filing of the patent oppositions on these essential drugs.

Consequently, the first opposition by a patient organization the Cancer Patient Aid Association (CPAA) was filed in September 05 on the anti-cancer drug "imitinib mesylate" (Gleevec). In January 06, as a result of the opposition filed by CPAA, the Indian Patent Office in Chennai issued a decision rejecting Novartis' patent application for the anti-cancer drug Gleevec. The significance of the above decision and the right to oppose patents before their grant cannot be understated. Firstly it enabled generic producers to continue producing affordable versions of "Gleevec" at a fraction of the price that Novartis sells it. It further set a legal precedent for the rejection of new forms, new use, and new combinations of existing and known medicines.

In 2006, Indian Network for People Living with HIV/AIDS and other state level PLHA networks legally opposed 13 key patent applications related to HIV/AIDS drugs and also publicly advocated against the grant of these AIDS related patent applications. As a result Glaxo withdrew one of the applications related to a lamivudine/zidovudine patent application. Further, Mumbai patent office also shared information that Abbott Co. Ltd had abandoned the ritonavir-lopinavir soft gel patent application. The other applications are being examined and will soon be up for hearings before the patent controller of the respective patent office.

Many other public interest groups are also getting involved in the patent opposition of essential drugs. The all India Drug Action Network is taking up the legal patent opposition of a key TB medicine. Others like the Torchbearers are keen to start the work on identifying patent applications related to psychotropic drugs used in the treatment of mental illness.

Besides the patent oppositions, other developments such as an ongoing legal challenge brought by Swiss pharmaceutical company Novartis. Novartis has legally challenged in the Chennai High Court the public health safeguard in India's Patent Act - a provision that stipulates that patents should only be granted on medicines that are truly new and

innovative. This provision lays down that companies should not be able to obtain patents in India for medicines that are not actual inventions, such as drug combinations or slightly improved formulations of existing medicines.

> e.g. In 1985 zidovudine a drug invented in the 1960s, was patented for a new use – 'AIDS treatment'. This patent granted first in the U.S blocked access to the crucial drug zidovudine for nearly a decade till Indian pharmaceutical companies in the absence of a local patent in India started manufacturing and exporting it at competitive prices to developing countries.

Therefore Indian Patent law (section 3d) was specifically targeted at preventing a common practice used by drug companies of trying to get additional patents on insignificant improvements of drugs. The provision was an effort to reward innovation, which is the rationale of the patent system to begin with. It also aimed to ensure that patents do not unnecessarily restrict access to medicines.

Public interest groups like Centre for Trade and Development (CENTAD), People s Health Movement and many other organisations are supporting a people s campaign asking Novartis to drop the case and to raise awareness in India regarding its potential to severely affect access to affordable essential medicines for millions of people across the developing world. The court hearings in Chennai are coming to an end and a judgement is expected in March 07 itself. Novartis is likely to appeal the dismissal of the challenge in the Supreme Court of India. Public interest groups are also likely to appeal any decision that dilutes section 3(d).

The technical and legal process of identifying patent applications on essential drugs, drafting and filing of the patent opposition, the hearings at the patent office have raised many queries among organisations and individuals involved in the advocacy-legal work around the patent oppositions on essential drugs.

With the aim of sharing information and expertise on the patent oppositions, the Campaign for Access to Essential Medicines would like to organise a workshop for organisations and networks involved in this work for the past three years. The workshop also provides an opportunity to meet and formulate joint advocacy, legal and communication strategies around the patents oppositions and the Novartis case.

Agenda will follow.

Leena Menghaney
Campaign for Access to Essential Medicines
Medecins Sans Frontieres
C 106 Defence Colony
New Delhi 110 014
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All India Drug Action Network (AIDAN)

Towards a people oriented, rational, drug policy!

AIDAN Statement **26 February 2007**

The Report of the Technical Expert Group on Patent Law Issues - A Retrograde Step

The group must not be allowed to re-submit the report. The matter must be referred to a Parliamentary Standing Committee.

It is regrettable that a group such as the *Technical Expert Group on Patent Law Issues*, comprising of such highly regarded persons in the country should submit a report with several sentences identical to submissions made by an interest group. This could lead to questions about the interests and motives about the group. The fact that certain sentences were quoted verbatim is a crucial issue, and cannot be taken merely as an error of omission.

While welcoming the move to withdraw the *Report of the Technical Expert Group on Patent Law Issues*, we would like to draw the attention back to the other contents of the report. The report of the group headed by Dr. R.A. Mashelkar, which was submitted in December 2006 is high on rhetoric and contains many unsubstantiated claims which can have **serious implications on people's access to medicines**. While the terms of reference of the group was to clarify the legal position with respect to TRIPS, the report has gone beyond its mandate and has attempted to **compromise public health** which will seriously hurt national interests in the long term.

The report rhetorically states, "*every effort should be made to prevent the grant of frivolous patents and 'ever-greening'*", but condemns the very provisions in the Indian Patents Act which were framed to prevent ever-greening. The report also states "*Article 7 and 8 as well as Doha Declaration on TRIPS Agreement and public health cannot be used to derogate the mandate under Article 27*", but **fails to explain the reasons** or basis for such an argument.

Grant of patent is based on applicant's ability to satisfy patentability criteria and any other relevant requirements. According to Article 27 patents are granted to an invention. Significantly TRIPS does not offer any definition for invention and gives freedom to member states to determine the meaning of invention and that too when they satisfy all three criteria i.e. novelty, inventive step and industrial application. This gives an opportunity to the implementing country to determine the scope of

Addresses for Correspondence:
Mira Shiva, A-60, Hauz Khas, New Delhi. Tel: 011-26855010, 09810582028. Email: mirashiva@yahoo.com
Gopal Dabade, 57, Tejaswinagar, Dharwad 580002. Tel: 0836-2461722, 09448862270. Email: drdabade@gmail.com

patentability i.e. whether it should be limited to new chemical entities or whether it can also include incremental innovations (not inventions).

The Article 27 of TRIPS quoted by the group prohibits discrimination of availability and enjoyment of patent rights on the ground of place of invention, field of technology, place of manufacture. Here, the prohibition is only against discrimination on the above grounds and not on differentiation. The WTO Disputes Panel also recognized this reasoning in the EC–Canada Case (WT/DS 114). Therefore **limiting the scope of patentability to new chemical entities does not violate the obligation of non-discrimination** as to the field of technology under Article 27(1).

The Doha Declaration on TRIPS agreement states, "*We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all*"(Para 4). There is no doubt that measurers like limiting the scope of patentability to new chemical entities will protect public health by providing space to generic companies to legally produce drugs and promote access to medicines. By ignoring these crucial commitments in the Doha Declaration on TRIPS Agreement, the group **tries to devalue the importance of the Doha declaration**.

In an ambiguous section titled "national interest perspective", to support its view on patent protection for incremental modifications/ innovations, the group does not make a single reference to public health concerns, leading one to question **whether public health is not a factor while considering national interest.**

In light of the above points, we submit that the *Report of the Technical Expert Group on Patent Law Issues* is a retrograde step in the discourse on patents in India, and call for a complete rejection of the report in its present form. In addition, since the group report has been found to contain several sentences identical to submissions made by an interest group, it would not be fair to continue with the group, as it could lead to questions about the interests and motives about the group. Hence the group should not be allowed to re-submit the report, and the matter must be referred to a Parliamentary Standing Committee.

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Mira Shiva, A-60, Hauz Khas, New Delhi. Tel: 011-26855010, 09810582028. Email: mirashiva@yahoo.com
Gopal Dabade, 57, Tejaswinagar, Dharwad 580002. Tel: 0836-2461722, 09448862270. Email: drdabade@gmail.com

INFORMATION MATERIAL

WHAT IS SECTION 3 OF THE INDIAN PATENTS ACT?

Section 3 is included in chapter 2 of the **Indian Patents Act, 1970**. Chapter 2 deals with **inventions that are NOT patentable.** Section 3 specifically lists the non-patentable inventions. Among other things it includes, inventions which are frivolous, claims anything obvious, contrary to well established natural laws, intended use of which would be contrary to law or morality or injurious to public health, the mere discovery of a scientific principle or the formulation of an abstract theory, a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components, mere arrangement or re-arrangement or duplication of known devices, a method of agriculture or horticulture, and so on.

Two specific clauses of interest to us are

Section 3 (d), which states that the mere discovery of any new property or new use for a known substance, or of the mere use of a known process is not an invention, untill such known process results in a new product or employs at least one new reactant.

and

Section 3 (i), which states that any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings, or similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products is not an invention.

The other sections in Chapter-2 of the Indian Patents Act, 1970 are Section 4 and Section-5. Section 4 deals with inventions relating to atomic energy, which are not patentable, and section 5 – the lifeline of the Indian drug industry, ruled out giving patent for substances (products) which could be used as food, medicine or drug. It also ruled out product patent for inventions relating to substances produced by chemical processes including alloys, optical glass, semi-conductors and inter-metallic compounds. Section-5 stated that patents would be allowed only the processes (or methods) of manufacture of these substances.

The Patents (Amendment) Act, 2005 completed did away with section-5 of the Indian Patents Act, 1970 thereby paving the way for patents on the substances which could be used as food, medicine or drug (product patent).

Prepared by Naveen,
initially for AIDAN.
To be further simplified,
broadened and sent
to different movements,
NGOs, etc. 6 briefing (trg.)
papers on drugs and
patent issues is being
planned. This will be one of them. naveen 28/7/07

P.T.O

In section 3 (d), the Patents (Amendment) Act, 2005 made the following change:

Indian Patents Act, 1970	The Patents (Amendment) Act, 2005
The following are not inventions within the meaning of this Act: **Section 3(d)** **The mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.**	The following are not inventions within the meaning of this Act: **Section 3(d)** **The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.**

The Patents (Amendment) Act, 2005 also gave the following eexplanation that—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

For the full text of the Indian Patent Act and its amendments, visit:

- http://www.patentoffice.nic.in/

ARTICLE 27 of TRIPS

TRIPS or Agreement on Trade Related Aspects of Intellectual Property Rights was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) treaty in 1994. Its inclusion was the culmination of a program of intense lobbying by the United States, supported by the European Union, Japan and other developed nations. Campaigns of unilateral economic encouragement under the Generalized System of Preferences and coercion under Section 301 of the Trade Act played an important role in defeating competing policy positions that were favoured by developing countries, most notably Korea and Brazil, but also including Thailand, India and Caribbean Basin states. In turn, the United States strategy of linking trade policy to intellectual property standards can be traced back to the entrepreneurship of senior management at Pfizer in the early 1980s, who mobilized corporations in the United States and made maximizing intellectual property privileges the number one priority of trade policy in the United States (Braithwaite and Drahos, 2000, Chapter 7).[1]

Article 27 relates to "Patentable Subject Matter". Paragraph 1 of Article 27 basically states that patents shall be available for any inventions, whether products or processes, in all fields of technology, (1) provided that they are new, (2) involve an inventive (non-obvious) step and (3) are capable of industrial application (useful). It further states that patents should be available without discrimination (1) as to the place of invention, (2) the field of technology being used and (3) whether products are imported or locally produced.

Paragraphs 2 and 3 of Article 27 deals with sections which can be excluded from patentability inventions. Paragraphs 2 states that countries can prevent commercial exploitation of things which are necessary to protect *public* order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment. It lays down the condition that the above can be done "provided that such exclusion is not made merely because the exploitation is prohibited by their law".

Paragraphs 3 of Article 27 states that members can exclude from patentability
(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
(b) plants and animals **other than micro-organisms**, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. It adds that , "Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof". The clause itself says that the provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

For the full TRIPS agreement, visit:

- http://www.wto.org/

[1] Agreement on Trade-Related Aspects of Intellectual Property Rights. (2007, February 18). In *Wikipedia, The Free Encyclopedia.* Retrieved 11:30, February 26, 2007, from http://en.wikipedia.org/w/index.php?title=Agreement_on_Trade-Related_Aspects_of_Intellectual_Property_Rights&oldid=109016838

Compiled by Naveen for AIDAN. This is part of the resource materials being put together for briefing paper on drugs & patents Naveen 28/2

----- Original Message -----
From: Ramya Sheshadri
To: Naveen
Cc: aidanindia@yahoogroups.com ; Anant Phadke ; Gopa Kumar ; Gopal Dabade ; Mira Shiva ; sathya mala ; anurag ; Bhargava Anurag ; Prasanna Saligram
Sent: Monday, February 26, 2007 7:08 PM
Subject: Re: Explanation of Section 3d and Article 27

Dear Naveen and all

The explanation looks good few more points to add

1. Sec 3(d) in simple means no patent will be granted on incremental improvements of an active molecule which will not show any therapeutic efficacy (for ex Gleevac imatinib mesylate beta crystalline form), having a new use of a already known substance (for example Moxifloxacin anti bacterial drug which is now proven to be effective in treating Tuberculosis), it goes on to say about the process how new use of a known process and new property of known process is not patentable if there is no new product.

2. Sec 3(d) of current patent act (defined in the explanation by Naveen) is included to keep a check on grant of frivolous patent leading to evergreening i.e. pharma companies by modifying the existing active molecules to salts, polymorphs, isomers apply for patent for the same drugs leading to extension of monopoly for the already patented drug. This will block the entry of generic companies.

3. The uniqueness of this clause is although as mentioned in Naveen's explanation that Sec 3 talks about inventions which are NOT PATENTABLE, 3(d) says that if the efficacy of the product and if new product is formed out of a process it will be PATENTED.

4. As everybody is aware that this clause (3(d)) is under attack by the Novartis company telling it is unconstitutional in Chennai high court which is a ongoing case. The main argumet being INDIA is not incompliant with TRIPS agreement and 3(d) is the reason for it.

ARTICLE 27 of TRIPS:
The brief history is already explained in Naveen explanation. To add to it

1. The Article 27 under Section 5 of TRIPS talks about patentable products under which we have 3 paras

27(1) talks about availability of patent in all fields of technology and there will be no descrimination in any field of technology on patenting.

27(2) this is about exclusion of inventions from patents mainly to protect public order or morality, human, animals, plant life, health to avoid serious harm to environment. Member countries cannot exclude certain inventions from patentability even though the exploitation of these is prohibited under local law. In other words, they have to grant patents regardless of any prohibition on the commercial exploitation of such a patent. For, example Indian patent laws did not provide for patents in pharmaceutical products but under the TRIPS agreement they will be forced to extend such protection from the year 2005.
The agreement does allow for the exclusion of certain patents if such action is necessary to protect public order or morality or to protect human life and health. This provision provides some flexibility for countries to promote public health policies by claiming their right to protect human life and health, especially in the wake of deadly pandemics like AIDS, which are wreaking havoc in 'developing' and 'least-developed' countries. However, most 'developed' countries do not read this provision as a general exception in favour of public health, thus making it difficult for developing and least developed countries to use it for the benefit of their citizens.

27(3) (a)and (b) is about products excluded from patentability.

27 (3)(b): Mainly animals, plants and biological processes excluded from the patent regime.

The interpretation of this last clause has been extremely contentious. The term *sui generis* (Latin for 'of its own gender/genus') is not defined in the agreement, but it is generally believed that it enables member countries to fashion their own protection scheme for plants. Possible protection mechanisms include the Plant Breeder's Rights system offered by UPOV Convention, plant patents or a licensing regime. More than one form of plant protection can be implemented in a given member country.

Controversy surrounding Article 27.3

One of the controversies of **Article 27.3** focuses on the meaning of '*sui generis*' and exactly what is considered an 'effective' form of plant variety monopoly right. In part because of the difficulties with this provision, Article 27.3 was to be reviewed in 1999, four years after the entry into force of the agreement. The review has never been completed, and this Article remains a hot issue. To date, some 30 countries are calling for further discussion on Article 27.3, and some have proposed:

1. rewriting the Article to exclude patents for any organisms or genetic material (although ostensibly countries could achieve this by defining these subject matters as "discoveries" and not "inventions");
2. defining in detail what an effective plant variety development right system is;
3. extending exclusionary rights of some sort to traditional or indigenous knowledge; and
4. making explicit linkages with obligations for the conservation and use of biodiversity, including mandatory disclosure of the source of genetic materials used in a patented invention, and creating obligations to record arrangements for access to genetic resources as evidence of prior informed consent.

It remains to be seen whether any of these proposals will be adopted.

http://www.patentlens.net/daisy/patentlens/415.html (source)

Hope this helps.

Regards

Ramya

On 2/26/07, **Naveen** <navthom@gmail.com> wrote:
Dear friends,

Anurag has suggested that the Section 3d of indian Patent's Act and Article 27 of TRIPS should be simplified. I have attempted to do it. It can be simplified still further. I can work on it with your suggestions.

Hope this is useful.

Best wishes,
Naveen

PRE-GRANT REPRESENTATION BY WAY OF OPPOSITION
UNDER SECTION 25(1) OF THE PATENTS ACT
1970(39 OF 1970) AND RULE 55 (1) OF THE RULES
AS AMENDED BY THE PATENTS (AMENDMENT) ACT, 2005

The Patent Controller,
Delhi

Re: Patent Application No. 315/Del/2000 filed on 27 March 2000 titled "New Crystal Modification of CDCH, And Pharmaceutical Formulations Comprising This Modification"

STATEMENT OF FACTS/ EVIDENCE

1. AIDAN (All-India Drug Action Network) was founded in the early 1980s as a network of like-minded individuals and groups in India to fight for a people oriented, rational, drug policy. AIDAN the opponents hereby make a representation by way of opposition under § 25(1) of the Patent Act 1970, as amended by the Patents (Amendment) Act, 2005 (the "Act") against the grant of patent application, titled: "New Crystal Modification of CDCH, And Pharmaceutical Formulations Comprising This Modification" made by Applicant Bayer Aktiengesellschaft (the "Applicant"), bearing Indian patent application No315/Del/2000 filed on 27 March 2000 (the "Application"). This representation is proper under § 25(1) of the Act as the application has been published but a patent has not been granted. Specifically, this representation is brought under the grounds as stated in § 25(1) (f), (h) of the act.

2. NEED TO INCLUDE THE REASON AS TO WHY AIDAN IS OPPOSING THE APPLICATION. The Opponents are opposing the above-mentioned application for a patent under section 25(1) of the Patents Act.

3. The patent application was filed at the Patent Office in Delhi, therefore, the Patent Controller has the jurisdiction to hear this pre-grant opposition in Delhi. Opponents hereby request a hearing as per provisions under Rule 55(1) of the Patent Rules, 2005.

4. The present Application relates to a treatment of infections caused by bacteria like acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, community acquired pneumonia, bacterial conjunctivitis and uncomplicated skin/skin structure infections. It is a broad spectrum antibiotic which is now being used to treat tuberculosis caused by *mycobacterium tuberculosis* complex. Nine million new cases of tuberculosis and nearly two million deaths are estimated to occur around the world every year, making it the leading cause of death among curable infectious diseases. The World Health Organization declared tuberculosis a global emergency in 1993. This application is of particular interest for the treatment of tuberculosis in HIV-positive people because it has no interactions with antiretrovirals and may be potent enough to shorten the duration of TB treatment, which currently stands at a minimum of six months which can be reduced to three months. (NEED TO INCORPORATE MORE INFORMATION ON ACCESS TO TREATMENT – ALSO CITE COST ISSUES)

5. The most effective way to lower the cost of these essential medicines is to promote competition, particularly within India's vibrant pharmaceutical industry. However, in order for there to be any effective generic competition, it is imperative that patents not be granted in India for uninventive, incremental improvements to already-known drugs. Although India was compelled by its WTO obligations to introduce product patent protection for pharmaceutical products through the Patents (Amendment) Act of 2005, India retains full sovereignty in determining the standards that must be met with respect to patentability. As such, India is under no obligation to follow the perilous path that many developed nations have taken in setting loose standards for novelty and inventive step that result in patent protection for incremental innovations, all too often at the cost of public health.

6. India's Patents (Amendment) Act, 2005 was passed in order to bring India into compliance with its TRIPS obligations under the WTO, and introduced for the first time a 20-year product patent regime in this country. India, however, is also a signatory to the Doha Declaration on the TRIPS Agreement and Public Health (the "Doha Declaration"), which states, in part, "we affirm that the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health ***and, in particular, to promote access to medicines for all***," (emphasis added).

7. In part due to the recognition of its obligations under the Doha Declaration, Parliament passed the Act with a few important provisions aimed at ensuring that a product patent regime would not harm public health. One of the most important is § 3(d) of the Act, a provision designed to discourage the pernicious but all-too-common practice of "ever greening," whereby pharmaceutical companies artificially extend the life of their monopolies by patenting trivial improvements to already existing drugs. Declaring that "a new form of a known substance which does not result in the enhancement of the known efficacy of that substance," and the discovery of a "new use for a known substance" are ***not*** inventions under the meaning of the Act, Parliament expressed through § 3(d) its unequivocal rejection of ever greening.

8. The present Application falls squarely in the category of "inventions" that Parliament intended in rejecting when it enacted § 3(d). The original patents for the active ingredients of this drug were granted prior to 1995, when India first incurred its obligations under the WTO. The sole "improvement" at issue is the conversion of the active ingredient into a particular crystalline form that does nothing to improve the drug's efficacy. Granting the current Application a patent will do nothing but further enrich the Applicant at the expense of human lives.

9. The Opponent humbly submits that the obligation to "promote access to medicines for all" has been incorporated into the Act by Parliament, and that the Act, whenever possible, can and must be interpreted in a manner that is consistent with the Doha Declaration's binding promise, as it is this Office that ultimately makes the decision that will determine whether millions of people will have access to essential medicines. The Opponents respectfully request that the Patent Office keep the Doha Declaration in mind as it examines the present Application and interprets the applicable law.

GROUNDS

10. The Opponent has closely studied the specification and claims made by the Applicant in the Application and strongly believe that the invention is not patentable under the following grounds of § 25(1) of the Act:

i. s25(1)(f) – that the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act, in particular under section 3(d).

ii. s25(1)(e) – that the invention so far claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step under this Act, in particular under section 2(j)(a).

iii. s25(1)(h) - that the applicant has failed to disclose to the controller the information required under section 8 especially form 3.

Accordingly, as permitted under s25(1) of the Act, which allows an opposition to be filed by any person after publication but before the grant of a patent, and Rule 55(1) of the Rules, the Opponent submits its opposition to the Application on the grounds set out below.

11. The Applicant has failed to meet its burden of showing that the alleged invention described in the Application is entitled to a patent under the Act. The present application merely relates converting a known pharmaceutical substance, referred to as CDCH, into a monohydrate crystalline form – a process well known in the art – in order to make the bulk manufacture of the drug substance more convenient. However, as will be explained below, the conversion of a drug substance to its monohydrate crystalline form in order to obtain certain benefits has been known in the pharmaceutical industry for years, and is obvious to one skilled in the art. Further, because whatever benefits may be derived from this conversion does nothing to make the final drug substance more effective, it is not eligible for a patent under s3(d) of the Act.

12. Specifically, the Applicant's claims can be summarised as follows:

a. Claim 1 relates to monohydrate form of active molecule CDCH.

b. Claim 2 relates to the prismatic crystal form of the compound described in Claim 1.

c. Claim 3 - 5 is dependent on Claim 1 and 2 and relate to the use of the alleged invention as antibacterial compositions.

The Alleged Invention Is Not An Invention Under § 25(1)(f) and § 3(d) Of The Act Because It Is The Mere "Discovery" Of A New Form Of A Known Substance.

13. The alleged invention is not patentable under the Act because it is, at most, the mere "discovery" of a new form of a known substance. Under § 3(d) of the Act, the "mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance" is not an invention within the meaning of the Act. The accompanying Explanation to § 3(d) states, "For the purposes of this clause, salts, esters…combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy," (emphasis added).Because the alleged invention claims to be and is in fact nothing more but only conversion of the active molecule in to monohydrate crystalline form with no improvement on efficacy of the drug.

14. The conversion to monohydrate form is already known and there are ways in which a hygroscopic active molecule can be manufactured with accurate dosage and not necessary that it needs to be converted to monohydrate form. This clearly explains the fact that this invention is just a new form of already known substance and has nothing to do with efficacy or therapeutic effect of the drug.

15. The alleged invention is already disclosed attached here in as **Exhibit D and E** respectively and the document says that the compounds can be used in various pharmaceutical preparations which includes tablets, capsules pills etc. A person skilled in art knows that for making tablets either one has to do wet or dry granulation, it's very well known in the art that granulation steps improve the flow properties of the active molecule and can be obtained even with out converting it to monohydrate form. (NEED TO GET PRIOR ART DOCUMENTS TO PROVE)

16. As the foregoing shows, all of the substances contained in the present Application are known. Nevertheless, the Applicant Claims and purports to stake ownership over the following: Monohydrate of CDCH in the prismatic crystal form used to treat bacterial infections. It is very clear that the applicant fails to show any invention and it is only a new form of a known substance with no enhancement on known efficacy under section 3(d) and therefore does not fulfill the criteria of patentability.

17. In order to meet its burden under § 3(d), the Applicant is required to present evidence that the claimed invention (i.e., the monohydrate form of CDCH) represents an enhancement in the known efficacy over the previously known substance. (i.e., anhydrous form of CDCH). The Applicant does not and cannot satisfy this requirement. The Applicant admits that the only *active* ingredient in the claimed invention is CDCH See, e.g., Application, p. 1, lines 4-10. Accepting the fact that the active molecule is converted to monohydrate form to make it non-hygroscopic and free flowing and in no way it has effected or enhanced the therapeutic activity of the active molecule.

18. This alleged "improvement" bears no relation to the ultimate therapeutic efficacy of the active ingredients. It is, at most, a tool that may facilitate: (i) the *mass* production (ii) of a *particular* dosage form of the active ingredients (i.e., the tablet form). However, there is no sound reason why the relevant comparison should be between the therapeutic efficacies of a active molecule converted to monohydrate form versus that of a active molecule without conversion to monohydrate form. The Applicant has put forth no evidence to show that the therapeutic efficacy of a active molecule converted to

monohydrate form is greater than that of, say, anhydrous CDCH which can be manufactured through different means.

19. The applicant claims that to get non-hygroscopic, free flowing active compound the active molecule is converted to monohydrate form which they claim is *new*. Attached here in is **Exhibit A, B and C** US Patent No. 5,068,440, US Patent No. 3,655,656 and US Patent No. 4,504,657 which clearly explains that hygroscopic materials are difficult to handle and to get a non-hygroscopic form we need to convert the active molecule to monohydrate form which is very much obvious and any person skilled in the art can obtain the same.

20. The Applicant has disclosed the existence of the active molecule CDCH, attached here in as **Exhibit D and E** EP-A-550903 and EP-A-591808 respectively, there by accepting the fact that the active molecule was already known prior to the present invention and therefore it's not *Novel.* The current invention only claims the monohydrate form of the active molecule which was used and prescribed *for years* prior to the present Application and the Applicant nonetheless claims that the alleged invention is patentable.

21. Thus the claims of the Application do not prove any efficacy of the drug and it is only about the monohydrate form of the active molecule which is insufficient to render the alleged invention patentable under the Act. This is because the mere conversion of the active molecule to monohydrate form to improve its flow characteristics is not an invention and also obvious under section 2(j)(a), the alleged invention is not patentable under section 3(d) as it is a new form of a known substance which does not result in the enhancement of the known efficacy, it is anticipated in the prior art and is not *Novel.* Furthermore, the applicant has failed to disclose the controller the information required under section 8 especially Form 3.

The Alleged Invention Is Not An Invention Under § 25(1)(e) and § 2(j)(a) Of The Act Because It Is Obvious To A Person Skilled In The Art and does not Involve any Inventive step.

22. For all of the reasons stated above, Claim 1 and its dependent Claims 2-5 of the present Application also fail because they lack the inventive step required for patentability. The claimed invention is obvious to a person skilled in the art i.e. obtaining monohydrate forms to over come the hygroscopicity of active molecule and it is very well known in the pharmaceutical industrial practices. Under § 2(j)(a) of the Act, "inventive step" is defined as "a feature of an invention that involves technical advance as compared to the existing knowledge that makes the invention not obvious to a person skilled in the art."

23. For the reasons already stated it would have been obvious to a person skilled in the art, given the disclosures contained in the US Patent No. 5,068,440 which clearly explains that hygroscopic materials are difficult to handle and to get a non-hygroscopic form we need to convert the active molecule to monohydrate form which is very much obvious and any person skilled in the art can obtain the same.

24. The sole "innovation" that the Applicant claims with respect to the conversion of active molecule to monohydrate form which is already known and practiced from many years does not involve any inventive step and it is very much a common practice i.e. obvious (to a person skilled in art) is carried through out the Pharmaceutical industries to obtain a non hygroscopic and free flowing active molecule.

The applicant has failed to disclose to the controller the information required Under §25(1)(h) by section 8 especially form 3.

25. Section 8 of the Patents Act requires an applicant for patent to furnish the Patent Office with detailed particulars of any patent applications for the same or similar inventions made in any other country, and to undertake to update the Patent Controller of detailed particulars of every other application made subsequent to filing within the prescribed time. Under Rule 12(1A), the statement and undertaking under section 8 must be made within 3 months of filing. Rule 12(2) requires the Applicant to inform the Patent Controller of additional particulars within 3 months of the additional filing. The details required by section 8 are clear from Form 3, and include status of the application. Under section 25(1)(h), a failure to comply with section 8 is a ground for opposition and is therefore sufficient to reject an application in its entirety.

CONCLUSION

26. Given all of the foregoing, Opponents hereby humbly request that the Patent Office reject the Application on the following grounds:

- The alleged invention is a "mere discovery of a new form of a known substance" and thus not an invention under § 3(d) of the Act;
- Claim 1 and its dependent Claims 2-5 of the present Application fail for lack of novelty;
- All of the Claims in the present Application fail for lack of inventive step.
- The Application fails to meet the formal disclosure requirements under section 8.

27. Opponents further request that the Office grant a hearing as per Rule 55(1) of the Patent Rules.

Respectfully submitted,

On Behalf of the All India Drug Action Network,

THE HINDU

Date: 22/02/2007
URL: http://www.thehindu.com/2007/02/22/stories/2007022206751200.htm

National

Mashelkar committee on Patent Law withdraws report; seeks more time

Ravi Sharma and Sara Hiddleston

Cites technical inaccuracy and plagiarism as reasons

BANGALORE/CHENNAI: The Dr. R.A. Mashelkar-headed expert committee on Patent Law has written to the Government of India asking that its 56-page report submitted last December is withdrawn on the grounds of "technical inaccuracy and plagiarism."

In a letter dated February 19 and addressed to Ajay Dua, Secretary of the Department of Industrial Policy and Promotion, Ministry of Commerce and Industry, the committee has requested three months to re-examine and resubmit the report.

The `Technical Expert Group on Patent Law Issues' was chaired by Dr. Mashelkar and comprised four other renowned experts (Professors Goverdhan Mehta, Asis Datta, N R. Madhava Menon, and Moolchand Sharma). It was set up in April 2005 to look into two contentious issues that were referred to it by the Government of India following a debate in Parliament after the Patents (Amendment) Bill, 2005 was introduced.

The issues were whether it would be compatible with the World Trade Organisation's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement to: a) "limit the grant of patents for pharmaceutical substances to new chemical entities or new medical entities involving one or more inventive steps only," and b) "exclude micro organisms from patenting." The committee took over a year and a half to reach its conclusions.

Dr. Mashelkar confirmed to *The Hindu* over the telephone that the group had "unanimously" sought the report's withdrawal. He said that certain lines used in their report's conclusion had been taken "verbatim" from a November 2005 paper (Limiting the Patentability of Pharmaceutical Inventions and Micro-organisms: A TRIPs Compatibility Review) that was authored by Shamnad Basheer, a doctoral student and an Associate at the Oxford Intellectual Property Research Centre, University of Oxford.

A footnote in Mr. Basheer's paper indicates that his work was commissioned by "the Intellectual Property Institute, a United Kingdom-based independent charitable organisation which carries out research on intellectual property matters." It was

"financially supported by Interpat, a Swiss association of major European, Japanese and U.S. research-based pharmaceutical companies committed to the improvement of intellectual property laws around the world."

According to Dr. Mashelkar, it was only after the committee had submitted its report that it came to their notice through newspaper articles that some plagiarism had occurred: "We have identified eight to ten lines that have been extracted verbatim from Basheer's paper. As a scientist I see this as not a good practice. In keeping with the highest and best ethical practices we want to withdraw the report."

Dr. Mashelkar termed it "very unfortunate" and expressed the opinion that the "technical inaccuracy" could have happened when the report was being "drafted by a sub group."

Asked whether the committee would now like to rewrite the report or just change the "eight to ten lines" that have been plagiarised, Dr. Mashelkar said that "that depended on the members of the committee."

Even while admitting that it had been ethically wrong to plagiarise, Dr. Mashelkar said that Mr. Basheer in an e-mail had indicated that he was "not aggrieved" by the Mashelkar report "using his conclusions." He also stressed that it was "mischievous" to insinuate that multinational pharmaceutical companies had funded the committee's study. "We are not aligned to any industry."

The recommendations of the technical expert group were significant for multinational pharmaceutical companies, the Indian generic industry, and patient groups.

Novartis AG stated in a press release dated February 15: "A report from the Mashelkar committee, commissioned by Indian Government and comprised of Indian experts, supports many of the concerns about Indian patent law expressed by Novartis, mentioning that the laws are not complying with international agreements like TRIPS."

Public health groups and patient associations were concerned that the recommendations would encourage renewals of patents and block entry of cheap generic drugs into the market. A paper by Professor Brook Baker, Northeastern University School of Law Programme on Human Rights and the Global Economy, said that the "Mashelkar report misstates India's right to define the scope of patentability and threatens access to medicines."

Draft AIDAN Statement on The Report of the Technical Expert Group on Patent Law Issues

23 February 2007

It is regrettable that a panel such as the *Technical Expert Group on Patent Law Issues*, comprising of such highly regarded persons in the country should submit a report with several sentences identical to submissions made by an interest group. This could lead to questions about the interests and motives about the panel. While welcoming the move to withdraw the *Report of the Technical Expert Group on Patent Law Issues*, we would like to draw the attention back to the other contents of the report. The report of the panel headed by Dr. R.A. Mashelkar, which was submitted in December 2006 is high on rhetoric and contains many unsubstantiated claims which can have serious implications on people's access to medicines.

The report rhetorically states, "every effort should be made to prevent the grant of frivolous patents and 'ever-greening'", but condemns the very provisions in the Indian Patents Act which were framed to prevent ever-greening. The report also states "Article 7 and 8 as well as Doha Declaration on TRIPS Agreement and public health cannot be used to derogate the mandate under Article 27", but fails to explain the reasons or basis for such an argument.

Grant of patent is based on applicant's ability to satisfy patentability criteria and any other relevant requirements. According to Article 27 patents are granted to an invention. Significantly TRIPS does not offer any definition for invention and gives freedom to member states to determine the meaning of invention and that too when they satisfy all three criteria i.e. novelty, inventive step and industrial application. This gives an opportunity to the implementing country to determine the scope of patentability i.e. whether it should be limited to new chemical entities or whether it can also include incremental innovations (not inventions).

The Article 27 of TRIPS quoted by the panel prohibits discrimination of availability and enjoyment of patent rights on the ground of place of invention, field of technology, place of manufacture. Here,

Addresses for Correspondence:
Mira Shiva, A-60, Hauz Khas, New Delhi. Tel: 011-26855010, 09810582028. Email: mirashiva@yahoo.com
Gopal Dabade, 57, Tejaswinagar, Dharwad 580002. Tel: 0836-2461722, 09448862270. Email: drdabade@gmail.com

the prohibition is only against discrimination on the above grounds and not on differentiation. The WTO Disputes Panel also recognized this reasoning in the *EC–Canada Case (WT/DS 114)*. Therefore limiting the scope of patentability to new chemical entities does not violate the obligation of non-discrimination as to the field of technology under Article 27(1).

The Doha Declaration on TRIPS agreement states, "*We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all*"(Para 4). There is no doubt that measurers like limiting the scope of patentability to new chemical entities will protect public health by providing space to gerenric companies to legally produce drugs and promote access to medicines. By ignoring these crucial commitments in the Doha Declaration on TRIPS Agreement the panel tries to devalue the importance of the Doha declaration.

In an ambiguous section titled "national interest perspective", to support its view on patent protection for incremental modifications/ innovations the panel does not make a single reference to public health concerns, leading one to question whether public health is not a factor while considering national interest.

In light of the above points, we submit that the *Report of the Technical Expert Group on Patent Law Issues* is a retrograde step in the discourse on patents in India, and call for a complete rejection of the report in its present form. In addition, since the panel report has been found to contain several sentences identical to submissions made by an interest group, it would not be fair to continue with the panel, as it could lead to questions about the interests and motives about the panel. Hence the panel should not be allowed to re-submit the report. If required, a new panel with representations from public health experts and consumer groups must be asked to relook at the issue.

Addresses for Correspondence:
Mira Shiva, A-60, Hauz Khas, New Delhi. Tel: 011-26855010, 09810582028. Email: mirashiva@yahoo.com
Gopal Dabade, 57, Tejaswinagar, Dharwad 580002. Tel: 0836-2461722, 09448862270. Email: drdabade@gmail.com

Pfizer's smoking cessation medicine receives FDA approval

New York

THE US FDA has approved Pfizer's anti-smoking pill, Chantix (varenicline). Chantix, the first new prescription medication approved for smoking cessation in nearly a decade, received priority review designation by the FDA because of its potential to be a significant therapeutic advance over existing therapies.

According to the company release, Chantix is specifically designed to partially activate the nicotinic receptor and reduce the severity of the smoker's craving and the withdrawal symptoms from nicotine. Moreover, if a person smokes a cigarette while receiving treatment, Chantix has the potential to diminish the sense of satisfaction associated with smoking. This may help to prevent the cycle of nicotine addiction.

"Pfizer's discovery and development of Chantix demonstrates groundbreaking science leading to the first prescription treatment aimed directly at smoking cessation in nearly a decade," said Hank McKinnell, chairman and CEO of Pfizer. "Smoking harms nearly every organ in the body. It is responsible for approximately one in five deaths in the US and costs the US health care system about $167 billion annually. This medical advance from Pfizer will now help many smokers end their addiction," he added. Chantix is the fourth new Pfizer medicine to receive FDA approval in 2006.

Chantix's approval was based on a comprehensive clinical trial programme including four pivotal trials involving more than 2,000 cigarette smokers. Subjects on average had smoked about 21 cigarettes per day for an average of approximately 25 years.

Dr Cheryl Oncken, a Chantix clinical investigator and associate professor of Medicine at the University of Connecticut Health Centre said, "It is never too late to quit smoking. People who quit smoking before the age of 50 have one-half the risk of dying of a smoking-related illness in the next 15 years compared to those who continue smoking. Patients who are unable to quit on their own should consider seeking medical support and treatment".

In November 2005, Pfizer submitted a European marketing authorisation application for varenicline for smoking cessation. ◆

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Novartis's Glivec may harm bones: Study

New York 18/5/06

NOVARTIS AG's drug Glivec, which has dramatically improved survival prospects for some cancer patients, can interfere with bone development, according to US researchers.

Results of a small study published in the New England Journal of Medicine found the drug could inhibit bone formation and resorption - a process known as bone remodelling.

The side effect was detected by Dr Ellin Berman and colleagues at the Memorial Sloan-Kettering Cancer Centre in New York after some patients on the drug developed low levels of serum phosphate, a mineral important in bone formation, said report.

The new finding, however, was based on just 16 patients with low mineral levels and the full significance of the discovery has yet to be ascertained.

Glivec, or Gleevec as it is known in the United States, was approved five years ago and has grown to be Novartis's second biggest selling product, with sales last year of $2.2 billion.

The drug has transformed life expectancy for people with chronic myeloid leukaemia (CML) and a type of stomach cancer called GIST. Five years of use shows patients taking Glivec have a 90 per cent survival rate, says the report. ◆

Barr Labs' isotretinoin receives approval

New Jersey

THE US FDA approves Barr Laboratories' application to manufacture and market Isotretinoin capsules USP, 30 mg. The company will launch the product immediately under the trade name Claravis. The company will now market the full line of Isotretinoin product strengths, including Claravis 10 mg, 20 mg, 30 mg and 40 mg capsules.

Claravis capsules, 30 mg will compete with Ranbaxy's Sotret (Isotretinoin) capsules USP, 30 mg that had total annual sales of approximately $15 million for the most recent twelve months ending March 2006, based on IMS data.

Barr filed a supplemental Abbreviated New Drug Application (sANDA) for the 30 mg strength of Isotretinoin capsules USP with the FDA in June 2004 seeking approval to manufacture market this additional strength.

Claravis is indicated for the treatment of severe recalcitrant nodular acne. Because of the significant adverse effects associated with its use, Claravis should be reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics. In addition, for female patients of childbearing potential, Claravis is indicated only for those females who are not pregnant and will not become pregnant. ◆

Medicis gets FDA nod for oral minocycline

Arizona

THE FDA has approved Medicis's NDA for Solodyn (minocycline HCl, USP) extended release tablets. Solodyn is the only oral minocycline approved for once daily dosage in the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older. Solodyn is also the only approved minocycline in extended release tablet form. Solodyn is lipid soluble, and its mode of action occurs in the skin and sebum. Solodyn is not bioequivalent to any other minocycline products, and is in no way interchangeable with other forms of minocycline.

The dosing and administration for Solodyn is unique, and redefines minocycline therapy for acne. Based on extensive multi-year clinical trials conducted by Medicis in which over 1,000 patients participated, the recommended dosage for Solodyn is 1 mg/kg daily

According to the release, Solodyn is patented until 2018 by U.S. Patent No. 5,908,838, which covers Solodyn's unique dissolution rate. Other patents covering solodyn's dosing, pharmacokinetics, and carrier composition are pending. The company continues to seek additional patent protection for its products.

Jonah Shacknai, chairman and CEO of Medicis commented, "Having the only oral patented minocycline extended release tablet for acne with once daily dosage is indicative of the innovation of our product pipeline. We believe Solodyn's unique, weight-based dosing will transform the way doctors prescribe minocycline, and improve the overall safety of oral antibiotic use in acne. With this highly specialized dosing method and safety profile, we believe Solodyn will be a leader in the oral antibiotic market for acne, where US dermatologists prescribe minocycline more frequently than any other molecule." ◆

Regn. No: MH/MR/South-84/2006-08 W.P.P. Lic No: South-52/2006-08 Posted at Mumbai Patrika Channel Sorting Office, Mumbai

Cancer patients protest against Novartis move to challenge Gleevec patent rejection

Joe C Mathew, New Delhi

PATIENT groups and health activists like Cancer Patients Aid Association and Lawyers Collective are planning a public protest in Mumbai on Wednesday against the decision of Novartis to challenge the Patent Controller's decision rejecting patent application for Gleevec (Imatinib Mesylate). The protest assumes significance as the Chennai High Court is to hear the Novartis case on August 23 rd.

According to patient groups, " Novartis's constant litigation threatens the lives of cancer patients and renews fears of future availability if the patent case of Gleevec is reopened. Further, it has raised concerns among other patient groups as the patent order set a good precedent for patent examination of other crucial AIDS drugs.

It was in May 2006, Novartis filed two cases in the Chennai High Court challenging the refusal of the application filed by Novartis for a patent on 'Gleevec' and the constitutionality of section 3(d) of the Indian Patents Act which was specifically introduced by the Indian Parliament to protect against obtaining patents on old medicines i.e. trivial patenting, new use patents etc. While the 3 (d) case is still to come up for hearing, the challenge of the patent order rejecting the Gleevec patent is up for hearing on the 23rd of August.

The Novartis appeal came after the Chennai Patent Office rejected the patent application in Jan 2006 on the ground that the application claimed 'only a new form of an old drug', which does not qualify for patentability. Cancer patients point out that the order of the chennai patent office "brought relief to cancer patients as it not only prevented a patent monopoly till 2018 but also automatically withdrew the EMR". The Gleevec patent order rejecting a new form of an old drug also set an important precedent for the examination of patent applications related to essential drugs including AIDS medicines, they add.

According to the patient groups, the situation of unavailability of affordable generic versions of the drug continued till 2006. While the generic versions of the drug 'Gleevec' in the Indian market were priced at about Rs 10,000 per patient per month, Gleevec was priced at Rs 1.2 lakh per patient per month. Patient groups say that after Gleevec was granted EMR, Cancer Patients Aid Association and other cancer groups who had provided the more affordable generic versions of 'Gleevec' to Myeloid Leukemia patients for their treatment had to withdraw such medical support to cancer patients. ◆

FMRAI complains against 17 pharma cos to state govt for ineffective enforcement of SPE Act

Gireesh Babu, Chennai

THE Federation of Medical and Sales Representatives Association of India (FMRAI) has asked Tamil Nadu government to take stringent action against violation of Sales Promotion Employees (SPE) Act, 1976, and rules made there under by the pharma companies operating in the state.

In a memorandum, demanding the effective enforcement of SPE (Conditions of Services) Act, the FMRAI asked the state minister for labour to activate the inspectors appointed under the Act for regular inspection of the premises of the companies without further delay as workers are being exploited by the managements.

The Association stated that the officials under the Act, have not inspected any of the premises of the companies for enforcement of the provisions of the Act and rules made there under though the Act gives specific direction to the inspectors for regular inspection of registers and documents.

FMRAI listed 17 Chennai-based pharmaceutical companies for allegedly violating the Act in the memorandum. The list includes companies like Tablets (India) Ltd, Indo French Labs Ltd, SPIC Pharma, TTK Health Care Ltd, Mano Orchid Healthcare Ltd, Apex Labs Ltd, Grandix Pharma Ltd, Fourrts India Labs Ltd. etc.

The Association said that the pharmaceutical companies are issuing appointments violating the Section 5 of the Act and Rule 22 (1) by not giving letters of appointment in prescribed Form A, Section 7 of the Act and Rule 23 under the Act in respect of details of SPE engaged by the company as per prescribed Form B, Service book for every SPE as per Form C, a register of service book in Form D, leave account of each SPE in Form E. Though the Act provides punishments for contravention of the provisions under Section 9, none of the companies so far has been punished despite contravention, the memorandum points out. ◆

Glivec case to defend international IP rights: Novartis

Our Bureau, Mumbai

NOVARTIS India said for the past 4-year Novartis has given Glivec free for over 6000 patients in India and the case it filed in Madras High Court is to demonstrate its commitment to defend international intellectual property standards and right to obtain patents for innovative compounds under the TRIPS agreement.

"Novartis demonstrated a significant commitment to patients in India through its Glivec International Patient Assistance Programme (GIPAP). As of Aug 2006, over 6000 diagnosed patients in India received Glivec completely free of charge through GIPAP, representing 99% of patients who are on Glivec in India. To date Novartis has given around Rs 1,100 cr of Glivec free of charge under GIPAP in India. Globally, GIPAP has helped more than 17,000 patients in 83 countries" said Novartis in a statement.

It noted that Glivec is a world-class drug for people suffering from certain forms of Chronic Myeloid Leukemia (CML) and gastro intestinal stromal tumours (GIST), the approved indications for Glivec in India, and is being studied for other rare diseases. Novartis has made this medicine accessible to eligible cancer patients suffering from these diseases through its GIPAP programme. It also said that the filing of the writ petitions with the Madras HC demonstrates Novartis' strong commitment to defending international intellectual property standards and its right to obtain patents for its innovative compounds under the TRIPS agreement.

As reported, patient groups and health activists staged a demonstration protesting against the decision of Novartis to challenge the Patent Controller's decision rejecting their patent application for Glivec on Aug 23. The demonstration was held on the pavement in front of the office of Novartis at Worli in Mumbai.

Sources with Lawyers Collective said the demonstrators were denied police permission to conduct the demonstration and thus had to stage a silent protest. About 95 protesters from various organisations like Cancer Patients Aid Association, Positive Peoples foundation, Humsafar Trust, Uddan Trust, Committed Childrens' Development Trust, Network of Maharashtra Positive People, Network by People Living with HIV/AIDS and Lawyers Collective HIV/AIDS Unit. The protest was held to coincide with the scheduled hearing of Novartis' application for stay of the Patent Controller's decision in the Madras HC. The matter has now been adjourned to Sept 13, 2006. ◆

DSP, Sumitomo settle patent dispute with Pfizer

Osaka City

DAINIPPON Sumitomo Pharma Company (DSP) and its parent company, Sumitomo Chemical Company, announced that they have come to an agreement with Pfizer (Pfizer LTd and Pfizer Corp. collectively) on a settlement in the lawsuits brought by Pfizer in Japan and England regarding the license for Amlodin, a company press release stated.

DSP is engaged in the manufacture and sale of Amlodin (generic name: amlodipine besilate, a therapeutic drug for hypertension and angina pectoris), for which Pfizer is the licensor. Pfizer filed a lawsuit with the Tokyo District Court against the two Japanese companies on Nov 17, 2005, claiming that the license agreement had terminated due to the merger of the former Dainippon Pharmaceutical Company and Sumitomo Pharmaceuticals Company to establish DSP and seeking damages from patent infringement as well as calling for the immediate cessation of the manufacture and sales of Amlodin by DSP.

Pfizer concurrently filed a suit with the High Court of Justice in England calling for cessation of the manufacture and sale of Amlodin by DSP and the return of all medical data and other information. DSP and Sumitomo Chemical applied for an order from the Court for lack of jurisdiction over the lawsuit, etc. On June 16, 2006, the High Court of Justice ruled that the Court would not exercise jurisdiction over the lawsuit and that the effect of the merger on the license agreement should be analyzed under the Japanese law relating to the statutory merger procedure.

This settlement will allow DSP to continue the manufacture and sale of Amlodin as before with no adverse impact to its earnings or the earnings of Sumitomo, the company release said. ◆

POLICY & RI

Prohibitive prices of cancer drugs force patients to turn away from treatment

P B Jayakumar, Mumbai

WHILE the Central Government is mulling ways to rein in the prices of essential drugs including AIDS and cancer drugs, cancer patient groups and NGOs lament that prohibitive costs of many critical cancer care drugs in India are causing treatment beyond the reach of common man.

Among the available 50 odd important drugs for cancer care in India, most of the original molecules for effective targeted treatment are unaffordable to more than 90% of the patients, says Y K Sapru, chairman and Shubh Maudgal, director of Cancer Patients Aid Association (CPAA), a Mumbai-based NGO in the field of cancer care for the last 35 years.

As examples, they cite that treatment with Roche's Mab Thera (Rituximab), used in the treatment of several types of non-Hodgkin's lymphoma or chronic lymphocytic leukemia (CLL), costs about Rs1.2 lakh for a cycle of three weeks and the patient has to undergo treatment for six such cycles for effective cure. Treatment with Roche's another drug Herceptin (Trastuzumab), to treat the aggressive HER2-positive form of breast cancer, is equally a costly affair in India. The patient has to spend over a lakh of rupees for three-week medication and will have to undergo treatment for about nine such cycles.

Treatment with Taxol (Paclitaxel), the ovarian cancer drug from Bristol-Myers Squibb, costs Rs 70,000 per a cycle of three weeks and six cycles are required for the treatment. Gleevec, Novatis' myeloid leukemia drug treatment also costs Rs 1,20,000 per patient per month. Many of the cancer drugs are used in a combo therapy involving surgeries, radiation and chemo therapy, and the patients will have to undergo lifelong medication.

CPAA alone spends about Rs 40 lakh in a year to help cancer patients prolong their lives through medication, says Dr Sapru. Novartis' offers free Gleevec to about 5400 patients out of the 25,000 odd cases detected myeloid leukemia cases in the country. CPAA treats another 50 odd patients with the help of free generics of Gleevec given by companies like Natco Pharma.

Countering the research based companies' argument that billions of dollars involved development costs are what that forces them to price the products high, the NGOs point out the lion's share of R&D expenditure is with public funds. Most of the drugs are born in the universities and the companies' only fast track them to commercialization.

To support the argument, sources with the Mumbai NGO Lawyers Collective cite the cases of Taxol and Gleevec. Taxol was invented by the US National Institute of Health and was not patented. ◆

NPPA finds no major fluctuations in prices of non-scheduled formulations in 3 years

Joe C Mathew, New Delhi

THE National Pharmaceutical Pricing Authority (NPPA) has found that the prices of 87.7 % of non-scheduled formulation packs monitored by the authority remained stable during 2005-06. The prices were even more stable during the previous two years, thereby allaying the fears of huge price fluctuation.

The major fluctuation in prices of non-scheduled packs happened in the months of August and September in 2005 when there was a sharp price increase of 27.25 % and 27.2% respectively. A substantial price decrease was also noted during these two months and was in the range of 21.59% and 23.63 % respectively. The prices were moreover stable during the rest of the year.

The observations have been extracted from the monthly monitoring of medicine prices carried out by NPPA. The monitoring is based on the monthly retail audit reports of ORG-IMS Research Pvt. Ltd.

According to NPPA analysis, the percentage of non-scheduled formulations prices that remained stable in 2003-04 was as high as 97.4. The situation was exactly the same in 2004-05 also as the prices of 97.3% of non-scheduled formulations monitored by NPPA remained stable.

NPPA officials could not be contacted to ascertain the reason for the seemingly abnormal price fluctuation during August and September last year. However, the common reasons given for rise in prices of medicines are increase in bulk drug prices, rise in cost of production or import, rise in cost of transport, freight rates, rise in cost of utilities like fuel, power, diesel etc, changes in taxes and duties and (for imported drugs) rise in c.i.f. prices and depreciation of rupee. ◆

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BUREAU CHIEFS

New Delhi : Joe C. Mathew

HEAD OFFICE: Saffron Media
Churchgate, Mumbai 400 02
E-mail: ipharma@vsnl.com/sal

PATENTS

21/9/06

Madras HC adjourns Gleevec case to Sept 26

Our Bureau, Chennai

THE Madras High Court has adjourned the hearing on the Gleevec patent case to September 26, 2006. The case has been adjourned a day before the hearing posted by a single bench in the Madras High Court on September 13, allowing time for the Indian Pharmaceutical Alliance (IPA) to file their version, according to sources. The sources informed that the single bench has decided to postpone the case after receiving a notice from the IPA impleading in the case as a respondent, within the last five days.

As reported earlier, IPA's involvement in the issue is expected to give a new dimension to the Gleevec issue, the first major pharmaceutical IP case in the new product patent era in India.

Meanwhile, some legal sources commented that the single bench might have adjourned the case in advance if any of the parties request more time for preparation. While IPA declined to confirm the implead move, the patent attorney firm for Novartis refused to respond to Pharmabiz on the development.

It is to be noted that Novartis has filed seven cases on May 19, 2006 against the Government of India, the Cancer Patients Aid Association (CPAA), a 35-year-old cancer patients group, and other generic companies in the High Court of Madras challenging the rejection of the patent application for Gleevec. Novartis also challenged section 3(d) of the Patents (Amendment Act), 2005. Novartis' 1998 application for a patent on imatinib myselate was opposed by CPAA and later rejected by the Chennai patent office on January 25, 2006.

Meanwhile, a protest march against Novartis on the Gleevec issue was organised last week in Mumbai at Azad Maidan, by Cancer Patients Groups and NGOs.

Netherland court prevents Ranbaxy for launching atorvastatin before Nov 2011

New York

PFIZER Inc said today that the District Court of The Hague in the Netherlands has ruled that the basic patent covering atorvastatin - the active ingredient in Lipitor - would be infringed by a competitor product from generics manufacturer Ranbaxy. The decision, which is subject to appeal, prevents Ranbaxy from launching its drug before Lipitor's basic patent (EP 247,633) expires in November 2011.

"Today's decision is another affirmation of the strength of the intellectual property behind Lipitor, one of the most important medical breakthroughs of our era," said Pfizer General Counsel Allen Waxman. "The court's ruling reinforces the fundamental principle that patent laws exist to support and encourage medical innovators, not undermine them."

Ranbaxy also had challenged a second patent covering the calcium salt of atorvastatin (EP 409,281). The court ruled that the patent, which expires in July 2010, is invalid. Pfizer said that, while it plans to appeal the ruling, it will have no practical effect on the patent life of Lipitor in the Netherlands because the basic patent will remain in effect beyond the expiration of the calcium salt patent.

Impax wins in Alza's appeal to oxybutynin

Hayward, California

IMPAX Laboratories, Inc. has announced that the US Court of Appeals for the Federal Circuit upheld a lower court ruling in favour of Impax in its defense of a lawsuit brought by Alza Corporation, a Johnson & Johnson unit.

The suit alleged patent infringement related to Impax's filing of an ANDA for a generic version of Ditropan XL (Oxybutynin Chloride) tablets, 5, 10 and 15 mg. Alza Pharmaceuticals markets Ditropan XL for the treatment of urge urinary incontinence. US sales of Ditropan XL were approximately $350 million in the 12 months ended May 31, 2006, according to Wolters Kluwer Health.

"We are pleased that yet another court has seen through Alza's attempt to delay the availability to patients of a lower priced alternative to the branded drug," commented Larry Hsu, president of Impax.

Swiss NGO, BD asks Novartis to withdraw Glivec appeal in India

Our Bureau, New Delhi

THE Berne Declaration (BD), a Swiss public-interest organisation with 19,000 members, has asked Novartis International to withdraw its appeal filed in Chennai HC against the rejection of patent application for Glivec. The leading NGO wanted the Swiss multinational to stop attempting to restrict using the flexibility permitted under the TRIPS agreement to meet public health needs.

"We are shocked that five years after the end of the trial brought by Novartis and other companies against the South African government, Novartis is trying again to restrict the flexibility given to a country to adapt the TRIPS agreement to its public health needs. The undersigned organizations demand that Novartis withdraws the cases against the Indian Patents Act and the decision of the Indian Patent Office on Glivec/Gleevec", stated Julien Reinhard, Campaign Director, BD.

The letter submitted to Dr Daniel Vasella, Novartis International AG has been endorsed in her private capacity by Ruth Dreifuss, chairperson of WHO's commission on IPR, Innovation and Public Health. The organisations that have supported BD demand include Aids-Hilfe Bern, Association of European Cancer Leagues (ECL), Bethleem Mission Immensee, - COOPERAID, Groupe sida Genève, Médecins Sans Frontières, medicuba, MIVA Schweiz, Pharmaciens Sans Frontières - Suisse, SID'Action (Lausanne), SolidarMed Suisse, Swiss Aids Care International, Swiss Cancer League, Swiss Aids Federation, terre des hommes schweiz, etc.

Dr Claudia Kessler Bodiang, member of aidsfocus.ch, Thomas Schwarz, Co-Director de Medicus Mundi Suisse and Helena Zweifel, Coordinator of aidsfocus.ch are among the members who have endorsed the stand in their individual capacity.

According to BD, the letter comes as an expression of solidarity to the Indian patients with cancer, health organizations and public interest groups, who alerted them on the Novartis move. "We are writing to you to express our concerns regarding the legal proceedings that Novartis has started in May 2006 in order to challenge the rejection of its patent application for imatinib mesylate (Glivec/Gleevec) as well as the compliance of the Indian Patents Act with the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). We are joining the Indian organizations in their demand that Novartis withdraws these cases", they stated.

The activists said that they are extremely concerned with Novartis's challenge of Section 3(d) of the Indian Patents Act, which Novartis claims is not compliant with the TRIPS Agreement.

"Section 3(d), which prevents the grant of patents for new forms or new uses of known substances, is one of the recognized flexibilities of the TRIPS agreement that countries are utterly free to adopt in their legislation. The importance of these flexibilities has been highlighted by the United Kingdom Commission on Intellectual Property Rights in its 2002 report as well as by the World Health Organization Commission on Intellectual Property Rights, Innovation and Health in its 2006 report. Such a challenge is in contradiction with the spirit and the letter of the Doha Declaration on the TRIPS agreement and Public Health", they said.

PATENTS

Gilead pact with 8 Indian cos for mfg tenofovir may turn against patients: NGOs

Joe C Mathew, New Delhi

THE patients groups and health NGOs who have filed a pre-grant opposition against Gilead Science's patent application on tenofovir disoproxil fumarate, feel that the recent decision of Gilead to sign non-exclusive license agreements with eight generic companies of India can prove harmful to the long term interests of the patient groups in ensuring affordable medicines to the needy.

The groups question the rationale behind running after Gilead when there is a strong case for rejection of its patent application in India. The public interest lawyers providing legal support to Indian Network for People Living with HIV/AIDS (INP+) and the Delhi Network of Positive People, who jointly filed the pre-grant opposition, argue that forming a salt (fumaric acid) out of an existing compound (tenofovir disoproxil), is a common practice within the pharmaceutical industry, and should not be considered a new invention. The scramble for marketing license can only weaken the chances of winning a pre-grant opposition, and thereby ensuring un-hindered low cost generic manufacturing and supply, they fear.

According to them, the apparently harmless license agreement has several in-built clauses that prevent the generic companies from supporting any move to oppose Gilead's 'patent' rights. "It prevents generic companies from having rights on any improvements, modifications or derivative works that they might work on Gilead's compound. Further, the agreement ensures that Gilead controls over the manufacturing and marketing channels of TDF world over, as formulators are required to source APIs only from licensed API manufacturers. The API manufacturers are bound by the agreement to provide raw material to only those companies that have license agreements with Gilead. The generic formulators are also to pay a royalty to Gilead," they explained.

The major problem with such agreements is that it allows a single pharmaceutical company to have a control over the manufacturing and marketing of an essential drug. Indian companies should have waited for the decision of the Patent Office on Tenofovir's patent status before jumping into such agreements, activists opined.

It is known that the license agreement requires the generic companies to assist Gilead on the issuing, maintenance and enforcement of the patents. In case of a patent infringement allegation, the generic company may be asked to assist Gilead in further proceedings and to lend its name to such actions or proceedings if required by law in order to help Gilead. The patient advocacy groups say that such actions may lead to a wrong precedence where trivial patent applications get approved due to lack of opposition from generic players. This would ultimately result in higher prices and monopoly control over marketing of essential medicines, they fear. ◆

Madras HC refers Gleevec case to Division Bench

Our Bureau, New Delhi

THE petition of Novartis AG challenging the refusal of Patent Office to grant patent for its block buster drug Gleevec (Imatinib Mesylate) will be heard by a division bench of the Madras High Court in October. The single bench decided to refer the case to the division bench as desired by the petitioner. Novartis had questioned the constitutionality of section 3(d) of the Indian Patents Act which was specifically introduced by the Indian parliament to protect against obtaining patents on old medicines i.e. trivial patenting, new use patents etc.

It was in May 2006, Novartis filed two cases in the Madras HC challenging the refusal of the application filed by Novartis for a patent on 'Gleevec' and the constitutional validity of 3 (D) of Patent Act. The Novartis appeal came after the Chennai Patent Office rejected the patent application in January 2006 on the ground that the application claimed 'only a new form of an old drug', which does not qualify for patentability.

In 1998, Novartis filed a patent application in India for Gleevec, the drug essential in prolonging the life of patients suffering from Myeloid Leukemia (Blood Cancer). Based on the patent application and a particular provision of the Indian Patents Act, Novartis in 2003 obtained an exclusive marketing right (EMR) for a period of five years. The EMR operated like a patent monopoly preventing Indian pharmaceutical companies from producing affordable generic versions of the drug Imatinib Mesylate (Gleevec). Companies like Hetero, Ranbaxy, Cipla had to withdraw from producing and marketing the drug in India and other developing countries. After the refusal of the patent application, all generic companies are once again in the fray with their versions of Imatinib Mesylate. ◆

Novartis strengthens R&D pipeline with 138 projects in development

London

NOVARTIS unveiled new data on its promising pipeline amid plans for multiple new product approvals and launches over the next two years. Many of these anticipated approvals are for potentially best-in-class medicines that would advance treatment standards for patients with hypertension, diabetes, cancer and other diseases.

Novartis highlighted progress throughout its pipeline, particularly the advance of pharmaceutical compounds to pivotal trials before regulatory submission as well as the development portfolio in the newly created Vaccines and Diagnostics division.

Its compounds FTY720 (fingolimod) for multiple sclerosis, QAB149 (indacaterol) for COPD and asthma, AG0178 (agomelatine) for depression and ABF656 (Albuferon for hepatitis C as well as RAD001 (everolimus) for cancer and SOM230 (pasireotide) for Cushing's disease are moving into pivotal late-stage trials.

"I am pleased that our sustained focus on innovation and drive to address unmet medical needs have enabled us to further strengthen our pipeline and file several new drugs for regulatory review over the past 12 months," said Dr Daniel Vasella, chairman and CEO of Novartis.

"Over the next two years we will launch several innovative medicines and continue to invest aggressively in discovery research and development activities and complement our own skills and technologies through attractive collaborations," Dr Vasella said.

In total, Novartis now has 138 projects in pharmaceutical clinical development. Of these, 94 projects are in confirmatory development (Phase IIb, phase III or registration with regulatory authorities). A total of 50 are new molecular entities (NMEs), while 88 are life-cycle management projects involving new indications or formulations. More than 20 projects have been added to the pipeline during 2006. Key R&D areas are cardiovascular/metabolic conditions, oncology and neuroscience as well as respiratory and infectious diseases.

Novartis has completed many submissions in 2006 to regulatory authorities for new compounds as well as new indications for medicines already available to patients.

The US and EU regulatory submissions were accelerated and completed ahead of schedule in 2006 for two compounds: Tasigna (nilotinib) as a new treatment option for patients with resistance and/or intolerance to treatment with Gleevec/Glivec for certain forms of chronic myeloid leukaemia (CML), and also for Aclasta/Reclast (zoledronic acid) as a once-yearly bisphosphonate infusion for women with postmenopausal osteoporosis.

US regulatory decisions are also expected for Tekturna (aliskiren), a renin inhibitor for hypertension, and Exforge (valsartan and amlodipine), a single-tablet combination of the two most prescribed hypertension medicines in their respective classes.

Awaiting European Commission approval are Exforge and Lucentis, a new treatment option for patients with the "wet" form of age-related macular degeneration (AMD), after both compounds received positive recommendations in November from the Committee for Medicinal Products for Human Use (CHMP). The Commission generally follows the recommendations of the CHMP and delivers a final decision within two to three months.

A US regulatory decision is also expected in the first half of 2007 for Galvus (vildagliptin) as a once-daily oral treatment for patients with type 2 diabetes. The US FDA extended the review period for Galvus by three months from November 2006 after recently available clinical data were submitted to support the proposed dosing and indications as well as complement earlier data on the risk/benefit profile.

IndoGlobal to develop R&D tool for chemists in pharma, biotech

Y V Phani Raj, Hyderabad

THE Pune-based IndoGlobal Knowl-

support in the near future, she added.

The company with a strong team comprising

MSF urges Novartis to drop its case against Indian patent law

Our Bureau, New Delhi

INTERNATIONAL medical humanitarian organisation Medicines Sans Frontieres (MSF) has launched an international petition to put pressure on the Swiss pharmaceutical company Novartis to drop its legal challenge against India's patent law which could restrict access to affordable medicines in the developing world.

India has long been an important source of affordable essential medicines because the country did not grant pharmaceutical patents until 2005. Generic antiretroviral medicines produced in India are used to treat over 80 per cent of the 80,000 people that receive treatment today in MSF's AIDS projects in more than 30 countries.

"We rely on less-expensive, good-quality medicines produced in India to treat as many people with AIDS as possible," said Dr. Christophe Fournier, MSF International Council President as the NGO officials held press conferences in this regard in New Delhi and Geneva simultaneously yesterday.

Novartis was one of the 39 companies that took the South African government to court over five years ago in an effort to prevent the government from importing cheaper AIDS medicines.

"It feels like we are back in South Africa in 2001," said Dr Tido von Schoen-Angerer, of MSF's Campaign for Access to Essential Medicines. "Just like five years ago, Novartis with its legal actions is trying to stand in the way of people's right to access the medicines they need," he said.

India's law contains provisions that help put people before patents, but Novartis is taking the Indian government to court to force a change in the law. The company is challenging a key public health safeguard enshrined within India's Patents Act that aims to restrict the granting of trivial patents. If Novartis gets its way, it could mean that essential drugs are more likely to be patented in India, thereby restricting generic production and keeping prices for newer medicines high.

A constant flow of affordable newer medicines is particularly important for the treatment of AIDS, as people inevitably become resistant to their medicines and need newer drug combinations. But currently, patent applications on crucial newer generation AIDS medicines await patenting decisions in India.

"For people like me, who live with HIV/AIDS, a win by Novartis will mean a step back in time to the days when we could not afford our medicines," said Loon Gangte of the Delhi Network of Positive People. "Generic competition is what has made first-line AIDS drugs affordable for people and for governments. Novartis needs to stop standing in the way of our right to access the medicines we need to stay alive," he said.

Novartis filed patent applications for the cancer drug imatinib in most countries in 1993. The company was not able to do so in India, as the country was not granting product patents at that time. In 1998, Novartis applied for a more specific patent on the beta-crystalline polymorph of a mesylate salt of imatinib i.e. imatinib mesylate, in order to try to obtain a patent monopoly in India.

In January 2006, the patent on imatinib mesylate, which Novartis produces under the brand name Gleevec, was rejected in India on the grounds that it only represented a new form of a known substance and therefore was not an innovation and not patentable under Indian law. In May 2006, the company filed an appeal to the patent rejection, as well as a challenge against Section 3(d) of India's Patents Act. ◆

Australian Federal Court rules against Ranbaxy

New York

AUSTRALIAN Federal Court in Victoria has upheld the exclusivity of Pfizer's basic patent covering atorvastatin, the active ingredient in Lipitor. The ruling, the culmination of a lawsuit filed in 2005 by generic drug manufacturer Ranbaxy. It includes an injunction against Ranbaxy's product and preserves Lipitor's patent coverage in Australia through May 2012. Ranbaxy can appeal the decision.

The court found that a proposed Ranbaxy generic product would infringe Pfizer's basic Lipitor patent (AU 601,981). A second patent covering the calcium salt of atorvastatin (AU 628,198), which expires in September 2012, was ruled invalid by the court. Pfizer will appeal that ruling.

The Australian decision will not impact ongoing Lipitor patent actions in other countries. Pfizer said it will continue to vigorously defend against challenges to its intellectual property, noting that patents provide the necessary incentive to invest in new and life-saving medicines that benefit millions of patients globally. ◆

Mirus Bio receives RNAi patent for delivery technology

Madison, USA

MIRUS Bio Corporation announced the grant of US Patent No.7,148,205 entitled "intravascular delivery of non-viral nucleic acid." The patent broadly covers administration of RNAi-inducing molecules via hydrodynamic intravascular injection.

A key bottleneck impeding the progress of the groundbreaking field of RNA interference (RNAi) has been the lack of effective delivery methods. This delivery breakthrough combined with RNAi creates a powerful discovery research tool for studying gene function in animal models, and in the long term might be used for certain human therapeutic tissues.

"Mirus Bio is increasingly being recognized for its world class expertise in nucleic acid chemistry and delivery," commented Russell Smestad, Mirus Bio's President. "Hydrodynamic injection has already been widely adopted in the RNAi research field as the most effective method for in vivo delivery to liver, where it is a unique tool for target identification and validation studies. In the future we anticipate that our proprietary Pathway IV hydrodynamic protocol for delivery of nucleic acids to limb skeletal muscle will similarly be recognized as an enabling platform for human therapeutics, both for RNAi as well as DNA based products. We are actively pursuing strategic alliances and licensees to apply this technology as widely as possible."

Hydrodynamic intravascular injection is a method to deliver nucleic acids through the bloodstream to surrounding cells and tissues. Normally, standard injection of DNA or RNA into a vein or artery would result in the nucleic acids being retained within the blood vessel until degraded and filtered out of the body. However, researchers at Mirus Bio together with collaborators at the University of Wisconsin-Madison discovered that rapid injection of a large volume nucleic acid-saline solution combined with simultaneous mechanical or biological alteration of the permeability of the vessel wall enabled the DNA/RNA to migrate into the surrounding tissue cells. This enables regional delivery throughout an entire limb or other tissue rather than being localized to a single point of injection as happens with a needle and syringe.

RNA interference (RNAi) is a natural cellular process wherein short nucleic acids known as small interfering RNA (siRNA) regulate gene expression and protein production. In normal cells, DNA is copied to messenger RNA (mRNA) which directs the synthesis of protein. The RNAi gene silencing process involves the introduction of double-stranded RNA molecules into a cell, after which a multistep cellular process creates single-stranded siRNA molecules that interfere with the translation of mRNA into the protein it encodes. Blocking production of disease causing proteins in this manner represents a fundamentally new approach for innovative medicines. The significance of this biological pathway was highlighted in October when the two researchers credited with discovering this powerful biological phenomenon were jointly awarded "The Nobel Prize in Physiology or Medicine for 2006". ◆

Novartis presents data on new leukaemia drug

Basel

NEW clinical data has demonstrated that Tasigna (nilotinib) eliminated or significantly reduced the presence of blood cells containing a defective chromosome in approximately half of adult patients with a form of life-threatening leukaemia who developed resistance or intolerance to treatment with Glivec (imatinib).

The reductions has achieved in these patients resistant to Glivec, one of the first oncology drugs developed based on an understanding of how some cancer cells work, may be the highest ever reported with a targeted therapy at a minimum of six months follow-up.

The phase II data, which forms the basis for US and EU regulatory submissions completed earlier in 2006, showed that the use of Tasigna in patients with Philadelphia chromosome-positive (Ph+) chronic myeloid leukaemia (CML) reduced or eliminated the presence of this defective chromosome in 51 per cent of Glivec-resistant patients in chronic phase of this disease and led to normalize white blood cell counts in 74 per cent of these patients.

The study also showed a similar magnitude of elimination or reduction of these defective cells in 55 per cent of intolerant patients. Data from this trial were presented at the American Society of Hematology annual meeting.

Novartis has filed applications with both the US FDA and European Medicines Agency (EMEA) for Tasigna as a therapy for adult patients with chronic or accelerated phase Ph+ CML with intolerance and/or resistance to Glivec.

Tasigna was developed by Novartis as a next-generation targeted therapy based on the success of Glivec. Although data from the landmark IRIS trial - the largest-ever conducted in CML patients - demonstrated that nearly 90 per cent of chronic-phase Ph+ CML patients taking Glivec were alive at five years, a small subset of patients develop resistance or cannot tolerate this therapy.

Both Tasigna and Glivec are designed to inhibit production of cells containing the Philadelphia chromosome by inhibiting the Bcr-Abl protein. Bcr-Abl is recognized as the key cause and driver of the proliferation of white blood cells that characterizes Ph+ CML.

While Tasigna and Glivec target the same pathways, the strategy behind the Tasigna research programme was to design a preferentially Bcr-Abl targeted therapy that would be more potent against Glivec mutations but avoid the potential side effects of less targeted agents.

"These exciting data demonstrate that Tasigna has the potential to offer a compelling new treatment option for patients with Ph+ CML. Designing Tasigna to be an even more targeted Bcr-Abl inhibitor than Glivec appears to be providing impressive efficacy results with a manageable safety profile," said David Epstein, CEO and president of Novartis Oncology. "We look forward to further exploring the potential benefits of Tasigna through our broad phase III clinical trial programme in earlier CML settings."

TRI at Narayana Hrudayalaya to commence trials of vaccine for heart attack prevention in 2008

Nandita Vijay, Bangalore

NARAYANA Hrudayalaya, the leading cardiac care major in Karnataka and the Thrombosis Research Institute, London, UK have teamed up to set up Thrombosis Research Institute, India. The facility located at the Narayana Hrudayalaya is undertaking research on heart vaccine to prevent heart attacks. The human trials should commence by 2008-2009 and an additional five years from there for commercialization of the vaccine. The research is a DBT funded programme and a Tata Trust initiative. The state-of-the-art research facility was inaugurated by President of India APJ Kalam.

The affordable vaccine is expected to immunize vulnerable adolescents against cardiovascular diseases including atherosclerosis, which is a condition of blood vessel thickening. The vaccine would be an effective way of arresting the disease even before it strikes, said Dr. Devi Prasad Shetty, managing director Narayana Hrudayalaya and Thrombosis Research Institute 's trustee.

Dr Shetty, a renowned cardiac surgeon in the country said that cardiovascular disorders are a recognizable complaint. For the research, the medico-scientists have assessed over 3,500 affected patients below the age of 55 who have suffered a stroke or a coronary disorder and then traced it as heredity linkage to establish the effectiveness of the vaccine. The study intends to investigate 12,500 cases before 2008. The present analysis already indicates that in India cardio vascular disease is not just a geriatric condition but a disease which has been affecting even the young population. Presently heart ailments are a dreadful epidemic growing in magnitude. Around 10 per cent of India's one billion population are affected with ischemic diseases. Every 140th person is diagnosed with congenital heart diseases and one in 1,000 are affected with rheumatic heart condition.

Cardiac surgeons need to perform 25 lakh heart surgeries every year but the current estimates indicate only 70,000 surgeries. The shortfall is attributed primarily to lack of awareness and affordability for surgery.

The joint venture with TRI London which is a multidisciplinary organization focusing on interrelated problems of thrombosis and atherosclerosis, has given a platform for TRI India to pursue genetic studies to assess the increased susceptibility to premature heart diseases using a broad strategy for genomic screening, fine mapping of candidate gene analysis and family association. This will allow faster drug discovery, in novel and affordable therapies. ◆

Global trials for CVD polypill from next year

Joseph Alexander, New Delhi

DR.Reddy's Lab's global trials to test the benefits of a `polypill', a combination of four drugs to treat heart diseases, will begin in the next year involving 600 people in eight countries, including India.

Prof Anthony Rodgers, of the University of Auckland's clinical trials research unit, who was an advisor to the WHO, will lead the team for the global trials. New Zealand, India, Australia , Brazil, China, South Africa, the US and the UK will be parties to the trials involving people with raised risk of having heart attack or stroke.

"The four medicines - aspirin, a statin to lower cholesterol and two blood pressure drugs - combined into one will potentially be much more effective," feels Prof Rodgers.

During his recent visit to India, as part of teaming up with Dr Reddy's Labs as partner in the global trials, Prof Rodgers said the people for trials would be recruited by second quarter of next year. One group will take the polypill and the second will take a placebo.

"The first trial will confirm whether the polypill lowers blood pressure and cholesterol. If it goes ahead, the second trial will measure the polypill's success in reducing the occurrence of heart attacks and strokes," he said.

> Prof Anthony Rodgers, of the University of Auckland's clinical trials research unit, who was an advisor to the WHO, will lead the team for the global trials

The Health Research Council of New Zealand is investing NZ $ 350,000 to support overall coordination of the trial. Dr Reddy's will invest NZ$ 7.5 million. New Zealand researchers will also conduct separate trials from early next year with people at high risk of heart attack and stroke.

Cardiovascular diseases (CVD) are reportedly responsible for about 30 per cent of all deaths worldwide. The number of disease cases is poised to go up from 380 lakhs of 2005 to 641 lakh cases by 2015, it is estimated.

"The polypill is expected to reduce the risk by 60 per cent. Research shows that people with chronic diseases like heart diseases only take half their medications. Polypill will provide an easier and more practical way to take the medications," Prof Rodgers said.

The pill is likely to cost only a few dollars a month in developing countries. A WHO report, prepared by Prof Rodgers and team, showed that it could be one of the most cost-effective interventions for CVD globally. WHO data showed that about 17 million people die prematurely from heart diseases or strokes every year and most of the cases are in low and middle-income countries. ◆

bottom lines and sales during the first nine months of 2006 and they are likely to achieve a growth rate of 23 to 25 per cent in the whole of 2006. The net profit of 15 companies in the nine months ended September 2006 increased by 23 per cent to $ 64,531 million from $ 52,460 million in the corresponding period of last year. The earning per share for the year full year 2006.

The Pharmabiz sample of 15 global companies namely Pfizer, GlaxoSmithKline, Novartis, Sanofi-aventis, AstraZeneca, Roche, Johnson & Johnson, Merck & Co, Bayer Group, Bristol-Myers Squibb, Wyeth, Eli Lilly, Amgen, Abbott and Baxter International, have recorded $ 243,435 million in the similar period of last year. The pharmaceutical sales of 15 companies in the US improved by 11.7 per cent to $ 135,266 million as compared to $ 121,099 million in the last period.

Pfizer remained on top with net sales of $ 35,768 million during the first nine months of the year 2006, registering only

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Decision on patentability criteria and data protection soon

PB Jayakumar, Mumbai

THE expert committee set up by the Central Government to define the patentability criteria in the Patent Act has submitted its report to the Government, and the crucial expert committee on data protection will submit its report within a month.

Addressing the Indian Drug Manufacturers Association (IDMA) annual convention in Mumbai, last week, Prithviraj Chavan, Minister of State, PMO, Government of India, said the Mashelkar Committee on patentability criteria submitted its report on 28th December 2006. The Committee has recommended various options and adequate safeguards to protect the interests of the Indian pharma industry, while defining patentability of NCEs. The committee has also suggested restricting of patentability to manmade and biological microorganisms and the Government is likely to accept this recommendation, considering the concerns of domestic industry, said Chavan.

The Committee was set up by the Department of Industrial Policy and Promotion (DIPP) and the Ministry of Commerce to see whether it would be TRIPs (Trade-Related Intellectual Property Rights) compatible to limit the grant of patents for pharmaceutical substance to new chemical entity or to new medical entity involving one or more inventive steps.

Talking to Pharmabiz, he said the Government was evaluating the suggestions of the Mashelkar Committee and soon the details will be announced. "There is no need to amend the Patents Act or DC Act to incorporate these decisions, which can be done by a notification. The Government is studying the recommendations and will soon announce the criteria", he said.

He also said the Committee on data protection, headed by the Joint Secretary, Dept. of Chemicals & Petrochemicals, will submit the recommendations either by the end of this month or early next month. He said the Government was exploring various models followed by other countries, especially like that of Brazil, which did not heed to the pressure from the US interest groups. ◆

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Joseph Alexander, New Delhi

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Novartis moves Chennai HC against invalidation of Glivec patent

Joe C Mathew, New Delhi

NOVARTIS India has approached Chennai High Court against the orders of the Patent Controller invalidating the patent claim on Novartis' blockbuster anti-cancer drug Glivec (Imatinib Mesvlate). The company has questioned the constitutional validity of Section 3(d) of the Patents Act 1970 itself and has pleaded that any decision considered under Section 3 (d) should be considered legally non-tenable. The HC has issued notices to all respon dents and has called for a hearing on August 23.

The Glivec was the only drug that had received exclusive marketing rights (EMR) during the mailbox period. Further examination of the patent application showed that the patent specification of Novartis AG does not bring out any improvement in the efficacy of the beta-crystal form over the known substances.

As per Section 3(d) of the Patents Act, any salt, polymorph or derivative of known substance is not patentable unless such salt, polymorph or other substance shows enhanced efficacy of the substance.

Giving its ruling in January 2006, Patent Office had stated that Glivec is only a new form of a known substance. Further, stating that Novartis AG failed to prove enhanced efficacy of the beta-isomer over the known substance, the patent office had concluded that, the subject matter of this (patent) application (filed by Novartis AG) is not patentable under Section 3(d) of the Patents Act 1970 as amended by the Patents (Amendment) Act, 2005.

It is against this ruling Novartis has now approached the High Court.

Interestingly, the Chennai HC had, in an earlier ruling, asked Novartis to give Glivec free of cost to all patients who are suffering from CML and are earning from less than Rs 3,36,000 per month. This was the time when Novartis was having EMR on the drug. Natco was the only generic company that had obtained permission to market the generic version of the drug at a fraction of Glivec's cost in the country. After the expiry of the EMR period, Chennai HC had allowed all generic manufacturers to enter the fray. All generic manufacturers who are into the manufacture and sale of the generic versions of Glivec are party to the new case.

Mologen gets EU patent for DNA-vaccine

Berlin

MOLOGEN AG has announced that the European Patent Office has granted patent for the DNA-vaccine against oncoviruses. Corresponding applications outside the European Union are pending before national patent offices, a company release said.

The invention relates to a DNA-vaccine against oncoviruses, based on Mologen's proprietary DNA-vector MIDGE-TH1. Oncoviruses cause severe diseases including cancer, anaemia and immuno-suppression. Especially cats can be protected against infections with the oncovirus FeLV (Feline Leukaemia Virus) by the vaccine.

FeLV is a feline virus infecting cats worldwide. Serious diseases following infection are a major cause for death of cats. Currently, approximately 10 per cent of all cats in Europe, USA and Japan, the most important markets for veterinary pharmaceuticals for pets, are infected with the virus.

Today, an effective therapy for FeLV infections is not available. In best case scenario, the disease can be suppressed for a certain time. Several chemotherapeutics are applicable in cats, but side effects are as serious as in applications for humans. The only effective way to prevent FeLV infections is vaccination. Some marketed vaccines have limited efficacy. Moreover, there are FeLV-vaccines which in a minor number of cats can cause severe side effects like tumours at the injection site. The estimated average annual sales volume of FeLV-vaccines is fare above 50 million USD.

Mologen uses its proprietary DNA technologies to create and develop treatments for high-unmet-need illnesses. The main focuses are the unique and patented MIDGE and dSLIM technologies. Based on these platforms, Mologen is developing DNA-based vaccines and therapeutics to prevent or cure a wide range of diseases.

Dear Naveen, Sent except NDTV.

Press Invite for Protest by Cancer patients groups and civil society groups in Bangalore faxed for the following:

1.	Indian Express	- 22866617
2.	DDI	- 23333990
3.	Udaya News	- 22357292
4.	ETV	- 22384483
5.	Deccan Herald	- 25880523
6	Times of India	- 25586617
7.	Samyuktha Karnataka	- 22214366
8.	NDTV	- 25543393
9.	Hindu	- 25064052
10.	Asian Age	- 22273561
11.	U.T	- 22357292

Regards
Maria

For Immediate Release **September 13, 2006**

BANGALORE CITIZENS STAND IN SOLIDARITY WITH CANCER PATIENTS

- DEMAND IMMEDIATE WITHDRAWAL OF CASES BY NOVARTIS

About 300 citizens of Bangalore gathered at Mahatma Gandhi statute on M.G. Road on Tuesday (September 12, 2006) in solidarity with cancer patients and protested against the threat of live-saving drugs being taken away from their reach. Karnataka Cancer Society, Karnataka Prantiya Raitha Sangha, Karnataka Prantiya Krishi Coolie Karmekara Sangha, Student Federation of India, BGVS, Samraksha, Freedom Foundation, Milana, KNP+, Action Aid, AMTC, Abhaya, Pragathi, CIEDS/ Karnataka Social Forum/ WSF, Sangama, Community Health Cell (CHC), Janaarogya Andolana – Karnataka (JAA-K), Student representatives of different city colleges, All India Drug Action Network (AIDAN) and many other civil society groups participated in the solidarity meet.

Cancer patient groups and the civil society groups have been fighting a long battle against the greed of companies to make a killing out of life-saving medicines. Novartis, a Multi National Drug Company filed an application for a patent on 'Imatinib Myselate' (Gleevec) in 1998. This was opposed by the cancer groups and generic companies and subsequently it was **rejected by the Chennai patent office on 25 January 2006 on the grounds that the application claimed not an invention but '*only a new form of an old drug*'.**

In May this year, Novartis has filed cases challenging the rejection of its patent application and questioning the Indian Patent Law. Novartis' constant litigation threatens the lives of cancer patients and renews fears of future availability if the patent case of Gleevec is reopened. ***"Novartis' actions in challenging India's patent law are an ominous sign of things to come."*** **Patient groups have to spend their invaluable time, energy and resources in expensive legal battles designed by drug companies to discourage oppositions to their patents and pricing policies.**

P.T.O.

Gleevec is a anti-blood cancer medicine. India has 25000 new Blood Cancer patients every year in urgent need of medicines, with one-third of them being children. **18,000 people die each year without treatment as they cannot afford the prices of the medicine.**

Novartis sells 'Gleevec' at ***Rs. 1,20,000 ($ 2500)*** per patient per month while generic versions of 'Gleevec', made by Indian companies are priced at about ***Rs. 8,000 ($ 175)*** per patient per month. If Novartis is granted a patent, Indian companies will have to stop manufacturing the medicine, which will greatly affect the prices and easy availability of the medicine.

"India while complying with the TRIPS agreement and introducing a product patent regime for new drugs that were invented, also coupled its law with a safeguard of refusing patents on discovery of new uses or forms of older drug. The patent decision on Gleevec was an implementation of this critical safeguard", says Gopa Kumar, Centre for Trade and Development (CENTAD). It is this crucial clause in the Indian Patent Act which Novartis is challenging.

The Novartis cases have raised concerns among public interest and health groups as the 'Gleevec' patent order set a good precedent for the examination of other essential drug patent applications. *"Patents have created 20 year monopolies over drugs and have directly resulted in the denial of life saving treatment to millions around the world as particularly evidenced in the case of AIDS drugs. The public health protections of the Indian Patent law have given hope to many who depend on generics manufacture and the Novartis litigation is a direct challenge to those protections",* says Leena Menghaney, Médecins Sans Frontières (MSF) India's Access Campaign Manager.

Patient and public interest groups are protesting and demanding a withdrawal of the cases by Novartis.

Bangalore Forum for Access to Medicines - Karnataka Cancer Society, Karnataka Prantiya Raitha Sangha, Karnataka Prantiya Krishi Collie Karmekara Sangha, Student Federation of India, BGVS, Samraksha, Freedom Foundation, Milana, KNP+, Action Aid, AMTC, Abhaya, Pragathi, CIEDS/ Karnataka Social Forum/ WSF, Sangama, Community Health Cell (CHC), *Janaarogya Andolana* – Karnataka (JAA-K), Garment Worker's Association, Student representatives (SJC), Student's representatives (ULC).

Contact person: Naveen, CHC, No. 359 (Old No. 367), Srinivasa Nilaya, Jakkasandra, 1st Main 1st Block, Koramangala, Bangalore - 560 034 Ph: 25525372, 25531518 Email: naveen@sochara.org

> Date: Wed, 30 Aug 2006 23:24:56 -0700 (PDT)
> From: Sreepathi Prafulla <prapulli@yahoo.com>
> Subject: Gleevac - novartis petition
> To: aidbangalore@yahoogroups.com,
> drdabade@gmail.com, navthom@yahoo.co.uk,
> chc@sochara.org
>
> Dear friends,
>
> NOVARTIS CHALLENGES INDIA'S PATENT LAW!!!
> SUPPORT INDIAN PATIENTS IN PROTESTING AGAINST
> NOVARTIS LITIGATION!
>
> Earlier this year we informed you of the first
> victory
> of patients groups in India when the Chennai Patent
> Controller rejected Novartis' patent application for
> 'Gleevec' a crucial anti cancer drug. Novartis has
> now
> filed three cases in India challenging this order
> and
> against the Government of India and the Cancer
> Patients Aid Association – a Mumbai based cancer
> patients group working in India for over 35 years.
>
> Gleevec is the test case of the Indian patent system
> that so many persons living with HIV/AIDS and other
> patients are relying on for the continuation of
> generics manufacture. It is the first test of the
> flexibilities of the TRIPS and Doha. Novartis'
> litigation is a direct challenge to our lives and
> health and we call on all activists and health
> groups
> to support Indian patients in this fight.
>
> WHAT IS GLEEVEC?
> Imatinib Myselate or Gleevec is a crucial cancer
> drug
> essential in prolonging the life of patients
> suffering
> from Chronic Myeloid Leukaemia (Blood Cancer). It is
> produced and marketed internationally by Novartis
> and
> various Indian pharmaceutical companies like Cipla,
> Ranbaxy, Natco, and Hetero also manufacture.
>
> WHAT HAPPENED WITH GLEEVEC IN INDIA?
> Indian generics companies started manufacturing and
> supplying affordable versions of Gleevec (much like
> they did AIDS medicines). In 2003 Novartis got
> 'Exclusive Marketing Rights' (EMR) under a provision
> of India's patent law for five years. The EMR acted
> like a monopoly right and Novartis succeeded in
> stopping generic manufacture of Gleevec.
>
> To put the effect of all this in perspective;
> generic
> versions of Gleevec were available in the Indian
> market at about Rs. 8,000 ($175) per patient per
> month. After Novartis prevented generic manufacture
> it
> marketed Gleevec at nearly ten times that price i.e.
> Rs. 1,20,000 ($ 2000) per patient per month. Gleevec
> was clear and damning proof of what happens when a
> drug company gets a patent.
>
> WHY WAS NOVARTIS' PATENT APPLICATION FOR GLEEVEC
> REJECTED?
> After India's patent law changed in 2005 to become
> TRIPS compliant (see attached note on Indian Patent
> law) Novartis patent application came up for
> examination. The Cancer Patients Aid Association,
> which had to stop treatment for cancer patients
> after
> generic versions on Gleevec became unavailable,
> challenged this. Novartis patent application was
> rejected by the Chennai Patent office for being
> merely
> a 'new form of an old drug', which under Section
> 3(d)
> of the Indian Patent Act is not patentable. This
> brought immense relief to cancer patients in India
> and
> indeed around the world whose lives could not wait
> for
> a 20-year drug monopoly to get over.
>
> WHAT IS NOVARTIS DOING NOW?
> Now Novartis has challenged the rejection of its
> patent application. It has also challenged Section
> 3(d) of the Indian Patent Act in a separate case
> questioning the constitutional vailidity of 3(d) in
> accordance of the TRIPS Agreement.
>
> URGENT ACTION
> The Cancer Patients Aid Association and the Lawyers
> Collective are organizing actions in India to
> coincide
> with the hearing on 13th August 2006 in the Chennai
> High Court of Novartis challenge.
>
> We request you to participate in a planning meeting
> on
> the 1st of September at 5 pm. to plan for a protest.
>
> The venue: Lawyers Collective HIV/AIDS Unit, First
> Floor No 4 A MAH Road, Off park Road Tasker Town,
> Shivajinagar, Bangalore –560051
>
> If you have any further clarification kindly contact
> Prafulla/Raja Kumar at 41239130/31
>
> also pls find the attachments for your further
> reading
>
> Lets all fight for access to medicine
>
> Prafulla

Gleevec Fact File

Cancer is a disease that is life threatening and a person affected requires monitoring and treatment for life long. There are about 25,000 new cases of CML (Chronic Myeloid leukemia). Leukemia accounts for nearly one third of pediatric malignancies. These numbers represent women, men and children from all strata of society. About 18,000 people die due to CML every year in India.

In 1993, research began on pyrimidine derivatives and processes for its preparation. The first STI1571 (crystalline form of Imatinib Mesylate, a pyrimidine derivative) studies began. Imatinib Mesylate was found to be effective as a Signal Transduction Inhibitor (STI). STI inhibits the action of the enzyme tyrosine kinase (BCR-ABL). The tyrosine kinase is the protein produced by a DNA translocation (Philadelphia chromosome) that appears central to the CML disease process.

Drugs which are available even by the generic companies, are out of their reach and unaffordable for them. Treatment for cancer even though available at some government hospitals is expensive. People affected by cancer die due to non-affordability of treatment.

The proposed patent application is for **Gleevec** which is β crystalline form of imatinib mesylate, patent for Gleevac not only deserves to be rejected on the grounds that there is no novelty, it is not an invention, it was obvious for person skilled in art, but also should be rejected as the applicants have only used the purported invention for commercial exploitation, by selling the drug in the Indian market at Rs.1,20,000/- per month, which cannot be afforded by patients affected by chronic myeloid leukemia.

By granting a patent for the alleged invention, it would only allow for commercial exploitation of the purported invention, thereby excluding all other generic companies, causing serious prejudice to human health.

Such monopolizing of the drug at the above-mentioned exorbitant price is, thereby causing an adverse affect on and serious harm to public health. It may be noted that this in itself is contrary to public order and morality, and the patent should not be granted.

Novartis claims to have spent hundreds and millions of dollars in Research and Development, manufacturing and clinically testing the drug that they have lead to set a world wide price of *Gleevec* at USD 27,000 (INR 13, 50, 000 {Rupees thirteen lakhs and fifty thousand only} approx.) per year per patient. The Petitioner has already earned about USD 1 billion from *Gleevec* sales alone in the year 2003.

However, much of the research and development of *Gleevec* was carried out by one Dr. Brian Drucker of Oregon Health and Science University. His laboratory worked in a partnership with the Petitioner and identified the compound STI1571. The funding sources for developing the drug was 50% from the National Cancer Institute (US government), 30% from the Leukemia and Lymphoma Society (US NGO sector), 10% from the Petitioner, and 10% from Oregon Health and Science Institute.

We urgently need references to support our arguments. Please read the current sections with this in mind and send your references to the current Penholder with copy to Rakhal.

We need to move quickly on the collection of personal data about research collaborators as well as SRUs. There are new materials on the site which refer.

Progress is being made!

cheers all

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The sales of *Gleevec* in 2002 were about USD 762 million and till September 2003 the sales in the international market was about USD 795 million. In India alone from May 2002 to December 2002 *Gleevec* sales were Rs.96.773 million and between January and November 2003 it was about Rs.112.354 million (Rupees eleven crores, twenty three lakhs and fifty four thousand).

Novartis imports the said drug for commercial purposes in India at a rate of Rs.90,000/- to Rs.1,20,000/-. The generic versions of the drugs were much cheaper and cost about Rs.90 per 100 mg capsule, and if 4 capsules are taken in a day it would cost Rs.360/- per day, compared to *Gleevec*'s cost of Rs.1,000/- per 100 mg capsule, and a cost of Rs.4,000/- per day.

S.NO	NAME OF COMPANY	PER MONTH COST OF THE DRUG	AVAILABILITY
1	M/s Novartis AG	Between Rs.90,000/- to Rs.1,20,000/-.	Not easily available in the market
2	M/s Sun	Between Rs. 8,500/- to Rs.10,200/-	Easily available in the market
3	M/s Natco	Between Rs.9,000/- to Rs.10,800/-.	Easily available in the market
4	M/s Cipla	Between Rs.8,500/- to Rs.10,500/-	Easily available in the market.
5	M/s Ranbaxy	Between Rs.9,000/- to Rs.10,500/-.	Easily available in the market.
6	M/s Hetero	Between Rs.8,500/- to Rs.10,500/-.	Not easily available in the market.
7	M/s Shantha	Between Rs.8,500/- to Rs.11,880/-	Not easily available in the market
8	M/s Intas	Between Rs.8,500/- to Rs.12,600/-.	Easily available in the market.
9	M/s Camlin	Between Rs.8,500/- to Rs.10,200/-.	Easily available in the market
10	M/s Emcure	Between Rs.8,500/- to Rs.11,000/-	Not easily available in the market.

Briefing Note
August 06

NOVARTIS FILES CASE IN INDIA CHALLENGING PATENT CONTROLLER'S ORDER AND PATENT LAW

CANCER PATIENTS DEMAND WITHRAWAL OF CASES

On 17th May 2006 Swiss pharma company Novartis Ltd. filed two cases against the Government of India and the Cancer Patients Aid Association (CPAA) challenging the rejection of the 'Gleevec' patent application and the Indian Patent Law. CPAA is a Mumbai based cancer patients group working in India for over 35 years.

Imatinib Myselate (Gleevec) – A Crucial Drug for Cancer Treatment
Imatinib Myselate (Gleevec) is a crucial cancer drug essential in prolonging the life of patients suffering from Myeloid Leukemia (Blood Cancer). It is produced and marketed internationally by the Swiss pharmaceutical company Novartis and various Indian pharmaceutical companies like Cipla, Ranbaxy, Natco, and Hetero. Novartis sells 'Gleevec' at **Rs. 1,20,000 ($ 2500)** per patient per month. Generic versions of the drug 'Gleevec' in the Indian market are priced at about **Rs. 8,000 ($175)** per patient per month.

Novartis files patent application in India – temporary monopoly granted
In 1998 Novartis filed an application in the Chennai Patent Office for a patent on Imatinib Myselate (Gleevec). Based on the patent application and a particular provision of the Indian Patents Act, Novartis in November 2003 obtained exclusive marketing rights (EMR) for a period of five years.

Cancer patient's access to generic 'Gleevec' affected
The EMR operated like a patent monopoly preventing Indian pharmaceutical companies from producing affordable generic versions of the drug Imatinib Myselate (Gleevec). Generic companies had to withdraw the production and sale of the generic versions of the drug in India and other developing countries.

With an over 10 fold increase in the price of the drug, Cancer Patients Aid Association and other cancer groups who provided the more affordable generic versions of 'Gleevec' to Myeloid Leukemia patients for their treatment had to withdraw their medical support to cancer patients. Patients of other developing countries who were importing generic versions of the drug were also seriously affected by the unavailability of the affordable versions of 'Gleevec'.

Cancer Patient Group filed Patent Opposition
This situation of unavailability of affordable generic versions of the drug continued till 2006. In 2005 India changed its patent law to become TRIPS compliant and Novartis' patent application on Gleevec came up for examination. The Indian patent law allows for any person or group to oppose a patent application and the Cancer Patients Aid Association (in addition to an already pending Supreme Court challenge to the EMR) filed an opposition on behalf of cancer patients in the Chennai patent office where the application of Novartis was pending.

Chennai Patent Office rejects 'Gleevec' patent application
In January 2006 the Chennai Patent office rejected Novartis' patent application on the ground that the application claimed '*only a new form of an old drug*'. This order of the Chennai patent office brought relief to thousands of cancer patients as it not only prevented a patent monopoly till 2018 but also automatically cancelled the EMR. The Gleevec patent order rejecting a 'new form of an

old drug' also set an important precedent for the examination of patent applications related to essential drugs including AIDS medicines.

Novartis challenges Patent Order and Indian Patent Law

In May 2006 Novartis filed two sets of cases in the Chennai High Court. The cases have been filed against the Government of India and the Cancer Patients Aid Association.

The first case challenges the patent order of the Chennai Patent office rejecting the Gleevec patent application filed by Novartis. This is scheduled for hearing on 23rd August 2006. Legal representatives of the Cancer Patients Aid Association will appear on their behalf before the Chennai High Court. Novartis' constant litigation threatens the lives of cancer patients and renews fears about the future availability of drugs if the patent case of 'Gleevec' is reopened. Further it has raised concerns among other patient groups as the 'Gleevec' patent order set a good precedent for the examination of crucial drugs patent applications including those for AIDS treatment.

The second case filed by Novartis challenges the constitutionality of section 3(d) of the Indian Patents Act, which was specifically introduced by the Indian parliament as a safeguard against the misuse of the product patent regime. Novartis in its petition is claiming that the section is not in compliance with the TRIPS agreement and hence should be declared unconstitutional.

Section 3 (d) of the Indian Patent Law - an important public health safeguard

The section is aimed at preventing pharmaceutical companies from obtaining patents on old medicines i.e. trivial patenting and new use patents etc. In the 1990s, pharmaceutical companies obtained additional patents on cancer drugs like Zidovudine for a new use i.e. HIV/AIDS treatment. The patent granted on Zidovudine prolonged the market monolpoly of Glaxo and deprived millions in the developing world from accessing AIDS treatment till Indian manufacturers produced generic versions in the absence of product patents in India.

Therefore India while complying with the TRIPS agreement and introducing a product patent regime for 'new drugs that were invented', also coupled its law with a safeguard of refusing patents on discovery of new uses or forms of older drugs (i.e. to prevent evergreening)[1]. This law is considered by experts to be in conformity with TRIPS as the agreement allows each country to set its criteria of patentability and does not prevent countries from including safeguards against the grant of patents on old drugs i.e. trivial patents. Each country can introduce a patent regime that is more suited to its socio-economic context. This is also in keeping with the 2001 Doha Declaration on the TRIPS Agreement and public health.

Cancer Patients demand withdrawal of cases

The Constitution of Indian guarantees the right to life and health and the reopening of the 'Gleevec patent order or a review of Section 3 (d) by the Chennai High Court, patient groups feel, threatens future access to affordable medicines.

For more information contact:
Pratibha S., Lawyers Collective HIV/AIDS Unit, Phone:+91-22-22875482, Email: aidslaw@lawyerscollective.org,
Leena Menghaney, Phone: +91-9811365412

[1] See a critique of the Indian patent law at http://www.msf.org/msfinternational/invoke.cfm?objectid=63C0C1F1-E018-0C72-093AB3D906C4C469&component=toolkit.article&method=full_html

NOVARTIS FILES CASE IN INDIA CHALLENGING PATENT CONTROLLER'S ORDER AND PATENT LAW

CANCER PATIENTS DEMAND WITHDRAWAL OF CASES

Chennai/Mumbai/New Delhi 22 August 2006 – Clearly concerned about Swiss Pharma Company Novartis action of filing a legal challenge to the rejection of a patent on a crucial cancer drug 'Gleevec', the Cancer Patients Aid Association (CPAA) is preparing for the legal battle ahead.

In May this year Novartis filed two cases against the government of India and the CPAA challenging the rejection of its patent application and the Indian Patent Law. Novartis' 1998 application for a patent on 'Imatinib Myselate' (Gleevec) was opposed by the CPAA and subsequently rejected by the Chennai patent office on 25 January 06. The basis of the rejection was that the application claimed not an invention but '*only a new form of an old drug*'.

"Imatinib Myselate (Gleevec) is a life saving drug essential in prolonging the life of patients suffering from Myeloid Leukemia (Blood Cancer). The order of the Chennai patent office brought relief to thousands of cancer patients as it prevented a patent monopoly on 'Gleevec' till 2018", said Y.K. Sapru from the Cancer Patient Aid Association.

The essential cancer drug is produced and marketed internationally by Novartis and Indian pharmaceutical companies like Cipla, Ranbaxy, Natco, and Hetero. Novartis sells 'Gleevec' at ***Rs. 1,20,000 ($ 2500)*** per patient per month while generic versions of 'Gleevec' in the India are priced at about ***Rs. 8,000 ($ 175)*** per patient per month. CPAA and other cancer groups provide the more affordable generic versions of 'Gleevec' to Indian cancer patients.

"India while complying with the TRIPS agreement and introducing a product patent regime for new drugs that were invented, also coupled its law with a safeguard of refusing patents on discovery of new uses or forms of older drug. The patent decision on Gleevec was an implementation of this critical safeguard", says Gopa Kumar, Centre for Trade and Development (CENTAD).

The Novartis cases have raised concerns among public interest and health groups as the 'Gleevec' patent order set a good precedent for the examination of other essential drug patent applications. *"Patents have created 20 year monopolies over drugs and have directly resulted in the denial of life saving treatment to millions around the world as particularly evidenced in the case of AIDS drugs. The public health protections of the Indian Patent law have given hope to many who depend on generics manufacture and the Novartis litigation is a direct challenge to those protections"*, says Leena Menghaney, MSF India's Access Campaign Manager.

Novartis' constant litigation threatens the lives of cancer patients and renews fears of future availability if the patent case of Gleevec is reopened. "*Novartis' actions in challenging India's patent law are an ominous sign of things to come*," said Anand Grover of the Lawyers Collective HIV/AIDS Unit that is representing CPAA. "*Patient groups will have to spend their invaluable time, energy and resources in expensive legal battles designed by drug companies to discourage oppositions to their patents and pricing policies.*"

Patient and public interest groups are protesting and demanding a withdrawal of the cases by Novartis.

For more information contact:
Leena Menghaney: tel +91 9811356412 or msfh-india-medco-assist@field.amsterdam.msf.org
Pratibha S.: tel 022-22875482 or aidslaw@lawyerscollective.org

Note : We have attached slogans if time permits translate it in Tamil and use it for the protest.

NO PATENT FOR NOVARTIS ON CANCER DRUG - "GLEEVEC"

TAKE BACK PATENT CASE

GLEEVEC IS A ESSENTIAL CANCER DRUG

NOVARTIS PRICE FOR CANCER DRUG = Rs. 14 LALHS A YEAR

WE WANT TO LIVE

NOVARTIS GO BACK

TAKE BACK CASE IN CHENNAI HIGH COURT

NOVARTIS WANTS TO KILL CANCER PATIENTS

PATENTS KILL PATIENTS

For Immediate Release **September 12, 2006**

BANGALORE CITIZENS STAND IN SOLIDARITY WITH CANCER PATIENTS

- DEMAND IMMEDIATE WITHDRAWAL OF CASES BY NOVARTIS

Citizens of Bangalore came to Mahatma Gandhi statute on M.G. Road today in solidarity with cancer patients and are protesting against the threat of live-saving drugs being taken away from their reach. Karnataka Cancer Society, Karnataka Prantiya Raitha Sangha. Karnataka Prantiya Krishi Coolie Karmekara Sangha, Student Federation of India, BGVS, Samraksha, Freedom Foundation, Milana, KNP+, Action Aid, AMTC, Abhaya, Pragathi, CIEDS/ Karnataka Social Forum/ WSF, Sangama, Community Health Cell (CHC), Janaarogya Andolana – Karnataka (JAA-K), Student representatives of different city colleges, All India Drug Action Network (AIDAN) and many other civil society groups participated in the solidarity meet.

Cancer patient groups and the civil society groups have been fighting a long battle against the greed of companies to make a killing out of life-saving medicines. Novartis, a Multi National Drug Company filed an application for a patent on 'Imatinib Myselate' (Gleevec) in 1998. This was opposed by the cancer groups and generic companies and subsequently it was **rejected by the Chennai patent office on 25 January 2006 on the grounds that the application claimed not an invention but '*only a new form of an old drug*'.**

In May this year, Novartis has filed cases challenging the rejection of its patent application and questioning the Indian Patent Law. Novartis' constant litigation threatens the lives of cancer patients and renews fears of future availability if the patent case of Gleevec is reopened. ***"Novartis' actions in challenging India's patent law are an ominous sign of things to come."*** **Patient groups have to spend their invaluable time, energy and resources in expensive legal battles designed by drug companies to discourage oppositions to their patents and pricing policies.**

P.T.O.

Gleevec is a anti-blood cancer medicine. India has 25000 new Blood Cancer patients every year in urgent need of medicines, with one-third of them being children. **18,000 people die each year without treatment as they cannot afford the prices of the medicine.**

Novartis sells 'Gleevec' at ***Rs. 1,20,000 ($ 2500)*** per patient per month while generic versions of 'Gleevec', made by Indian companies are priced at about ***Rs. 8,000 ($ 175)*** per patient per month. If Novartis is granted a patent, Indian companies will have to stop manufacturing the medicine, which will greatly affect the prices and easy availability of the medicine.

"India while complying with the TRIPS agreement and introducing a product patent regime for new drugs that were invented, also coupled its law with a safeguard of refusing patents on discovery of new uses or forms of older drug. The patent decision on Gleevec was an implementation of this critical safeguard", says Gopa Kumar, Centre for Trade and Development (CENTAD). It is this crucial clause in the Indian Patent Act which Novartis is challenging.

The Novartis cases have raised concerns among public interest and health groups as the 'Gleevec' patent order set a good precedent for the examination of other essential drug patent applications. *"Patents have created 20 year monopolies over drugs and have directly resulted in the denial of life saving treatment to millions around the world as particularly evidenced in the case of AIDS drugs. The public health protections of the Indian Patent law have given hope to many who depend on generics manufacture and the Novartis litigation is a direct challenge to those protections"*, says Leena Menghaney, Médecins Sans Frontières (MSF) India's Access Campaign Manager.

Patient and public interest groups are protesting and demanding a withdrawal of the cases by Novartis.

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Bangalore Forum for Access to Medicines - Karnataka Cancer Society, Karnataka Prantiya Raitha Sangha, Karnataka Prantiya Krishi Collie Karmekara Sangha, Student Federation of India, BGVS, Samraksha, Freedom Foundation, Milana, KNP+, Action Aid, AMTC, Abhaya, Pragathi, CIEDS, Karnataka Social Forum/ WSF, Sangama, Community Health Cell (CHC), *Janaarogya Andolana* Karnataka (JAA-K), Garment Worker's Association, Student representatives (SJC), Student's representatives (ULC)

For Immediate Release September 12, 2006

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P.T.O.

If you want the cancer patients to die then don't read this

Cancer Medicine can become costlier!!!! PATIENTS LIVES ARE THREATENED!! Gleevec, a cancer drug will cost Rs. 1,20,000 per month instead of Rs. 8000 per month!!!!

⇒ Cancer is a life threatening disease and a person affected requires life-long monitoring and treatment.

⇒ **India has 25000 new Blood Cancer patients every year. 1/3 of them are children. 18000 die each year without treatment as they cannot afford the prices of the medicine.**

⇒ Gleevec is the Anti-blood cancer drug made and sold worldwide by **Novartis,** a Multinational drug company. **Indian drug companies also make them**

⇒ **BUT ... Novartis' Gleevec price is Rs. 1,20,000/patient/month. Indian drug companies' price is Rs. 8,000 -10000/patient/ month.**

⇒ Novartis claims to have spent hundreds and millions of dollars for research and development for so-calle 'invention' of Gleevec. Novartis has already earned about **Rs.** 4500 crores **from worldwide Gleevec sales alone in 2003.**

⇒ The sales of Gleevec by Novartis in India in 2002 were Rs. 435crores and about Rs.504crores in 2003.

⇒ Novartis tried to prevent Indian companies from making and selling Gleevec through its patent applicatio filed in Chennai in 1998. But this was rejected by the Patent Controller. This brought relief to thousands cancer patients as Indian companies were free to make and sell a cheaper version of Gleevec.

⇒ However, Novartis has challenged this patent rejection by filing a case against the Cancer Patients' Aid Association..

Novartis' greed to make profits at the cost of health through constant litigation threatens th lives of cancer patients and renews the fears of future availability of the medicine.

Patient and public interest groups are protesting and demanding a withdrawal of the cases by Novartis, which wants profits over cancer patients' lives.

Join the battle to attain a person's FUNDAMENTAL RIGHT TO HEALTH and resist International drug companies FUNDAMENTAL NEED FOR GREED.

ಕ್ಯಾನ್ಸರ್ ರೋಗಿಗಳು ಸಾಯಬೇಕೆ ಹಾಗ್ಗಿದ್ದಲ್ಲಿ ಇದ್ದನ್ನು ಓದಬೇಡಿ

ಕ್ಯಾನ್ಸರ್‌ನ ಔಷಧಿಗಳ ಬೆಲೆ ಕೈಗೆಟುಕದಿರಬಹುದು, ರೋಗಿಗಳ ಜೀವ ಅಪಾಯದಲ್ಲಿದೆ
Gleevcc ಕ್ಯಾನ್ಸರ್ ಔಷಧ ರೂ. 8,000/- ಬದಲು ರೂ. 1,20,000/- ಆಗಬಹುದು

= ಕ್ಯಾನ್ಸರ್ ಜೀವಕ್ಕೆ ಅಪಾಯ ತರುವಂತಹ ಒಂದು ಕಾಯಿಲೆ, ಅದಕ್ಕೆ ಜೀವನವಿಡೀ ಔಷಧ, ನಿರ್ವಹಣೆ ಮತ್ತು ನಿಗಾದ ಅವಶ್ಯಕತೆ ಇದೆ.

= ಭಾರತದಲ್ಲಿ 25,000 ರೋಗಿಗಳು ಪ್ರತಿ ವರ್ಷ ಹುಟ್ಟುತಿದ್ದಾರೆ, ಅದರಲ್ಲಿ ಮೂರನೇ ಒಂದು ಭಾಗ ಮಕ್ಕಳು,

= 18,000 ರೋಗಿಗಳು, ಔಷಧವನ್ನು ಖರೀದಿಸಲಾಗದೆ, ಚಿಕಿತ್ಸೆ ಇಲ್ಲದೆ ಸಾಯುತ್ತಿದ್ದಾರೆ.

= Gleevc ರಕ್ತದ ಕ್ಯಾನ್ಸರ್‌ಗೆ ಔಷಧ. ಅದನ್ನು ವಿಶ್ವದಾದ್ಯಂತ ನೋವಾರ್ಟಿಸ್ ಎಂಬ ಕಂಪನಿಯು ತಯಾರಿಸುತ್ತದೆ. ಭಾರತದ ಕಂಪನಿಗಳೂ ತಯಾರಿಸುತ್ತವೆ.

= ಆದರೆ ನೋವಾರ್ಟಿಸ್‌ನ ದರ ರೂ. 1,20,000/- \ಒಂದು ತಿಂಗಳಿಗೆ\ ಒಂದು ರೋಗಿಗೆ; ಭಾರತದ ಕಂಪನಿಗಳ ದರ 8,000/- 10,000/- \ ಒಂದು ರೋಗಿಗೆ\ ಒಂದು ತಿಂಗಳಿಗೆ!!!

= ನೋವಾರ್ಟಿಸ್ ಕಂಪೆನಿಯು ಈ ಔಷಧಿಯ ಸಂಶೋಧನೆಗಾಗಿ ಹಲವು ಕೋಟಿ ರೂಪಾಯಿ ಖರ್ಚು ಮಾಡಿದ್ದೇವೆ ಎಂದು ಹೇಳಿಕೊಳ್ಳುತ್ತದೆ, ಆದರೆ ಈಗಾಗಲೇ ಈ ಕಂಪನಿಯು ವಿಶ್ವದಾದ್ಯಂತ ಈ ಔಷಧ ವ್ಯಾಪಾರದಿಂದ 45,000/- ಕೋಟಿ ರೂಪಾಯಿ ಲಾಭ ಮಾಡಿದೆ

= ಭಾರತದಲ್ಲೇ 2002ನೇ ಇಸವಿಯಲ್ಲಿ 432ಕೋಟಿ ರೂ. ಮತ್ತು 2003ರಲ್ಲಿ 504 ಕೋಟಿ ರೂ. ಲಾಭವನ್ನು ಪಡೆದಿದೆ.

= ಪೇಟೆಂಟ್ ಅರ್ಜಿಯ ಮೂಲಕ ನೋವಾರ್ಟಿಸ್ ಕಂಪೆನಿಯು, ಭಾರತದ ಕಂಪೆನಿಗಳು ಈ ಔಷಧವನ್ನು ತಯಾರು ಮಾಡದಂತೆ ಮಾಡಲು ಪ್ರಯತ್ನಿಸಿತು ಆದರೆ ಆದರ ಪೇಟೆಂಟ್ ಅರ್ಜಿ ತಿರಸ್ಕೃತವಾಯಿತು.

= ಇದರಿಂದಾಗಿ ಕ್ಯಾನ್ಸರ್ ರೋಗಿಗಳು ದೇಶೀಯ ಕಂಪನಿಗಳು ತಯಾರಿಸುವ ಕಡಿಮೆ ಬೆಲೆಯ ಇದೇ ಔಷಧವನ್ನು ಕೊಂಡುಕೊಳ್ಳಲು ಅವಕಾಶವಾಯಿತು. ಆದರೆ ನೋವಾರ್ಟಿಸ್ ಕಂಪೆನಿ ಪೇಟೆಂಟ್ ತಿರಸ್ಕರಣೆ ವಿರುದ್ಧ ಮೈಕೋರ್ಟ್‌ನಲ್ಲಿ ಕೇಸು ಹಾಕಿದೆ.

= ನೋವಾರ್ಟಿಸ್ ನ ಲಾಭ ಮಾಡುವ ದುರಾಸೆ, ರೋಗಿಗಳ ಜೀವಕ್ಕೆ ಕುಂದು ತರುತ್ತಿದೆ ಮತ್ತು ಔಷಧದ ಬೆಲೆ ಹೆಚ್ಚಳದಿಂದ ನೋವಾರ್ಟಿಸ್‌ಗೆ ರೋಗಿಗಳ ಜೀವಕ್ಕಿಂತ ತನ್ನ ಲಾಭ ಹೆಚ್ಚಾಗಿದೆ

= ರೋಗಿಗಳು ಮತ್ತು ನಾಗರಿಕ ಹಿತಾಸಕ್ತಿ ಸಂಸ್ಥೆಗಳು ಈ ಕೇಸನ್ನು ಹಿಂತೆಗೆದು ಕೂಳ್ಳಲು ಆಗ್ರಹಿಸಿ ಚಳುವಳಿ ನಡೆಸುತ್ತಿವೆ.

ಯುದ್ಧಕ್ಕೆ ಸೇರಿ, ಮಾನವನ ಮೂಲಭೂತ ಹಕ್ಕಾದ ಆರೋಗ್ಯ ದೊರೆಕಿಸಿಕೊಳ್ಳಲು ಮತ್ತು ಈ ಬಹುರಾಷ್ಟ್ರೀಯ ಕಂಪನಿಗಳ ದುರಾಸೆಯ ವಿರೂಧಿಸಿ ಹೊರಾಡಲು, ಯುದ್ಧಕ್ಕೆ ಸೇರಿ, ಬೆಂಬಲ ನೀಡಿ.

If you want the cancer patients to die then don't read this

Cancer Medicine can become costlier!!!! PATIENTS LIVES ARE THREATENED!! Gleevec, a cancer drug will cost Rs. 1,20,000 per month instead of Rs. 8000 per month!!!!

⇒ Cancer is a life threatening disease and a person affected requires life-long monitoring and treatment.

⇒ **India has 25000 new Blood Cancer patients every year. 1/3 of them are children. 18000 die each year without treatment as they cannot afford the prices of the medicine.**

⇒ Gleevec is the Anti-blood cancer drug made and sold worldwide by **Novartis,** a Multinational drug company. **Indian drug companies also make them**

⇒ **BUT ... Novartis' Gleevec price is Rs. 1,20,000/patient/month. Indian drug companies' price is Rs. 8,000 -10000/patient/ month.**

⇒ Novartis claims to have spent hundreds and millions of dollars for research and development for so-calle 'invention' of Gleevec. Novartis has already earned about **Rs.** 4500 crores **from worldwide Gleevec sales alone in 2003.**

⇒ The sales of Gleevec by Novartis in India in 2002 were Rs. 435crores and about Rs.504crores in 2003.

⇒ Novartis tried to prevent Indian companies from making and selling Gleevec through its patent applicatio filed in Chennai in 1998. But this was rejected by the Patent Controller. This brought relief to thousands cancer patients as Indian companies were free to make and sell a cheaper version of Gleevec.

⇒ However, Novartis has challenged this patent rejection by filing a case against the Cancer Patients' Aid Association..

Novartis' greed to make profits at the cost of health through constant litigation threatens th lives of cancer patients and renews the fears of future availability of the medicine.

Patient and public interest groups are protesting and demanding a withdrawal of the cases by Novartis, which wants profits over cancer patients' lives.

Join the battle to attain a person's FUNDAMENTAL RIGHT TO HEALTH and resist International drug companies FUNDAMENTAL NEED FOR GREED.

ಕ್ಯಾನ್ಸರ್ ರೋಗಿಗಳು ಸಾಯಬೇಕೆ ಹಾಗ್ಗಿದ್ದಲ್ಲಿ ಇದ್ದನ್ನು ಓದಬೇಡಿ

ಕ್ಯಾನ್ಸರ್‌ನ ಔಷಧಿಗಳ ಬೆಲೆ ಕೈಗೆಟುಕದಿರಬಹುದು, ರೋಗಿಗಳ ಜೀವ ಅಪಾಯದಲ್ಲಿದೆ
Gleevcc ಕ್ಯಾನ್ಸರ್ ಔಷಧ ರೂ. 8,000/- ಬದಲು ರೂ. 1,20,000/- ಆಗಬಹುದು

= ಕ್ಯಾನ್ಸರ್ ಜೀವಕ್ಕೆ ಅಪಾಯ ತರುವಂತಹ ಒಂದು ಕಾಯಿಲೆ, ಅದಕ್ಕೆ ಜೀವನವಿಡೀ ಔಷಧ, ನಿರ್ವಹಣೆ ಮತ್ತು ನಿಗಾದ ಅವಶ್ಯಕತೆ ಇದೆ.

= ಭಾರತದಲ್ಲಿ 25,000 ರೋಗಿಗಳು ಪ್ರತಿ ವರ್ಷ ಹುಟ್ಟುತಿದ್ದಾರೆ, ಅದರಲ್ಲಿ ಮೂರನೇ ಒಂದು ಭಾಗ ಮಕ್ಕಳು,

= 18,000 ರೋಗಿಗಳು, ಔಷಧವನ್ನು ಖರೀದಿಸಲಾಗದೆ, ಚಿಕಿತ್ಸೆ ಇಲ್ಲದೆ ಸಾಯುತ್ತಿದ್ದಾರೆ.

= Gleevc ರಕ್ತದ ಕ್ಯಾನ್ಸರ್‌ಗೆ ಔಷಧ. ಅದನ್ನು ವಿಶ್ವದಾದ್ಯಂತ ನೋವಾರ್ಟಿಸ್ ಎಂಬ ಕಂಪನಿಯು ತಯಾರಿಸುತ್ತದೆ. ಭಾರತದ ಕಂಪನಿಗಳೂ ತಯಾರಿಸುತ್ತವೆ.

= ಆದರೆ ನೋವಾರ್ಟಿಸ್‌ನ ದರ ರೂ. 1,20,000/- \ಒಂದು ತಿಂಗಳಿಗೆ\ ಒಂದು ರೋಗಿಗೆ; ಭಾರತದ ಕಂಪನಿಗಳ ದರ 8,000/- 10,000/- \ ಒಂದು ರೋಗಿಗೆ\ ಒಂದು ತಿಂಗಳಿಗೆ!!!

= ನೋವಾರ್ಟಿಸ್ ಕಂಪೆನಿಯು ಈ ಔಷಧಿಯ ಸಂಶೋಧನೆಗಾಗಿ ಹಲವು ಕೋಟಿ ರೂಪಾಯಿ ಖರ್ಚು ಮಾಡಿದ್ದೇವೆ ಎಂದು ಹೇಳಿಕೊಳ್ಳುತ್ತದೆ, ಆದರೆ ಈಗಾಗಲೇ ಈ ಕಂಪನಿಯು ವಿಶ್ವದಾದ್ಯಂತ ಈ ಔಷಧ ವ್ಯಾಪಾರದಿಂದ 45,000/- ಕೋಟಿ ರೂಪಾಯಿ ಲಾಭ ಮಾಡಿದೆ

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= ಇದರಿಂದಾಗಿ ಕ್ಯಾನ್ಸರ್ ರೋಗಿಗಳು ದೇಶೀಯ ಕಂಪನಿಗಳು ತಯಾರಿಸುವ ಕಡಿಮೆ ಬೆಲೆಯ ಇದೇ ಔಷಧವನ್ನು ಕೊಂಡುಕೊಳ್ಳಲು ಅವಕಾಶವಾಯಿತು. ಆದರೆ ನೋವಾರ್ಟಿಸ್ ಕಂಪೆನಿ ಪೇಟೆಂಟ್ ತಿರಸ್ಕರಣೆ ವಿರುದ್ಧ ಮದ್ರಾಸ್ ಹೈಕೋರ್ಟ್‌ನಲ್ಲಿ ಕೇಸು ಹಾಕಿದೆ.

= ನೋವಾರ್ಟಿಸ್ ನ ಲಾಭ ಮಾಡುವ ದುರಾಸೆ, ರೋಗಿಗಳ ಜೀವಕ್ಕೆ ಕುಂದು ತರುತ್ತಿದೆ ಮತ್ತು ಔಷಧದ ಬೆಲೆ ಹೆಚ್ಚಳದಿಂದ ನೋವಾರ್ಟಿಸ್‌ಗೆ ರೋಗಿಗಳ ಜೀವಕ್ಕಿಂತ ತನ್ನ ಲಾಭ ಹೆಚ್ಚಾಗಿದೆ

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ಯುದ್ಧಕ್ಕೆ ಸೇರಿ, ಮಾನವನ ಮೂಲಭೂತ ಹಕ್ಕಾದ ಆರೋಗ್ಯ ದೊರೆಕಿಸಿಕೊಳ್ಳಲು ಮತ್ತು ಈ ಬಹುರಾಷ್ಟ್ರೀಯ ಕಂಪನಿಗಳ ದುರಾಸೆಯ ವಿರೂಧಿಸಿ ಹೊರಾಡಲು, ಯುದ್ಧಕ್ಕೆ ಸೇರಿ, ಬೆಂಬಲ ನೀಡಿ.

For Immediate Release

September 12, 2006

BANGALORE CITIZENS STAND IN SOLIDARITY WITH CANCER PATIENTS

- DEMAND IMMEDIATE WITHDRAWAL OF CASES BY NOVARTIS

Citizens of Bangalore came to Mahatma Gandhi statute on M.G. Road today in solidarity with cancer patients and are protesting against the threat of live-saving drugs being taken away from their reach. Karnataka Cancer Society, Karnataka Prantiya Raitha Sangha, Karnataka Prantiya Krishi Coolie Karmekara Sangha, Student Federation of India, BGVS, Samraksha, Freedom Foundation, Milana, KNP+, Action Aid, AMTC, Abhaya, Pragathi, CIEDS/ Karnataka Social Forum/ WSF, Sangama, Community Health Cell (CHC), Janaarogya Andolana – Karnataka (JAA-K), Student representatives of different city colleges, All India Drug Action Network (AIDAN) and many other civil society groups participated in the solidarity meet.

Cancer patient groups and the civil society groups have been fighting a long battle against the greed of companies to make a killing out of life-saving medicines. Novartis, a Multi National Drug Company filed an application for a patent on 'Imatinib Myselate' (Gleevec) in 1998. This was opposed by the cancer groups and generic companies and subsequently it was **rejected by the Chennai patent office on 25 January 2006 on the grounds that the application claimed not an invention but '*only a new form of an old drug*'.**

In May this year, Novartis has filed cases challenging the rejection of its patent application and questioning the Indian Patent Law. Novartis' constant litigation threatens the lives of cancer patients and renews fears of future availability if the patent case of Gleevec is reopened. ***"Novartis' actions in challenging India's patent law are an ominous sign of things to come."*** **Patient groups have to spend their invaluable time, energy and resources in expensive legal battles designed by drug companies to discourage oppositions to their patents and pricing policies.**

P.T.O.

Gleevec is a anti-blood cancer medicine. India has 25000 new Blood Cancer patients every year in urgent need of medicines, with one-third of them being children. **18,000 people die each year without treatment as they cannot afford the prices of the medicine.**

Novartis sells 'Gleevec' at ***Rs. 1,20,000 ($ 2500)*** per patient per month while generic versions of 'Gleevec', made by Indian companies are priced at about ***Rs. 8,000 ($ 175)*** per patient per month. If Novartis is granted a patent, Indian companies will have to stop manufacturing the medicine, which will greatly affect the prices and easy availability of the medicine.

"India while complying with the TRIPS agreement and introducing a product patent regime for new drugs that were invented, also coupled its law with a safeguard of refusing patents on discovery of new uses or forms of older drug. The patent decision on Gleevec was an implementation of this critical safeguard", says Gopa Kumar, Centre for Trade and Development (CENTAD). It is this crucial clause in the Indian Patent Act which Novartis is challenging.

The Novartis cases have raised concerns among public interest and health groups as the 'Gleevec' patent order set a good precedent for the examination of other essential drug patent applications. *"Patents have created 20 year monopolies over drugs and have directly resulted in the denial of life saving treatment to millions around the world as particularly evidenced in the case of AIDS drugs. The public health protections of the Indian Patent law have given hope to many who depend on generics manufacture and the Novartis litigation is a direct challenge to those protections"*, says Leena Menghaney, Médecins Sans Frontières (MSF) India's Access Campaign Manager.

Patient and public interest groups are protesting and demanding a withdrawal of the cases by Novartis.

Bangalore Forum for Access to Medicines - Karnataka Cancer Society, Karnataka Prantiya Raitha Sangha, Karnataka Prantiya Krishi Collie Karmekara Sangha, Student Federation of India, BGVS, Samraksha, Freedom Foundation, Milana, KNP+, Action Aid, AMTC, Abhaya, Pragathi, CIEDS, Karnataka Social Forum, WSF, Sangama, Community Health Cell (CHC), *Janaarogya Andolana* – Karnataka (JAA-K), Garment Worker's Association, Student representatives (SJC), Student's representatives (ULC)

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Q&A ON PATENTS IN INDIA AND THE NOVARTIS COURT CASE

Q: Why do millions of people rely on India for affordable medicines?
A: Drugs produced by companies in India are among the cheapest in the world. That is because until recently, India did not grant patents on medicines. India is one of the few developing countries with production capacity to manufacture quality essential medicines. By producing cheaper generic versions of drugs that were patented in other countries, India became a key source of affordable essential medicines, such as antiretroviral medicines to treat HIV/AIDS. Drugs produced in India have been used for the country's domestic market and are also imported by many developing countries that rely on India to provide the medicines needed e.g. to run national AIDS treatment programmes. Over half the medicines currently used for AIDS treatment in developing countries come from India and such medicines are used to treat over 80% of the 80,000 AIDS patients in Médecins Sans Frontières projects today.

Q: What is the relationship between patents and affordable medicines?
A: Patents grant local monopolies to companies who hold them for a certain amount of time. This means that a company that holds a patent on a drug in a particular country can prevent other companies from producing or selling the drug in that country for the duration of the patent's term, which, according to World Trade Organization (WTO) rules is a minimum of 20 years. This in turn allows companies to charge high prices in countries where they hold patents, because there are no competitors in the market. Competition among producers is the tried and tested way to bring prices down. Competition among generic manufacturers is what helped bring the cost of AIDS treatment down from $10,000 per patient per year in 2000 to $130 per patient per year today. In the absence of patents, multiple producers compete for a share of the market, driving the price down as low as possible. In addition, having multiple sources helps increase the availability of drugs. Further, the absence of patents in India has helped the development of e.g. three-in-one AIDS medicines and formulations for children.

Q: Why does India grant patents on drugs now?
As a WTO member, India has to comply with trade rules set by the WTO. One of these is the Agreement on Trade-related Aspects of Intellectual Property, or TRIPS, which obliges WTO countries to grant patents on technological products, *including pharmaceuticals.* To comply with this international obligation, India changed its patent law in 2005 and started to grant patents on medicines. As a result, if patents are granted in the country, Indian generic manufacturers will not be able to produce cheaper generic versions of these medicines, which will have an impact not only in India domestically, but also on other countries that import Indian generics. Only a few new medicines have been patented in India today. Roche obtained the first pharmaceutical patent in India in March 2006 for a hepatitis C treatment - but this is likely to increase in the future. Currently, nearly 10,000 medicine patent applications await examination in India. If India begins to grant patents the same way that wealthy countries do - where medicines are routinely protected by several patents covering each small modification - it could mean the end of affordable medicines in developing countries.

Q: Why is Novartis suing the Indian Government?
A: Novartis applied for a patent in India on the cancer drug imatinib mesylate, which the company markets under the brand name Gleevec/Glivec in many countries. The patent was rejected in India in January 2006 on the grounds that the drug was a new form of an old drug, and therefore was not patentable under Indian law. In other countries where Novartis has obtained a patent, Gleevec is sold at $2,600 per patient per month. In India, generic versions of Gleevec are available for less than $200 per patient per month. Novartis is therefore trying to

have the patent decision overturned so that it can sell Gleevec at the same price in India as in other countries. Novartis is also trying to challenge the Indian patent law so that patents are as easily granted in India as they are in most other countries.

Q: How is it possible for India to reject a patent that is granted in other countries?
There is no such thing as an international or global patent. Patent applications are examined by patent offices in individual countries, and each office deliberates whether a particular drug should be patented or not on the basis of local patent regulations. Fortunately, India designed its new patent law so that the number of patents granted would be kept to a strict minimum. This was an effort to reward innovation, which is the rationale of the patent system to begin with. The Indian law states that patents should only be granted on medicines that are truly new and innovative. This means that companies should not be able to obtain patents for drugs that are not really new, such as for combinations or for slightly improved formulations of existing drugs. This part of the law was specifically targeted at preventing a common practice of drug companies of trying to get patents on insignificant improvements of existing drugs, in order to extend their monopolies on drugs as long as possible. Novartis is challenging this part of the Indian law, which the company says violates WTO rules.

Q: Does India have the right to have this particular patent law?
In 2001, all WTO countries signed the Doha Declaration, which states "that the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." The same declaration allows countries to take measures to protect public health. India's patent law is based on this declaration. India chose to design a patent law that contains a key public health safeguard, namely the provision that only truly new or innovative drugs should be patented.

Q: Aren't patents needed to stimulate innovation for new drugs by pharmaceutical companies?
An increasing number of studies are showing that while patent protection has increased over the last 15 years, the innovation rate has been falling, with an increase in the number of 'me-too drugs' of little or no therapeutic gain. A survey published in April 2005 by La Revue Prescrire, concluded that 68 percent of the 3,096 new products approved in France between 1981 and 2004, brought 'nothing new' over previously available preparations[1]. Similarly, the British Medical Journal published a study rating barely five percent of all newly-patented drugs in Canada as 'breakthrough.'[2] And a breakdown of over one thousand new drugs approved by the US Food and Drug Administration between 1989 and 2000 revealed that over three quarters have no therapeutic benefit over existing products[3].

Q: What will happen if Novartis wins the case?
If Novartis wins the case and succeeds in getting the provision of Indian law changed to resemble patent laws in wealthy countries, patents may be granted in India as broadly as they

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[1] "A review of new drugs in 2004: Floundering innovation and increased risk-taking.", Prescrire International, April 2005, vol.14, n. 76 pp. 68-73.
[2] "Breakthrough drugs and growth in expenditure on prescription drugs in Canada", Morris L Barer, Patricia A Caetano and Charlyn D Black, Steven G Morgan, Kenneth L Bassett, James M Wright, Robert G Evans, British Medical Journal, 2nd September 2005, 331:815-6.
[3] "Changing Patterns of Pharmaceutical Innovation", The National Institute for Health Care Management Research and Educational Foundation,. Washington, DC, NIHCM Foundation, May 2002, http://www.nihcm.org/innovations.pdf

are in wealthy countries. This will mean that fewer and possibly no generic versions of newer drugs will be able to be produced by Indian manufacturers during the patent terms of at least 20 years, and India will no longer be able to supply much of the developing world with cheap essential medicines.

The example of HIV/AIDS medicines is a good illustration of the problem. Even though older drugs to treat HIV/AIDS have become affordable thanks to generic competition, the availability of newer and improved drugs is crucial, as people become resistant to the drug combinations they take after a certain amount of time and inevitably need to be switched to newer "second-line" drug regimens. Data from MSF's project in Khayelitsha, South Africa, illustrates this growing need: 17.4% of people on treatment there for five years have had to switch to a newer drug combination. Yet today, newer drugs are largely still only available from originator companies holding patents, which keeps prices high and availability low. This is because Indian manufacturers have been reluctant to start producing these newer medicines, as they fear production would have to stop if patents were granted on these drugs in India. This in turn has led to the fact that prices for newer AIDS medicines can be up to 50 times more expensive than older drugs.

TIMELINE – Some key dates on the Indian Patent Act and the Novartis Case

1994/1995 - Creation of the World Trade Organization & entry into force of the TRIPS Agreement, which obliges developing countries to grant patents on medicines no later than 2005.

2003- Novartis launches Gleevec in the US at $2,600 per patient per month. Generic versions of Gleevec soon become available in India for under $200 per patient per month.

April 2005 - Amendment of India's Patents Act: medicines can now be patented in India. However, the law stipulates that only true medical innovations will be protected by patents. Section 3(d) specifies that *new forms of known substances* do not deserve patents.

Jan. 2006 – Novartis' patent application on Gleevec rejected by Indian patent office, on the grounds that it is simply a *new form of a known substance*.

May 2006 - Novartis appeals patent office's decision in High Court in India. Novartis also challenges Section 3(d) of the Indian Patents Acts.

September 2006 – First hearing of the appeal and challenge. No decision made, but broader hearing set for later date.

29 Jan. 2007 – Next scheduled hearing in Chennai High Court in India

A KEY SOURCE OF AFFORDABLE MEDICINES IS AT RISK OF DRYING UP

- The case of Novartis's challenge against the Indian government and what it could mean for millions of people across the globe -

Médecins Sans Frontières Briefing Note - December 2006

Swiss pharmaceutical company Novartis was one of the 39 companies that took the South African government to court five years ago, in an effort to overturn the country's medicines act that was designed to bring drug prices down. Now Novartis is up to it again and is targeting India. An ongoing legal challenge brought by Novartis against the Indian government has the potential to severely affect access to affordable essential medicines for millions of people across the developing world. Novartis is challenging a public health safeguard enshrined within India's Patents Act. If the company is successful, the era of India being a producer of affordable generic medicines for much of the world could be coming to an end with regard to newer and future medicines. This would have a devastating impact on people the world over who rely on affordable medicines manufactured in India.

Patents in India threaten a key source of affordable medicines

India produces affordable medicines that are vital to many people living in developing countries. As an example, over half the medicines currently used for AIDS treatment in developing countries come from India, and such medicines are used to treat over 80% of the 80,000 AIDS patients in Médecins Sans Frontières (MSF) projects today.

That is because until recently, India did not grant patents on medicines, which allowed Indian generic manufacturers to compete with patent holders and amongst each other to produce lower-priced generic versions of drugs patented in other countries. This sort of generic competition among multiple producers is what made the cost of AIDS medicines fall dramatically and helped facilitate global AIDS treatment scale-up thus far.

However, India is drying up as a source of affordable versions of newer and future medicines. This is due to changes made to India's patent law in 2005, when the country was required to begin reviewing pharmaceutical patents according to its international obligations under the World Trade Organization (WTO) Agreement on Trade Related aspects of Intellectual Property Rights (TRIPS).

Widespread medicines patenting in India could mean that cheaper versions of newer medicines will no longer be able to be produced by Indian manufacturers. Precisely such newer drugs are crucial e.g. for the treatment of HIV/AIDS.

Fortunately, when the Indian government designed its patent law, an effort was made to find a balance between the intellectual property rights of pharmaceutical companies and the need to make drugs as affordable as possible. However, with this legal challenge brought by Novartis, access to newer affordable medicines produced in India could further worsen.

Generic competition needed to drive prices down: the example of AIDS medicines

Thanks to competition among generic manufacturers since 2000, which was strongly encouraged by civil society pressure in countries such as India, Thailand and Brazil, the price of first-line antiretroviral drug regimens has fallen by 99% from an average of US $10,000 to the current price of US $132 per patient per year (see graph 1).[1]

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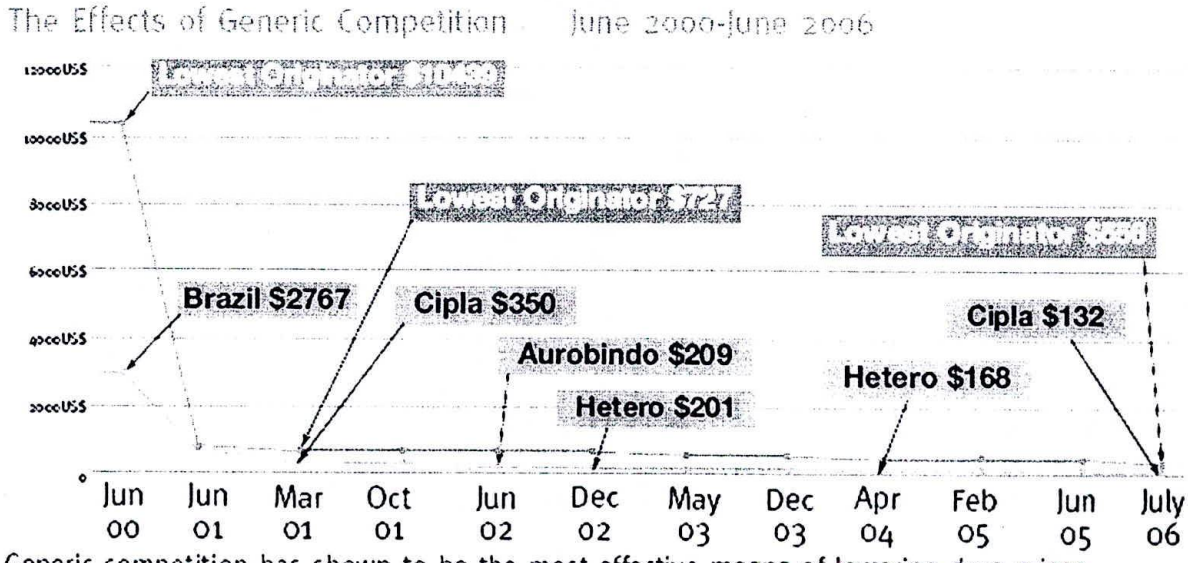
[1] Untangling the Web of Price Reductions: A pricing guide for ARVs in the developing world, 9th edition, 2006

Graph 1: *Sample of ARV triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest world prices per patient per year.*



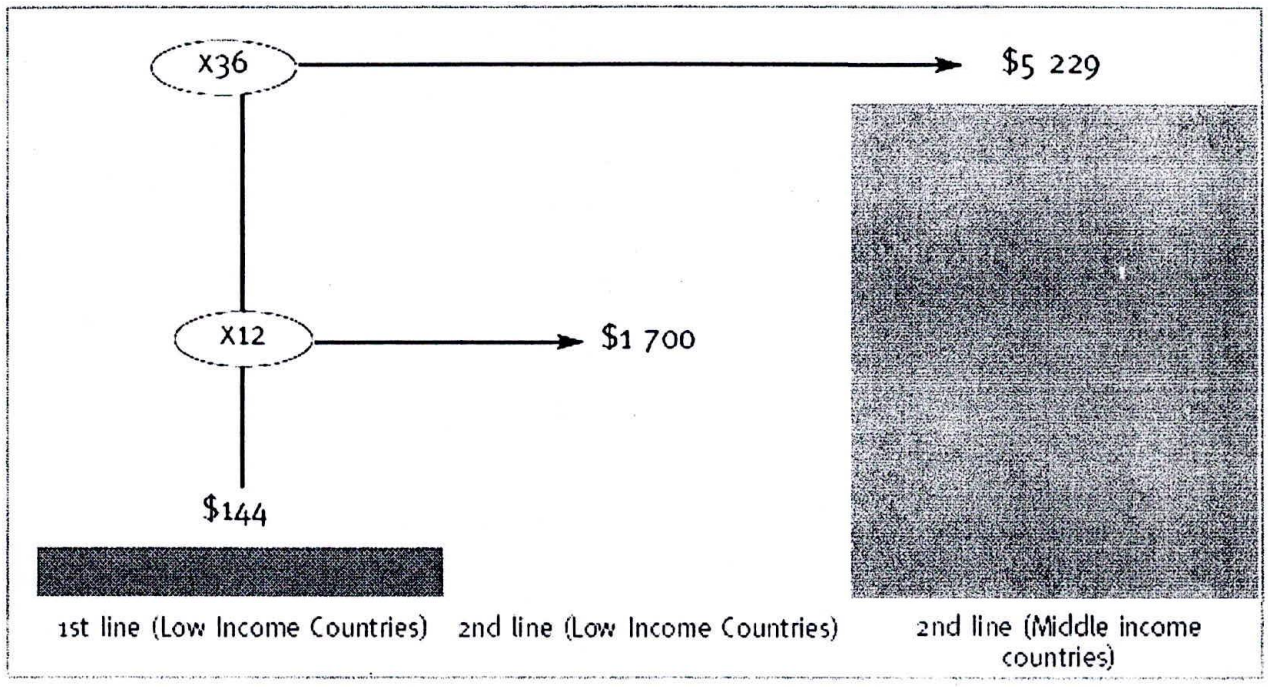
Generic competition has shown to be the most effective means of lowering drug prices.

However, a new problem is looming. Assuring the availability of newer and improved drugs is crucial, as after a certain amount of time people become resistant to the drug combinations they take and inevitably need to be switched to newer "second-line" drug regimens. Data from one of MSF's longest-running treatment programmes, in Khayelitsha, South Africa, shows that 17.4% of people who have been on treatment for five years have had to switch to such second-line therapy. Additionally, improved first-line medicines also require newer drugs.

Today, however, newer AIDS medicines are largely still only available from originator companies. Contrary to medicines used in first-line regimens, these newer drugs are under patent in other key countries with generic production capacity, Brazil and Thailand, which keeps prices high and availability low. These medicines are also awaiting patent review in India, which explains why competition on these newer medicines is still limited among Indian manufacturers. If patents are granted on these medicines in India, production of generic versions will not be possible. Even the production of medicines for which patent applications are pending is a high-risk investment for generic manufacturers, as companies do not know if they will be able to continue production and sell the drugs in the future. This lack of competition on newer AIDS drugs today has had the result of prices for these medicines remaining much higher than those for older drugs, despite price reductions offered by originator companies (see graph 2)[2].

[2] Untangling the Web of Price Reductions: A pricing guide for ARVs in the developing world, 9th edition, 2006

Graph 2: *Average weighted prices paid in 2005, reported to WHO GPRM for second-line ARVs in low- and middle-income countries, compared with first-line regimens*



Public health safeguards included in India's Patents Act

WTO rules made it mandatory in 2005 for India to have a patent regime for medicines, and as a result, the Indian parliament approved the country's new Patents Act, thereby allowing pharmaceutical products to be patented in India. This new law puts severe constraints on generic competition. However, the new law at least contains several crucially important features to prevent patents from being granted too easily, such as provisions that specifically prohibit patenting of known compounds, and the possibility for anyone to object to a patent before it is granted.

An effort to prevent "evergreening:" Section 3(d)

At the time of amending the Patents Act, the Indian parliament was aware of the concerns about patenting of medicines that are not new. As a result, Indian lawmakers introduced a provision in the Patents Act that stipulates that patents should only be granted on medicines that are truly new and innovative. This means that companies should not be able to obtain patents in India for medicines that are not actual inventions, such as drug combinations or slightly improved formulations of existing medicines.

This part of the law [section 3(d)] was specifically targeted at preventing a common practice used by drug companies of trying to get additional patents on insignificant improvements of drugs already patented. The provision was an effort to reward innovation, which is the rationale of the patent system to begin with. It also aimed to ensure that patents do not unnecessarily restrict access to medicines. It is this part of the law that Novartis is challenging, claiming it is in violation of WTO rules.

Further, manufacturers of patented medicines make minor variations to existing medicines in order to extend companies' monopolies for as long as possible. Also called "evergreening," this practice impacts the ability of patients to access affordable medicines by delaying or restricting the introduction of competition among other pharmaceutical manufacturers that could lead to lower prices.

An example of evergreening is the case of the ulcer medicine omeprazole, which Astra Zeneca sells under the brand name Losec. Sale of generic omeprazole in Canada was successfully blocked by the evergreening of patents by Astra Zeneca. As the basic patent on omeprazole was about to expire, Astra Zeneca switched the product from a capsule to a tablet and acquired new 20-year patents on the tablet form.

Pre-grant oppositions: the right to oppose a patent before it may be granted

India's Patents Act also allows room for any interested party to oppose a patent application that is awaiting a patenting decision. This "pre-grant opposition" process was used for the first time on an AIDS medicine in March 2006, when the Indian Network for People Living with HIV/AIDS (INP+) filed the an opposition to the patent claim for a fixed-dose combination of zidovudine and lamivudine filed by GlaxoSmithKline (GSK). INP+ based its opposition on Section 3(d) of the patent law, as the patent claim in question was not for a new invention but simply for the combination of two existing drugs. Similar oppositions on AIDS medicine patent applications have followed as most of the patent claims are for known pharmaceutical substances such as polymorphs, salts, and combinations. Soon after its patent was opposed in India, GSK announced the withdrawal of all its patents and patent applications for the fixed-dose combination of zidovudine and lamivudine.

In January 2006, the Indian patent office for the first time rejected a patent, on Novartis' patent application for the cancer drug imatinib mesylate, which the company sells under the brand name *Gleevec*. The patent was rejected on grounds that the application claims a "new form of a known substance." The rejection was a major success for the Cancer Patient Aid Association of India, which had submitted a pre-grant opposition to the patent office.

Novartis's challenge against the Indian government could have global consequences

If Novartis succeeds in its challenge against Section 3(d) of India's Patents Act, patents could end up being granted in India just as broadly as they are in wealthier countries. This would mean that virtually no generic versions of newer drugs could be produced by Indian manufacturers during patent terms lasting at least 20 years. And that would mean that much of the developing world would no longer be able to rely on Indian manufacturers for their supply of cheap essential medicines, in particular newer medicines.

Patent applications have been filed in India by originator companies for all newer AIDS medicines needed for second-line treatment regimens. These applications now await patent examination in Indian patent offices. Under the terms of Section 3(d) of India's Patents Act, many of these medicines may not be granted a patent in India because the molecule is already known and therefore does not represent a real innovation. If patents on these newer drugs are not granted, Indian generic manufacturers will be allowed to produce generic versions, compete amongst each other and with originator companies and sell these urgently-needed medicines at prices much more affordable for people in developing countries.

But if Novartis succeeds in getting the Indian Patents Act changed, India may apply the same standards of intellectual property protection as wealthier countries, granting far more patents than required by the WTO or envisioned by India's lawmakers. This could lead to generic competition on newer drugs ending entirely and prices for these in both India and developing countries increasing. This in turn would further deteriorate access to essential medicines in the developing world.

Likely patent for newer AIDS medicine lopinavir/ritonavir if Novartis succeeds

Lopinavir and ritonavir are two key AIDS medicines that need to be taken in combination by people who have developed resistance to their first set of medication. Although both medicines were first discovered in the early 1990s, pharmaceutical company Abbott Laboratories has applied for patents in India on new forms of these known medicines, in order to be granted a monopoly in India. Both patent applications are still under review at the Indian patent office, and have been opposed by civil society organisations.

Different countries need different patent regimes

Although the TRIPS Agreement obliges all WTO countries to grant patents on medicines, nothing obliges developing countries to replicate patent systems of wealthy countries. The agreement allows each country to set its criteria of patentability and does not prevent countries from including safeguards against the grant of patents for known substances, i.e. trivial patents. The Doha Declaration on TRIPS and Public Health, which was signed by all WTO countries, states that "the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."[3] Developing countries therefore have the right to design their patent laws in a way that takes their public health needs into account. This is precisely what India did when it amended its Patents Act in 2005. India fulfilled its obligation to grant patent protection according to WTO rules. The consequences for access to newer medicines for developing countries are severe; they should not be worsened further by making patenting too easy. Novartis should not be standing in the way and challenging India's rights.

NOVARTIS APPEALS PATENT REJECTION ON CANCER DRUG IMATINIB MESYLATE (GLEEVEC)

Novartis filed patent applications for the cancer drug imatinib in most countries in 1993. The company was not able to do so in India, as the country was not granting product patents at that time. In 1998, Novartis applied for a more specific patent on the beta-crystalline polymorph of a mesylate salt of imatinib i.e. imatinib mesylate, in order to try to obtain a patent monopoly in India

In January 2006, the patent on imatinib mesylate, which Novartis produces under the brand name *Gleevec*, was rejected in India on the grounds that it only represented a new form of a known substance and therefore was not an innovation and not patentable under Indian law. In May 2006, the company filed an appeal to the patent rejection, as well as a challenge against Section 3(d) of India's Patents Act.

Imatinib mesylate (Gleevec) is a crucial cancer drug essential in prolonging the life of patients suffering from chronic myeloid leukemia. In countries where Novartis has obtained a patent on Gleevec, the drug is sold at US $2,600 per patient per month. In India, generic versions are available for less than US $200 per patient per month. Novartis is now trying to have the patent decision overturned, so it can sell Gleevec at the same price in India as in other countries. The company is also challenging the Indian patent law, in an effort to make patents as easily granted in India as they are in most other countries.

[3] Doha Declaration on TRIPS and Public Health, signed at WTO Ministerial meeting in Doha, Qatar on 14 November 2001

सत्यमेव जयते

प्रधान मंत्री कार्यालय
Prime Minister's Office

नई दिल्ली - 110011
New Delhi - 110011

Sub: PETITION OF Sh. N I THOMAS,
NO.359,(OLD NO.367) SRINIVASA
NILAYA,JAKKASANDRA 1 MAIN BLOCK, KORAMANGLA-560034

A copy of letter dated 05-JUL-2006 received in this office from Sh. N I THOMAS is forwarded herewith for action as appropriate.

(O.D. SHARMA)
SECTION OFFICER

SECRETARY, D/O CHEMICALS & PETROCHEMICALS, M/O CHEMICALS & FERTILIZERS

PMO ID NO. 07/3/2006-PMP-4/726108 Dated - 28-JUL-2006

Copy for information to :-

Sh. N I THOMAS
NO.359,(OLD NO.367) SRINIVASA
NILAYA,JAKKASANDRA 1 MAIN BLOCK,
KORAMANGLA-560034

(O.D. SHARMA)
SECTION OFFICER

To
NT
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14/8/06

सत्यमेव जयते

प्रधान मंत्री कार्यालय
Prime Minister's Office

नई दिल्ली - 110011
New Delhi - 110011

Sub: PETITION OF Sh. NAVEEN THOMAS,
NO.359(OLD NO.367),SRINIVASA NILAYA
JAKKASANDRA,1ST MAIN,1ST BLOCK, BANGALORE-560034

A copy of letter dated 25-JUL-2006 received in this office from Sh. NAVEEN THOMAS is forwarded herewith for action as appropriate.

(O.D. SHARMA)
SECTION OFFICER

SECRETARY, D/O CHEMICALS & PETROCHEMICALS, M/O CHEMICALS & FERTILIZERS

PMO ID NO. 07/3/2006-PMP-4/726262 Dated - 08-AUG-2006

Copy for information to :-

Sh. NAVEEN THOMAS
NO.359(OLD NO.367),SRINIVASA NILAYA
JAKKASANDRA,1ST MAIN,1ST BLOCK,
BANGALORE-560034

(O.D. SHARMA)
SECTION OFFICER

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the filed letter

Lawyers Collective HIV / AIDS Unit

29th August 2006

Adv/thrmt/J/285/06

Re: Lawyers Collective HIV/AIDS Unit Monthly Thursday Meeting, 7th September, 2006

Dear Friends,

Participants at the last Monthly Thursday meeting held at our office on 3rd August 2006 discussed **"Pre-grant oppositions."** The minutes of the meeting are attached.

At the forthcoming Thursday meeting, we will be discussing **"Novartis challenges the denial of patent for Gleevec".** Gleevec, an anti-cancer drug is a life-saving drug for patients suffering from Chronic Myeloid Leukemia (CML). There are about 25,000 new cases of CML and about 18,000 people die every year in India. If patent is granted to Novartis, a Swiss pharmaceutical company it would allow for commercial exploitation of the purported invention, thereby excluding all other generic companies, causing serious prejudice to human health. Such monopolizing of the drug at an exorbitant cost of Rs 1,20,000 per month will cause serious harm to public health and is unaffordable to patients affected by CML. **Prafulla Saligram** of **Lawyers Collective HIV/AIDS Unit** will discuss the implications of Novartis's fight over the price of life and discuss strategies to mobilize support to advance the treatment of cancer patients.

The meeting is scheduled for **7th of September 2006** between **3 pm – 5 pm** at our office at **4A, I Floor, M.A.H. Road, Tasker Town, Off Park Road, Shivajinagar, Bangalore 560051.**

We look forward to the participation of representatives from groups of persons living with HIV/AIDS, Cancer Patients Association, NGOs, as well as partner organizations working in related areas. Please call us on **080- 41239130 / 31** to confirm your participation.

Hoping to see you there,

Warm Regards,

Lakshmi

Lakshmi Murthy
Advocacy Officer
Lawyers Collective HIV/AIDS Unit

TO NT reading
can we start a ~~PROT~~ file on Patents Advocacy
and put these in them ?
BPD
4/9/06

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11/9/06

PMU : Gr. Floor, Jalaram Kripa, 61, Janmabhoomi Marg, Fort, Mumbai 400 001. INDIA Tel : 91-22-2287 5482, 2287 5483, 2283 2779 Fax : 91-22-2282 1724
email : aidslaw@lawyerscollective.org
PO : 1st Floor, 63/2 Masjid Road, Jangpura, New Delhi 110 014. INDIA Tel : 91-11 2437 7101 / 2437 7102, 2437 2237 Telefax : 91-11-2437 2236
email : aidslaw1@lawyerscollective.org
PO : 1st Floor, No. 4A, M.A.H. Road, Off Park Road, Tasker Town, Shivajinagar, Bangalore 560 051. INDIA Tel : 91-80-51239130/1, 51125273 Telefax : 91-80-51239289
email : aidslaw2@lawyerscollective.org
Regd. Office : 4th Floor, Jalaram Jyot, 63 Janmabhoomi Marg, Fort, Mumbai 400 001. INDIA Tel : 91-22-2283 0957, 2285 2543 Fax : 91-22-2282 3570
www.lawyerscollective.org

Minutes of the Monthly Thursday Drop In Meeting

03 August 2006, Lawyers Collective HIV/AIDS Unit, Bangalore Project Office

Participants:

S.No	Name	Organization
1.	Jyothi Kiran	Milana
2.	Neelamma	Milana
3.	Amudha	Milana
4.	Rachael Beiggs	DFTI
5.	Stephanie Godliman	DFTI
6.	Kirsten Harwood	
7.	Vishwanath K.S	
8.	Siju Mathew	INSA-INDIA
9.	Pradeep K.R	INSA-INDIA
10.	Jacob George	INSA-INDIA
11.	Lakshmi Omana Kuttan	INSA-INDIA
12.	Kamala Bhat	Freedom Foundation
13.	Devaraj	Samraksha
14.	Benjamin	Samraksha
15.	Dr.Latha	Samraksha
16.	Shivu	Samraksha
17.	Ranjitha	Samraksha
18.	Radha.S	Samraksha
19.	Jagadevi S.J	Samraksha
20.	Suma C.T	Samraksha
21.	Vidyalatha	Samraksha
22.	Malathi	Arunodhaya Network
23.	Kanya Kumari	Arunodhaya Network
24.	Elizabeth	Asha Foundation
25.	Sujatha	Asha Foundation
26.	Gowramma	Asha Foundation
27.	Basavarajappa. C	Samraksha
28.	Laveena D`souza	Samraksha
29.	Sunil George	Snehadaan
30.	Chan Park	Lawyers Collective HIV/AIDS Unit
31.	Raj Kumar	Lawyers Collective HIV/AIDS Unit
32.	Prafulla	Lawyers Collective HIV/AIDS Unit
33.	Ramya Sheshadri	Lawyers Collective HIV/AIDS Unit
34.	Varsha Iyengar	Lawyers Collective HIV/AIDS Unit
35.	Manasi Kumar	Lawyers Collective HIV/AIDS Unit

AGENDA: PRE GRANT OPPOSITIONS

Raj Kumar introduced the topic on Pre Grant Oppositions and announced that the resource persons will be Chan Park and Prafulla from Lawyers Collective HIV/AIDS Unit. The participants introduced themselves.

Prafulla conducted a group exercise: 2 sheets of paper were given to every person. One was a list ARVs of first line and second line regimen. The second list contains the places ARVs are available. Every person was asked to tick on the names of the ARVs that they know was being used by PLHAs and the places they recommended. It was also found whether they were getting drugs free of costs or whether anybody paid for the drugs. The following was the outcome:

A. First form

1. Combivir- 22
2. Efavirenz- 5
3. DDI- 2
4. Stavudine- 1
5. Nevirapine- 8

B. Second Form

1. ART centers- 10
2. Government- 11
3. Pharmacy- 3
4. Private Clinics- 6
5. Care home- 5
6. NGOs- 5
7. Rural- 2
8. Urban- 1

The discussion led to the revelation that Combivir is one of the most widely used ARV drug. There were responses indicating people also bought from pharmacies and paid for the treatment at private clinics. A question was put before the audience, 'What would happen if a rule comes into force wherein it stops multiple manufacturing and only one company is allowed to produce?' The reactions were high prices, supply shortages, no competition among generic companies, chances of corruption, and delay in access to drugs which would lead to more casualties. The discussion was led to understand patents and what could do to access to medicine if Combivir is granted patent.

Chan's Presentation:

What is WTO?
It is an international organization regulating free trade between countries.

Why does it exist?

- Fair trade
- Globalization
- Protect US interests
- Main reason is to promote free trade, is to allow more competition and thereby reduction in prices.

One of the main agreements under WTO is the TRIPS- Agreement on Trade Related Aspects of Intellectual Property.

What is Intellectual property?

It is a property of the mind. It includes patents, copyright, trademarks, design protection. The government gives patents as an exclusive right. The government can choose to give or deny a patent.

The granting of a patent indicates granting of an exclusive right on an invention that could prevent others in using the invention. Therefore, no competition will arise as only the inventor company can manufacture the product. This is in fact the opposite of the objective of "free trade" projected by the WTO.

How did Cipla manufacture drugs, before India became signatory of WTO?

India did not have product patents for medicines before 2005. Hence generic companies such as Cipla began to manufacture medicines at much lower prices in late 2000 – 2001.

In 2001, when only MNCs produced ARVs it cost around Rs.5,00,000 per person per year. Since India did not recognize product patents for medicines, companies like Cipla, Aurobindo etc started producing the ARVs at much lower prices. The government started giving free ARVs in 2004. It spends about Rs. 5-6000 per person per year. The government buys the drugs at low prices from generic companies,

Affordability of medicines Post March 2005

March 2005, India had to introduce product patents to medicines, and some amendments to patent laws, as it had to comply with its obligation under TRIPS.
If product patents are given on life saving drugs, it will be 20 years before the generic companies can manufacture them. At present there are about 9000 patent applications pending - Eg. Combivir, Atazanavir, Tenofovir, Abacavir, Valganciclovir etc.

Role of Pre-grant oppositions

In the 2005 amendments to the patent laws, the companies have to apply for patent, and when it is under examination interested persons can oppose it before it is granted – pregrant oppositions. There is also a post-grant opposition that is usually filed after the patent is granted.
As a sign of opposing patents for life saving drugs, an opposition was filed against Gleevec manufactured by Novartis. This was filed by the CPAA. Gleevec is a life saving cancer drug, that cost Rs. 8,000 per month per person and this is the price of the generic version. Novartis was granted Exclusive Marketing Right and the price shot up to Rs.

1,25,000 per person per month. The opposition was filed in September 2005 and in 2006, the patent controller denied patent for Gleevec. Gleevec had patents in 35 other countries.

Taking this as an example, patent oppositions are being filed on ARV drugs by People Living With HIV/AIDS networks like INP+, DNP+, MNP+, TNNP+, and KNP+ etc. Currently the oppositions are filed for Atazanavir, Combivir, Tenofovir, Nevirapine, Abacavir, and Valganciclovir.

In Thailand, there is likelihood of Combivir getting a patent. In connection with that the Thai People Network Living with HIV/AIDS and the Thai NGO Coalition on AIDS will organize a big demonstration in front of GSK office in Bangkok demanding them to drop the patent application. As a mark of solidarity and support to the cause of affordability of life saving drugs a protest is scheduled on 7/8/06 at 3 pm in front of the Glaxo Smith Kline office on Cunningham road against the grant of the patent.

Questions asked by the participants:

Why can't Indian companies get patents?
Nothing is preventing the Indian companies from getting patents. The situation is such that life saving drugs has been patented by MNCs as they invent most of the drugs, which sell them at high prices.

What about compulsory licensing as a measure to lower the prices?
Compulsory licensing (CL) can only be done in certain circumstances and it is the prerogative of the government. The Indian government is very hesitant to grant CL because of pressure from USA and strong lobbying by pharmaceutical companies.

How does one ensure quality of drugs as PLHAs had their reservations in using the generic versions?
WHO is monitoring the procedures and standards followed by generic companies and as and when required withdraws the drugs from the marketing.

The letters explaining the impact of Combivir getting a patent and the protest being held on Monday afternoon i.e. Aug 7th was distributed to one and all and they were requested for their active participation for the cause.

सत्यमेव जयते

प्रधान मंत्री कार्यालय
Prime Minister's Office

नई दिल्ली - 110011
New Delhi - 110011

Sub: PETITION OF Sh. NAVEEN THOMAS, NO.359,9OLD NO.367) SRINIVASA NILAYA,JAKKASANDRA 1 MAIN,1 BLOCK, BANGALORE-560034

A copy of letter dated 26-JUL-2006 received in this office from Sh. NAVEEN THOMAS is forwarded herewith for action as appropriate.

(O.D. SHARMA)
SECTION OFFICER

SECRETARY, D/O CHEMICALS & PETROCHEMICALS, M/O CHEMICALS & FERTILIZERS

PMO ID NO. 07/3/2006-PMP-4/726259 Dated - 08-AUG-2006

Copy for information to :-

Sh. NAVEEN THOMAS
NO.359,9OLD NO.367) SRINIVASA
NILAYA,JAKKASANDRA 1 MAIN,1 BLOCK,
BANGALORE-560034

(O.D. SHARMA)
SECTION OFFICER

458 → N.T.
21/8/06

Lawyers Collective HIV / AIDS Unit

28th June 2006

Adv/thrmt/J/ 263 /06

Re: Lawyers Collective HIV/AIDS Unit Monthly Thursday Meeting, 1st June, 2006

Dear Friends,

Participants at the last Monthly Thursday meeting held at our office on **1st June 2006** discussed **"Pre –Marital Mandatory HIV testing."** The minutes of the meeting are attached.

At the forthcoming Thursday meeting, we will be discussing **"Access to Medicines and Data Exclusivity."** The Indian government is currently planning to amend the Drugs and Cosmetics Act in a way that could seriously impact the affordability of essential medicines, including medicines critical in fighting the AIDS epidemic. We will discuss the proposed "data exclusivity" provision, its potential impact on access to medicines, and what we can do to make our voices heard. Chan Park and Arti Malik of Lawyers Collective HIV/AIDS Unit will present the contours of this important issue.

The meeting is scheduled for **6th July, 2006** between **3 pm – 5 pm** at our office at **4A, I Floor, M.A.H. Road, Tasker Town, Off Park Road, Shivajinagar, Bangalore 560051.**

We look forward to the participation of representatives from groups of persons living with HIV/AIDS, NGOs, as well as partner organizations working in related areas. Please call us on **080- 41239130 / 31** to confirm your participation.

Hoping to see you there,

Warm Regards,

Lakshmi

Lakshmi Murthy
Advocacy Officer
Lawyers Collective HIV/AIDS Unit
Bangalore

290
3/7/06

EPD → Naveen
3/7/06
Note the above meeting
back to HIV or Lawyers collective file

PMU : 7/10, Botawalla Building, 2nd Floor, Horniman Circle, Mumbai 400 023. INDIA Tel. : 91-22-2267 6213, 2267 6219 Fax : 91-22-2270 2563
email : aidslaw@vsnl.com / aidslaw@lawyerscollective.org

P.O. : First Floor, No. 4A, M.A.H. Road, Off Park Road, Tasker Town, Shivajinagar, Bangalore 560 051. INDIA Tel.: 91-80-5123 9130/1 Fax : 91-80-5123 9289
email : aidslaw2@lawyerscollective.org

P.O. : 1st Floor, 63/2 Masjid Road, Jangpura, New Delhi 110 014. INDIA Tel : 91-11 2432 1101 / 2432 1102, 2432 2237 Fax : 91-11-2432 2236
email : aidslaw1@ndb.vsnl.net.in / aidslaw1@lawyerscollective.org

Regd. Office : 4th Floor, Jalaram Jyot, 63 Janmabhoomi Marg, Fort, Mumbai 400 001. INDIA Tel.: 91-22-2283 0957, 2285 2543 Fax : 91-22-2282 3570
www.lawyerscollective.org

Minutes of the Monthly Thursday Drop In Meeting

01 May 2006, Lawyers Collective HIV/AIDS Unit, Bangalore Project Office

Participants:

S.No	Name	Organization
1	Dawat	Samraksha
2	Jyothi Cardoza	NIMHANS
3	Hamsa Krishna	NIMHANS
4	Suchitra	Freedom Foundation
5	Shobhna	Freedom Foundation
6	Kamala Bhat	Freedom Foundation
7	Okoronkwo	Milana Foundation
8	Vishwanath	KNP+
9	Chandrashekaran	KNP+
10	Shantha	KNP+
11	Sapthami	Samraksha
12	Sangeeta	"
13	Laveena	"
14	Vidyalatha	"
15	Regina	"
16	Manasi	Lawyers Collective HIV/AIDS Unit
17	Varsha	"
18	Benjamin	Samraksha
19	Pradeep	INSA – India
20	Edwina Pereira	INSA – India
21	Prabhavathy	KSAPS
22	Jagadevi	Samraksha
23	Lakshmi	Lawyers Collective HIV/AIDS Unit
24	Rajakumar	"

Agenda: Mandatory Pre-Marital HIV Testing

After an introduction of participants, Rajakumar from Lawyers Collective introduced the topic `Mandatory Pre-marital testing'. On 18th March, 2006 the Goa government had announced that it would amend the public health Act by making HIV test mandatory for couples before registration of marriage. It is based on the trend that more young women in the age group of 15 to 29 are getting infected with HIV.

On 29th April 2006 a national meeting was organised by Lawyers Collective HIV/AIDS Unit and Positive People, Goa to discuss and plan strategies to take the campaign forward. The public opinion in Goa is divided on this issue. It is in this context that there is a need to debate the pros and cons of pre-marital testing.

The objection was that there seemed to be little concern about the window period i.e. the time between infection and testing positive, which would defeat the purpose of the pre-marital tests.

A pre-marital HIV test would not really prevent the spread of infection to the unmarried sexual partners or the needle sharing partners of the person affected by HIV.

It would also cause unnecessary distress for those with false positive results. The family members will also face stigma and discrimination. There is scope for false certificates. It should also be noted that people seeking marriage licenses are a very low-risk population. HIV prior to marriage would only mean a false sense of security and a false belief that the infection is being effectively prevented from spreading. Will the government take responsibility if a person is tested HIV+ after marriage?

In United States of America, two states i.e. Illinois and Louisiana introduced mandatory pre-marital testing, but ultimately repealed them when it was found to be an extremely costly yet ineffective tool in the fight against HIV. It was a waste of important resources in terms of counsellors, administrators, nurses, doctors and infrastructure costs. During the six months of mandatory pre-marital testing there were fewer marriages than before. People get married outside the state where such laws are absent.

Johor was the first state in Malaysia to carry out mandatory pre-marital HIV tests on Muslim couples. Experts, however admit that the policy has been a failure and physicians from Malaysia commented that singling out HIV/AIDS for pre marital testing has contributed to stigma while having zero impact on the number of new infections.

Many viewed pre-marital mandatory testing as a very ineffective method to combat the spread of HIV/AIDS. Some of the issues discussed in this regard were:

- Studies have indicated that it is during the pregnancy of the wife that the husband tends to stray away and contract HIV. The wife may later contract HIV from her husband. Thus, pre-marital testing serves no purpose.
- Experience tells us that law making is not a solution to all problems. Violating laws is a common practice. A classic example being traffic laws that are violated several times.
- Enforcement of laws is a critical issue. The question raised was who will ensure that a couple have undergone the test before tying the knot. This problem is further amplified in India because of different personal laws for different people.
- Counterfeit certificate markets will flourish with the requirement for pre-marital mandatory test certificates.

With several loopholes, mandatory testing was viewed as an utter waste of the State's resources. It was opined that these resources should instead be utilised to generate awareness among the people. People should be encouraged and educated to use condoms in the hope of reducing their risk of HIV/STI infection.

Lack of awareness is an issue of tremendous concern. Some experiences in day-to-day life were shared:

- The girl's parents are willing to marry off their daughter to a HIV+ person with the ignorance that it's a curable disease.
- In Punjab ICSE teachers have said that it's our karma that our husbands are straying.

The positive aspects of pre-marital mandatory testing were also discussed:

- In *X* v. *Hospital Z*, the Court upheld the right to life of the spouse as superior to the right to confidentiality of the HIV+ person. Thus, mandatory testing cannot be viewed as an infringement of the right of the HIV+ person.
- Studies have indicated that the chances of a woman contracting HIV from her sexual male partner are higher than vice versa. Thus, mandatory testing would help many women know about their partners' HIV status.

Lawyers Collective HIV / AIDS Unit

28th July 2006

Adv/thrmt/J/273/06

Re: Lawyers Collective HIV/AIDS Unit Monthly Thursday Meeting, 3rd August 2006

Dear Friends,

Participants at the last Monthly Thursday meeting held at our office on 6th July 2006 discussed "**Access to Medicines and Data Exclusivity.**" The minutes of the meeting are attached.

At the forthcoming Thursday meeting, we will be discussing **"Access to Medicines and Pre-Grant Opposition."** Affordable and access to quality medicine is a major issue because of the policy changes the government is bringing to accelerate industrial growth. In this process there are some provisions which help to improve access to drugs and treatment. Under the Indian Patent Act there is a provision to oppose inventions of new pharmaceutical formulations before granting patents. At present there are many patent applications for ARV drugs (second line regime) in the patent offices. If patent is granted for these drugs it will impact the ARV rollout program of the government, which gives free ARV drugs for the HIV+ persons. We will discuss the pre-grant opposition provision and the role played by HIV+ people networks in the country to reduce the impact on access to medicine. **Chan Park** of **Lawyers Collective HIV/AIDS Unit** will explain the legal aspects and the process involved in the pre-grant opposition.

The meeting is scheduled for **3rd of August 2006** between **3 pm – 5 pm** at our office at **4A, I Floor, M.A.H. Road, Tasker Town, Off Park Road, Shivajinagar, Bangalore 560051.**

We look forward to the participation of representatives from groups of persons living with HIV/AIDS, NGOs, as well as partner organizations working in related areas. Please call us on **080- 41239130 / 31** to confirm your participation.

Hoping to see you there,

Warm Regards,

Raja Kumar
Advocacy Officer
Lawyers Collective HIV/AIDS Unit
Bangalore

414
2/8/06

To NT
pass it on for filing
EPD
3/8/06

PMU : Gr. Floor, Jalaram Kripa, 61, Janmabhoomi Marg, Fort, Mumbai 400 001. INDIA Tel : 91-22-2287 5482, 2287 5483, 2283 2779 Fax : 91-22-2282 1724
email : aidslaw@lawyerscollective.org
PO : 1st Floor, 63/2 Masjid Road, Jangpura, New Delhi 110 014. INDIA Tel : 91-11 2437 7101 / 2437 7102, 2437 2237 Telefax : 91-11-2437 2236
email : aidslaw1@lawyerscollective.org
PO : 1st Floor, No. 4A, M.A.H. Road, Off Park Road, Tasker Town, Shivajinagar, Bangalore 560051. INDIA Tel : 91-80-51239130/1, 51125273 Telefax : 91-80-51239289
email : aidslaw2@lawyerscollective.org
Regd. Office : 4th Floor, Jalaram Jyot, 63 Janmabhoomi Marg, Fort, Mumbai 400 001. INDIA Tel : 91-22-2283 0957, 2285 2543 Fax : 91-22-2282 3570
www.lawyerscollective.org

Minutes of the Monthly Thursday Drop In Meeting

06 July 2006, Lawyers Collective HIV/AIDS Unit, Bangalore Project Office

Participants:

S.No	Name	Organization
1.	Dheepak	SPAD
2.	Rebecca Desouza	Independent Researcher
3.	Hamza.	Freedom Foundation, Bangalore
4.	Diwakara	Freedom Foundation, Bangalore
5.	Nataraj	Accept, Bangalore
6.	Dr Manish	Abhya, Action Aid , Bangalore
7.	Meghna Girish	Action Aid, HIV Thematic Unit
8.	Radha	Samraksha
9.	Vidyuth	Lawyers Collective
10.	Vidyalatha	Samraksha
11.	Regina	Samraksha
12.	Amit. M. Lobo	Prarana
13.	Charles Allwin	Prarana
14.	Christopher	ICYE
15.	Mary Bosco	KHPT
16.	Varsha	Lawyers Collective
17.	Lakshmi	Lawyers Collective
18.	Rajakumar	Lawyers Collective
19.	Chan Park	Lawyers Collective
20.	Ramya	Lawyers Collective
21.	Arti	Lawyers Collective
22.	Prasanna	Public Health Movement
23.	Naveen	Community Helath Cell

Agenda: "Access to Medicines and Data Exclusivity"

Lakshmi introduced Arti, Prasanna and Naveen and said they will be resource persons for the meeting. Also, she requested the participants to introduce themselves. Arti made the first presentation, which was the introduction to "Data Exclusivity" and the second part, was dealt by Prasanna and Naveen who shared further information about the campaign on data exclusivity.

What is Data exclusivity?

The Government is preparing to amend the Drugs and Cosmetics Act 1940, which is going to affect the people accessing affordable medicines in the country. According to Drugs and Cosmetics Act (DCA), the drug controller has to approve any medicine that is going to be marketed in India for its safety and effectiveness on human beings.

If any drug is a new drug and first of its kind to be marketed in India, the drug needs to be tested on human beings though clinical trials. Based on the results of such trials the drug controller can make a determination as to whether it is safe for human consumption. Only then license will be issued for marketing.
If any company wants to produce a generic version of the branded medicine, instead of repeating the clinical trial that have already been conducted, the company only needs to show that its drug is bioeqivalent to the already approved. This is the present procedure available for approval of drugs for marketing, and allows for quick introduction of cheaper generic drugs into the market.

The amendment proposed by the government will change all of this. Now, the Drug Controller will be prohibited from even looking at the information already submitted by the first company in approving a generic version until the expiration of the exclusivity period – anywhere from 3-7 years. The MNC drug companies are claiming that they need this protection because otherwise it would constitute "unfair commercial use" by the generic companies of data that took years and millions of dollars to generate. However, under the current scheme, the generic drug companies do not actually "use" the data. It is the Drug Controller that relies upon the data to approve a generic company's drug application. But then, the Drug Controller is not using this information for "commercial" purposes – it is only relying on this data to perform its official duties, which is to ensure that every drug marketed in India is safe and effective. Therefore, there is no "unfair commercial use" going on anywhere under the current system.

ARVs manufactured by generic companies will get affected, as a data exclusivity provision would give a monopoly over any new ARV drug introduced in India throughout the duration of the exclusivity period. By bringing in this provision, access to affordable medicines to the Indian public will be affected to a great extent. It is from this point of view that civil society throughout India and internationally is opposing the introduction of data exclusivity.

The need and update on Data Exclusivity Campaign:

Prasanna from Public Health Movement explained the need for a campaign on Data Exclusivity as the ministerial meeting is going to take place on the 12th July in Delhi to take a decision on introducing data exclusivity in India.[1] It is in this context that public health movement has launched a global week of action from 6th –11th July to lobby and advocate against data exclusivity provision. The Health Ministry is against data exclusivity, as it will affect access to treatment and health of the common people in India. However, the Chemicals Ministry and the Commerce Ministry are supporting this new proposed amendment. Hence more civil society organizations should express their view to the government so that data exclusivity is not introduced into the DCA.
Even if the 12th inter-ministerial meeting takes a decision to introduce the data exclusivity it has to be approved by parliament. In that sense the campaign has to continue even after the 12th July.

[1] The meeting was subsequently postponed to 26 July in light of the recent Bombay bombings.

Q. Why after patent act is amended they are brining one more provision giving monopoly rights? What are they achieving?

Chan explained that Patent Act and its provision are separate from data exclusivity. Patent Act gives monopoly to the invention at a very early stage. Data exclusivity is introduced through Drugs and Cosmetics Act during the time of marketing approval by the drug controller. Another monopoly status created preventing them from using the data shared to the drug controller.

Prasanna explained health has become a commercial venture and investments are made to make profit. Cosmetics and diseases likes diabetics, blood pressure, cancer that affect the rich countries, attract research and development initiatives of the multinational corporations. Research and development of drugs involves lot of financial involvement and the companies do not want to part easily with drugs until they can make maximum profit out of the drugs. That is why they lobby for more monopoly rights through Patent Act and data exclusivity so that they can hold rights for selling beyond 20 years.

Q. What are Exclusive Marketing Rights? Gleevec continue to get the rights?

Exclusive Marketing Right is a temporary arrangement given for the interim period between 1995 the year we become the member of WTO till we amended Patent Act in 2005. Gleevec applied for it, as they don't want generics to produce the drug as they have applied for patent. When the patent application for Gleevec was denied, the EMR was automatically dissolved.

Q. If Data Exclusivity is introduced will it not allow Drug controller from using it?

Yes, under data exclusivity provision drug controller cannot refer to the clinical trial data submitted by the branded drug companies under the official secrets act. Data exclusivity is a TRIPS + requirement. According to section 39.3 of TRIPS, protection need to be given for preventing unfair commercial use of the data provided by the branded companies. According to the Drugs and Cosmetics Act a drug controller only refers to the data of the branded drug company for approval of the generic company drugs are safe and efficacy for human consumption. Drug Controller (DC) will not publish the document, DC only refers the document and approves and there is no unfair commercial use by another company involved in it. The proposed amendment goes beyond the TRIPS requirement that is why it is TRIPS+.

Naveen shared about national level campaign is going on Data Exclusivity even global week of Action is launched from 6th July to 10th July and following emerged as major action points. Reading material on data exclusivity was circulated to the participants of the meeting.

There is also a web site one can log on for further reading material http://data-exclusivity.blogspot.com

1. There is need for lobbying by writing letters to Prime Minister, Health Ministry, Chemical &Fertilizers and Commerce Minster. Around 1000 NGO's belongings to 20 networks are lobbying against this law through PHM.
2. Templates for writing the letters to PM and other ministers are available which the groups can use. The templates are available with Lawyers collective and PHM, which can be used. It was decided that Lawyers collective would send to all the organizations the templates by 07.06.06. An on-line petition can be signed at www.shaii.org
3. The Health Ministry is convinced that this proposed amendment will have serious effect on the health of the poor people and are opposing data exclusivity, whereas Chemical and Commerce ministry are in favor. Hence it is decided to send as many letters as possible from all the groups so that government will not bring this amendment.
4. Apart from Individual letters by NGO's it was also decided that a letter on behalf of Bangalore NGO"s can be sent and the NGO's who have attended this Thursday meeting can be signatories to this letter.
5. By 07.07.07 Lawyers collective will send a summary of the decisions arrived at in the meeting to all the NGO's.
6. Those NGO's who are sending separate letters to the PM and other ministries and send one copy to lawyers collective at aidslaw2@lawyerscollective.org. Lawyers Collective will compile and hand it over to PHM. They intern can compile for the entire country and give it to PM and other ministries which will be base to show that civil society is not supporting this amendment.
7. PHM also announced that they have announced a global week of action from 6th -10th July 2006. They announced that 12th July inter ministerial meeting is being organized before that all the letters to be sent. However, even if the Inter Ministerial Meeting is decides in favor of data exclusivity, Parliament has to approve this so we may have to continue this battle it is not ending on 12th July itself.
8. Each Participant of the meeting said from their organisation what can be done by 10th July. Most of them agreed to send a letter to the PMO; others asked for the minutes of the meeting so that they discuss with in their organisation and take a decision.
9. Lawyer's collective is having an informal press briefing on this issue on the 7th July for Kannada journalists. It was suggested that CFAR could be of help in organizing a more formal press conference.
10. It was decided that due to time constraints a protest rally could not be organized in Bangalore. There was also information provided on lobbying activities from US contact person guptahr@yahoo.com

Sri Kamal Nath
Honourable Minster of Commerce & Industry
Room No. 45, Udyog Bhavan
New Delhi
Tel: 23061008, Fax: 23012947

Shri Jairam Ramesh
Minister of State for Commerce
Udyog Bhavan, New Delhi
Tel: 23061194, Fax: 23062807

Dear Naveen it seems you did not recieve my longish earlier communication .
you must mention that Data Protection against commercial misuse as mentioned in TRIPS is TOTALLY DIFFERENT from DATA EXCLUSIVITY .They are eing used synonamously to confuse . Use y the DRUG CONTROLLER to compare _PIOAVAILAILITY & PIOEQUAVALENCE DATA is LEGITIMATE USE & TRIPS COM PLIANT. The letter after "A" has died in my computer & therefor I am using "P" instead .
Preventing comparative use cf data supmitted for getting MARKETING LICENSE from the drug controller & that too for 5to 7 years is definately TRIPS PLUS MEASURE .Such measures are eing forced on developing countries as part of FTA's & PILATERAL TRADE AGREEMENTS .We are not aware of what Dr Ramdoss has signed during his U.S .visit .
The pressure on PM's office is mainly from PFIZER esides others . DR MASHELKAR IS STONGLY SUPPORTING "DATA EXCLUSIVITY " THc IPR commission report docs not get legitimacy ccausc of his presence there , infact earlier his STATEMENTS had een found very opjectionale at a meeting in Geneva . Mr HARDEEP PURI INDIA's AM PASSODER wrote to GOI complaing that Dr MASHELKAR"S poition as taken py him was not in national interest . A cover up was done & it was announced that he had made those statements in his personal capacity.
Ido not think a statement y JSA is enough , several letters from different organizations & individuals must go .
I have taken up the issue with the WTO CELL OF THE HEALTH MINISTERY ,At the PLANNING COMMISSIONS STEERING COMMITTEE ON PRIMARY HEALTH CARE , TASK FORCE ON SAFETY OF FOOD & MEDICINE, ,
with thc south Asian J ournnalists at a session on what their rolc could play in improving 's women's health. This issue was also dealt with grassroot groups working on children's issue .I have promised to write a simple note on this & drug related issues in HINDI
I tried to deal with the health persons in the P.M"s OFFICE to ensure the pulic health aspects are protected . In the earlier schduled meeting only Commerce & Chemicals Ministery were invited
.It is definately not enough .
Thc pregnant silencc of health NGO"s as policy threats of major magnitudc arc taking placc is indeed very tragic,
DATA EXCLUSIVITY IS JUST ONE OF THE ATTACKS ON PEOPLES HEALTH.MORE ARE IN THE PIPELINE . The wheat & vegetaple prices shooting up is just a reflection of the Market Havoc . The DRUG POLICY is expected shortly.
More on that later,
Regards
Mira Shiva

Dear naveen and others,

faxing mashelkar is not a good idea. its better that he does not know where the opposition is coming from or who are supporting health ministry....

however i would like to clarify what the govt is proposing - both the proposal of health and ministry of chemicals & fert. there seems to be

Resource Person
Database Form

People's Health Movement

January 2004

Dear

Thank you for your participation in the International Health Forum as a resource person. People's Health Movement is building a database of resource persons and volunteers for future reference. Kindly fill in the enclosed form in BLOCK LETTERS, even if you have filled in the registration form earlier. Thank you for your co-operation.

Best wishes,
PHM Secretariat Team

NAME: ..... OFFICE ADDRESS: .... Tel (with country/ area code) : .... E-mail:..... ..... Fax:.....	NAME: ..... HOME ADDRESS: .... Tel (with country/ area code) : .... E-mail:..... ..... Fax:.....

Organisation(s): .....

Interest Areas/ Expertise:

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Any other information:

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some confusion. early working etc come in when DE is to introduced and not in the case of Data protection. also - the early working requirment is part of the DE proposal by the ministry of chemicals & fertilizers:

the ministry of health is supporting Protection against disclosure only (no data exclusivity) i.e. Minor amendment in rules to the Drugs and Cosmetic Act to ensure that the specified data submitted for the purpose of marketing approval of pharmaceutical products should not be disclosed to any third party for a period of three years. Ministry of commerce is supporting them.
further data protection will be only available to 'new chemical entities' never marketed anywhere in the world. since big pharma rarely registers over here they have very smartly even restricted data protection to a few drugs.

what is chemicals & fertilizers saying:

Ministry of chemicals is supporting data exclusivity i.e. non reliance by drug controller for a period of three years. availability of drugs like kaletra, atanazavir may get affected.

however their proposal is even more dangerous because market exclusivity is available to 'new chemical entities" however they have defined new chemical entity as a pharmaceutical product not marketed in India before - that effectively will cover improvements, derivatives of older drugs first marketed elsewhere and then they can prevent generic production by claiming market exclusivity for 3 years.

safeguards they (ministry of chemicals & fertilizers) have suggested (wh are good if DE is introduced):

The protection period in India should begin on the date of marketing approval in the first country recognized by India (US, Canada, EU, etc). Thus the data protection clock could be set running by a registration in another country. Such a system would positively encourage originators to expedite registration in that developing country, so as to benefit from the longest possible period of protection. For example if a medicine is first registered in Germany and only registered in the India 2 years later then only one year of data protection would be left in India.

Review of the second applicant's application is permitted to take place during the period of exclusive rights. A generic product could be approved during the latter period of exclusive rights and placed on the market the first day after the expiry of the market exclusivity period. If this were not permitted, their period of exclusivity would include the specified term plus the amount of time that it would take a generic firm to gain marketing approval based on their filing their application on the first day after the expiry of that period. this again we have to lobby for.

Ø If for a patented drug compulsory licence is granted then a provision for accompanying compulsory licence for the necessary data

Resource Person
Database Form

People's Health Movement

January 2004

Dear

Thank you for your participation in the International Health Forum as a resource person. People's Health Movement is building a database of resource persons and volunteers for future reference. Kindly fill in the enclosed form in BLOCK LETTERS, even if you have filled in the registration form earlier. Thank you for your co-operation.

Best wishes,
PHM Secretariat Team

NAME: ..... OFFICE ADDRESS: .... Tel (with country/ area code) : .... E-mail:..... ..... Fax:.....	NAME: ..... HOME ADDRESS: .... Tel (with country/ area code) : .... E-mail:..... ..... Fax:.....

Organisation(s): .....

Interest Areas/ Expertise:

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Any other information:

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is needed so that the licenced drug can be given marketing authorisation. To do otherwise would render empty the value of a compulsory licence. India will need to ensure that the use of compulsory licences are not restricted by Article 39.3.

Ø The period of Data protection to be capped by the expiry of a relevant patent.

public health organisations are aiming for data protection but even if it is DE (if they succeed) then the following safeguards in addition to the above should be included:

Safeguards:

Ø No protection to be provided for new indications. Restrict Data protection or exclusivity rights to New Chemical Entities as understood under patent law. Article 39.3 is after all aimed at protecting data, which is the result of "considerable effort". Subsequent data relating to new indications, routes of administration and dosages - should not receive a separate period of data protection. Ministry of Chemicals & Fert refuses to agree to this. this is something we must fight for in the event DE is intorduced.

A 'working' requirement should also be considered, where the originator has to market the relevant product after obtaining regulatory approval, failing which they forfeit their rights of data protection/exclusivity. (we may get this but we have to lobby for it).

Ø Ensure that health and safety data would be immediately available to the public. Also the DCGI in public interest should be authorized to use and disclose any data turned over to it by an applicant for registration.

hope that clarifies,

Leena

Dear Naveen ,
I just wrote a long letter & it has just disappeared . DR MASHELKAR is strongly supporting DATA EXCLUSIVITY ' He did not play a very good role earlier inGENEVA , Mr Hardeep Puri had to write to GOI .
There is a PIL filed agaist him .Chemicals ministrry is also supporting DATA EXCLUSIVITY .Health ministery is OK
Ihave taken it up with the WTO CELL of HEALTH MINISTERY , Planning commission - Health advisor ., & PM"S office -Health.
We needto respond as JSA , AS INDIVIDUAL ORGANIZATIONS & get individuals to respond.
I had written about many other urgent issues that needed to be responded to.
It takes me very very long to complete a letter with 2 fingure typing & when it all dissappears it is very saddening .
WARM REGARDS

Resource Person
Database Form

People's Health Movement

January 2004

Dear

Thank you for your participation in the International Health Forum as a resource person. People's Health Movement is building a database of resource persons and volunteers for future reference. Kindly fill in the enclosed form in BLOCK LETTERS, even if you have filled in the registration form earlier. Thank you for your co-operation.

Best wishes,
PHM Secretariat Team

NAME: ..... OFFICE ADDRESS: .... Tel (with country/ area code) : .... E-mail:..... ..... Fax:.....	NAME: ..... HOME ADDRESS: .... Tel (with country/ area code) : .... E-mail:..... ..... Fax:.....

Organisation(s): .....

Interest Areas/ Expertise:
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Any other information:
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Main Identity

From: "Priti Radhakrishnan" <priti.radhakrishnan@gmail.com>
To: <ravi@phmovement.org>
Sent: Wednesday, July 05, 2006 12:50 AM
Subject: Update

Dear Dr.Ravi,

Hello! How are you? Hope all is well.

The current debate in India on data exclusivity has severe implications for patients globally. Please find our paper modeling the impact of the latest Government of India proposal, as well as brief discussions on other potential alternatives:

www.i-mak-org.blogspot.com

We hope you find it useful in your efforts to advocate for access to medicines and a more equitable intellectual property regime.

Warm regards,

Priti Radhakrishnan
Vishwas Devaiah
Tahir Amin

Initiative for Medicines, Access & Knowledge (I-MAK)
www.i-mak.org (site is under construction)

NT - Keep her involved with yours/JSA efforts

RV
5/7/06

Why Is KALETRA Important?

A newly approved form of the combination drug Lopinavir/Ritonavir is now being marketed as KALETRA by Abbott Laboratories. Earlier this year, the World Health Organization recommended KALETRA as a critical 2nd-line medication for the 40-million+ people currently living with HIV.

This tablet version of KALETRA is important because, unlike the previous formulation, it can be stored at room temperature, has no dietary restrictions and significantly reduces the number of pills a patient needs to take each day. These three features directly address the needs of many developing countries, since this version needs no refrigeration and simpler regimens are easier for patients and clinics to buy, store and take.

At the moment, however, the tablet form of KALETRA is not being made available to the very people it appears to have been created for. Why?

Abbott's Current Stance on KALETRA

Currently, Abbott is primarily focusing on marketing the drug in the United States and Western Europe, where profits are highest. Abbott has been reluctant to sell KALETRA affordably in developing countries where the need for KALETRA is tremendous and where the features of the tablet would be most useful. As a result, patients and advocates are challenging Abbott's position on the pricing and patenting of KALETRA in order to make it affordable and accessible to the millions who need it.

What Is India's Role in the KALETRA Debate?

India is at the center of the KALETRA debate for one crucial reason: as the world's leading producer of generic medications, India has in the past supplied affordable drugs for many diseases. Due to recent changes in its patent laws, however, India's integral role as the "world's pharmacy" may drastically change, limiting the ability of companies to manufacture and sell key medications.

This year, the Indian government will review patent applications for several important HIV drugs. If patents are granted, under India's new law the length of monopolies for brand-name manufacturers will be 20 years, ultimately jeopardizing global access to many essential medications such as KALETRA.

Abbott has applied for several patents on KALETRA in India. If granted, Abbott will have exclusive rights to manufacture the drug without any competition, ultimately allowing the company to set the price however it chooses. At the current time, Abbott maintains that KALETRA cannot be produced for less than US$ 500 per year, making it unaffordable for most people living with HIV in the world. With exclusive patent rights, no one will try to produce KALETRA for less and challenge Abbott's claim, which means a key drug will be out of reach for millions of people.

Patenting of KALETRA?

Recently, the Delhi Network of Positive People (DNP+) and the Indian Network for People Living with HIV/AIDS (INP+) have formally opposed patent applications in India on key HIV drugs. These *patent oppositions* are filed at one of India's four governmental Patent Offices and argue against a pharmaceutical company's often doubtful assertion that these key drugs are new inventions. In the case of KALETRA, three patent oppositions have recently been filed on this basis to block the applications for Ritonavir, Lopinavir, and the soft-gel formulation of KALETRA.

What Is The Next Step in India?

We will continue to look for KALETRA patent applications and, where appropriate, file oppositions against these applications. For instance, the patent application for the form of KALETRA that can be stored at room temperature will also be opposed because it is not a new invention.

What Can You Do To Support This Effort?

If you are concerned about ensuring affordable access to KALETRA and other key HIV drugs, you can advocate for this cause by asking Abbott and other key brand-name manufacturers of AIDS treatment to withdraw their patent applications in India!

You can also support I-MAK, which is leading the focused effort against patents on HIV drugs in India. You can reach us at contact@i-mak.org.

----- Original Message -----
From: sahajbrc
To: Anurag Bhargava ; Anant Phadke ; drdabade@gmail.com ; mirashiva@yahoo.com ; sahajbrc
Cc: Naveen ; Prasanna Saligram
Sent: Sunday, October 01, 2006 6:37 PM
Subject: Re:

Dear Anurag and others,

We need to rebut 3 points in a press release:

1) The tokenism of the drug banks idea
2) Cap on generic and branded generic drugs touch only Rs 2000 cr whereas the majority of the high priced top-selling 300 drugs of ORG list (Rs25,000 cr) is untouched.
3) Setting up a commitee of industry wallahs

We shld also write to Paswan.

I have added points 9 and 10 in the piece drafted by Anurag. Will Naveen or Prasanna makeit into a press release?

---

http://www.blonnet.com/2006/09/24/stories/2006092403880100.htm
Govt to set up drug banks in 600 districts

Our Bureau

Industry commits Rs 45 cr free medicines annually.

New Delhi , Sept. 23

The Government will set up district-level drug banks in the approximately 600 districts across the country in public-private partnership (PPP).

On profit margins, the Minister said the industry had agreed to cap trade margins on generic-generic and branded-generic drugs at a minimum of 15 per cent for wholesalers and 35 per cent for retailers. As a result, prices of these drugs would come down between 2 and 70 per cent, he said.

Anu 4/10/06

Prepared a draft press release & sent it to AIDAN SP.

HEALTH SYSTEMS

Green Pharmacy

Darshan Shankar

Indian people had an incredible knowledge of phyto-medicine driven apparently by a tremendous passion for the study of medicinal plants. This is evident both in the living folk traditions in the rural communities as well as the scholarly systems i.e. Ayurveda, Siddha, Unani and Tibetan. Indians obviously care for medicinal plants because they know so much about them and have done so much work has so extensive, detailed and deep an understanding about the medicinal value of plants.

History of Medicinal Plans Use

The traditional definition of medicinal plants is given in Astaanga Hrdaya (600 AD) sutra sthana Ch.9-verse 10 as:

'Jagatyevam anoushadham
Na kinchit vidyate dravyam vashaannaarthayagayoh'

'there is nothing in this universe, which is non-medicinal which cannot be made use of for many purpose and by many modes'

This definition rightly suggest that in principle medicinal value, although in practice a plant is referred to as medicinal when it is so used by some system of medicine. There is evidence since early Vedic period (Atharva veda) of plants being used for a wide range of medicinal purposes. They have in fact been used in a continuous unbroken tradition for over four millennia. Medicinal plant use, is still a living tradition. This is borne around a million traditional, village-based carriers of herbal medicine traditions in the form of traditional birth attendants, visha vaidyas, bonesetters, herbal healers and wandering monks. Apart from these specialised carriers, there are millions of women and elders who have traditional knowledge of herbal home-remedies and of food and nutrition. As per recent statistics published by the Health Ministry. Government of India, there are 6,00,000 licensed and registered traditional physicians in India today.

At the folk level, in every ecosystem from the trans-Himalayas to the coast, local communities have keenly studied the medicinal plants found in their locality. Every 100 km or so throughout the length and breadth of the country. One can observe variation in ethnic names and use of local bio-diversity indicating the intimate and independent appraisal that local communities have made of their local resources. Striking illustrations of Eco-system knowledge can be seen in the case of medicinal plants known to the Thakur tribals of coastal Maharashtra and the multiple regional uses of the same species

There is a verse in "Caraka" that explains how local communities understood and explored nature's gift of medicinal plants to every eco-system:

"Yasmin deshe tu yo jaatah tasmin tajjoshadham hitam"

Natures is so (benevolently) organized that it has provided every mico-environment, the natural resources (in the form of plants, animals and minerals) necessary for the health needs of the people living in that environment". It was perhaps this confidence in local eco-system resources and nature's benevolence that inspired local communities to discover the medical uses of local plant resources.

The Indian system of medicine today uses across the various systems i.e. folk and codified around 8,000 species of plants. The maximum numbers of medicinal plants are utilized by the folk traditions, followed by Ayurveda, Siddha, Unani, Homeopathy.

In terms of life forms, medicinal plants are equally distributed across habitats viz. trees, shrubs and herbs, Roughly. One third of the known medicinal plants are trees and an equal proportion of shrubs and the remaining one-third herbs, epiphytes, grasses and climbers, and a very small proportions of medicinal algae. The majority of medicinal plants are higher flowering plants.

Preliminary analysis of the distribution pattern shows that medicinal plants are distributed across diverse habitats and landscape elements. Around 70 percent of India's medicinal plants are found in the tropical zone, mostly in the forest of the Western and Eastern Ghats, the Vindhyas, Chotta Nagpur plateau, Aravalis the Terai region in the foothills of the Himalayas and the North East. Less than 30 percent of these medicinal plants are confined to the temperate and colder zones, although species of great medicinal value occur in some of these habitats. A quick analysis of the available data shows that the proportion of medicinal plants recorded in the dry and moist deciduous tropical forest is higher as compared to those recorded in the tropical evergreen forests.

The knowledge of the Indian people about plants and plant products is not based on the application of western categories of knowledge and approaches to studying natural products, like chemistry and pharmacology. It is based on sophisticated, indigenous knowledge category called "Dravya Guna Shastra"

On the basis of such schemes of study, this approach has resulted in around 25,000 brilliantly designed plant drug formulations, in the codified tradition, in a variety of dosage forms, although the traditional processing technology is pre-industrial, the range of methods of processing plants and principles of drug design are sophisticated

In the folk system a guestimate suggest that over 50,000 herbal drug formulations have been developed by the 4600 odd ethnic communities of India across her diverse ecosystem for a very wide range of applications. The value of folk knowledge can be dramatically illustrated from a single example of phyllanthus nirui, which is used by

village communities in southern India for treatment of jaundice. The application of this plant for treatment of viral hepatitis B has been validated and patented by an American Noble Prize winner. During the last 200 years, there are several examples of local folk knowledge contribution to global health care. It is well known for instance that quinine extracted from the cinchona bark was used traditionally by natives of Peru for cure of malaria fevers.

According to an all India Ethno-botanical survey conducted (1985-90) there are 6000 species of medicinal plants in India which can be used by traditional practitioners in tribal areas and other village communities. In the local tradition, the internal fleshy mucilaginous jelly of the aloe plant known locally as Korphad Kumari etc. is used externally on burns and wounds and orally for any gynecological disorder. In Karnataka, a decoction of the bark of the bark of the astonia scholaris a flowering branch is used in virtually every household at the onset of the monsoon to prevent malarial fevers. The neck of the turtle is sometimes used for the treatment of a pro-lapsed rectum or uterus, adathoda vassica or Adusi vasa, as it is locally known, is a common treatment for coughs and to stop bleeding in the case of pies or dysentery

Boerhavia diffusa (punarva) is commonly used in the treatment of oedema as it has diuretic properties it is also use to combat anaemia paticularly. The nomenclature of medicinal plants is itself very rich. One can illustrate this with the example of "Guduchi" i.e Tinospora cordifolis. It has 52 meaningful names. Such examples suggest the passion with which the Indian people have indulged in the study of medicinal plants. The plant name Guduchi which comes from the Sanskrit root gudu rakshane (that which protects) has the following synonyms.

Amruthavalli, (a weak-stemmed plant which acts as an elixir), mandali (circular), kundali (stem gets entangled with twiners) naagakumari (stem has a twining nature like that of a young snake) tantrika (spreading nature of the plant, looks after the health of the body), madhuparni (honey-like leaves) chadmika (thick foilage which forms a canopy) catsaadani
(leaves eaten by calves), shyaama (smoky due), dhaara (young stems have slight longitudal grooves) chakralakshana (wheel-like appearance of cross section) vishalya (no thorns or other irritant appendage, removes disease chinna, chinnruha, chinnad bhaca, chinnangi (these four names indicate the capacity of the cut bits of stem to withstand or endure severe adverse conditions and to produce buds to develop new plants) abdikaahvaya (reservoir of water) amtrutha (person using the plant would live long and be healthy) soma (powerful action of the plant as an elixir), rasaayani, vayastha, jeevanti (three names indicate rejuvenating nature of the plant) jvaranaasini, jvaraari (two names indicate the specific use if the plant in fevers, bhishapriya, bhishakjita (favourite of the physicians or that which has won the favour of physicians), vara best among medicines), soumya (benevolent in action), chandrahassa (cresent moonlike smile) decanirmita (created by God), amruthasambhava originated from nectat, surakritha (created by God)

The depth of study of plants is clearly reflected in their manifold applications. It is not uncommon to see several hundred applications of a particular plant used in various formulations for different purposes. This can be illustrated by the example of a very common plant called amla (Emblica officinalis).

There are nearly 180 formulations of amla. These formulations are used in wide range of disorders e.g.: eye disorders like conjunctivitis, vision disorders, hyperacidity, rheumatic disorders, abdominal disorders, jaundice, hiccough, breathing disorder, fever, cough, ear disorders, good for hair growth and texture, skin disorders, intoxication due to alcohol and gynecological disorders.

It is thus the ancient medical knowledges that has, though marginalized tremendously, the holistic remedies that modern and allopathic system cannot cure.

Main Identity

From: "jvarghese" <jvarghese@cmai.org>
To: "pha" <pha-ncc@yahoogroups.com>; <reprohealth_india@yahoogroups.com>
Sent: Friday, September 22, 2006 10:53 AM
Attach: 621-c.pdf
Subject: [pha-ncc] Fw: BMJ: Favour needed

=> forwarded to Cherian on 22/9/06

Please see the attached BMJ report on Hepatitis vaccination in India. Though late, the fact that Indian Medical Association has now taken a position needs to be appreciated.
Joe

On 9/21/06, **Puliyel** <puliyel@gmail.com> wrote:

Dear Sujith
First thing in the morning tomorrow please see BMJ issue of next week that is released on Friday.
Send me the pdf of the hep b news item from India.

Any luck with the German papers?
Jacob

Naveen - check if this is sent to cc mfc yahoo groups - aidan

RN
4/10/06

Naveen

Indian association questions plan for hepatitis B immunisation

Ganapati Mudur

BMJ 2006;333;621-
doi:10.1136/bmj.333.7569.621-c

scientific and medical research a public resource.

The organisation is funded by a $1.1m (£590 000; €870 000) grant from the Bill and Melinda Gates Foundation as part of a new $68.2m grant for research into neglected tropical diseases announced on 14 September.

Peter Moszynski *London*

See www.plosntds.org.

NHS Logistics staff plan strike

The NHS was this week facing its first national strike in 18 years, as supplies staff throughout England voted to take industrial action in protest at the privatisation of the supply agency NHS Logistics.

The first 24 hour strike was due to start at 10 pm last Thursday, 21 September, with another one day strike planned next week and further industrial action to follow. Unison, the union representing most of the organisation's 1300 staff, is also calling for a judicial review into how the contract was awarded.

The action, which could lead to cancelled operations, according to Unison, follows the Department of Health's decision earlier this month to transfer the work of NHS Logistics and its staff, to the German company DHL, which is best known for its courier service.

The new contract, worth £22bn (€33bn; $41bn) over the next 10 years, comes into force on 1 October and will, according to health secretary Patricia Hewitt, yield savings of about £1bn.

She dismissed as "absolute rubbish" suggestions that this was part of a wider plan to privatise the NHS.

Andrew Cole *London*

Hungary confronts corruption in its health service

The Socialist-Liberal coalition government in Hungary has promised to tackle what it describes as widespread corruption in the health service. It proposes to restructure healthcare finance and discard the 50 year old state monopoly provider of medical insurance.

The cabinet will publish draft legislation early this autumn, after a month long consultation period. It blames the problem of corruption on the low pay of medical staff and the insurance structure inherited from the bygone communist regime.

Dr Lajos Molnár, the health minister, described the dependence of healthcare provision on ubiquitous "gratuity" payments for supposedly free services as "a minefield of explosive conflicting interests."

Patients make such payments to medical staff to purchase privileged treatment at the expense of other patients, he says, with most people paying for fear of losing out. He calculates that such payments total as much as 100bn forints (£250m; €370m; $470m) a year.

Several recent studies have examined corruption in the service. They describe various practices, such as nurses ignoring the discomfort of patients unless they are given gratuities of about 1000 forints and GPs being paid two to three times as much for home visits to patients.

Thomas Land *Budapest*

Dr Matthias Rath: an apology

In a news item published in the 22 July 2006 issue of the *BMJ* (2006;333:166) and on the bmj.com website, it was reported that Dr Matthias Rath had gone on trial in Hamburg "for fraud." In this context we suggested that Dr Rath stood accused of the serious crime of fraud in relation to the death in 2004 of Dominik Feld, a 9 year old boy with bone cancer; that he was culpably responsible for Dominik Feld's death; and, in particular, that he had improperly pressured Dominik Feld's parents into refusing to allow hospital doctors to amputate the boy's infected leg in an effort to save him.

We now accept that the allegations we published were without foundation, and in the circumstances the *BMJ* wishes to set the record straight and to apologise to Dr Rath for publishing these allegations.

Indian association questions plan for hepatitis B immunisation

Ganapati Mudur *New Delhi*

The Indian Medical Association has criticised a government proposal to expand universal immunisation against the hepatitis B virus throughout India, saying that it would be "wasteful spending" on a low priority health problem.

In a report sent to the health ministry, the association said that a systematic review of studies indicates that the rate of chronic carriage of hepatitis B in India is 1.6% and not 4% as projected. It has also cautioned that the proposal to immunise infants at 6, 10, and 14 weeks would not significantly change rates of chronic carriers because most cases result from vertical transmission (directly from mother to baby during and after pregnancy).

The report, made public by the association last week, has evoked sharp reactions from some doctors who have said that the lower estimate of rates of chronic carriers should not deter universal immunisation. "When an effective, inexpensive vaccine is available, it would be unethical to deny it to the population," said Subrat Acharya, a gastroenterologist at the All India Institute of Medical Sciences in New Delhi.

After a pilot project to immunise infants against hepatitis B in 15 cities and 32 districts, the health ministry has proposed to scale up the programme nationwide at an estimated annual cost of 5bn rupees (£58m; €86m; $110m).

The lower estimate of chronic carrier rate translates into only 16 million cases instead of 40 million, the association said in its report, which follows a 10 month long consultative process.

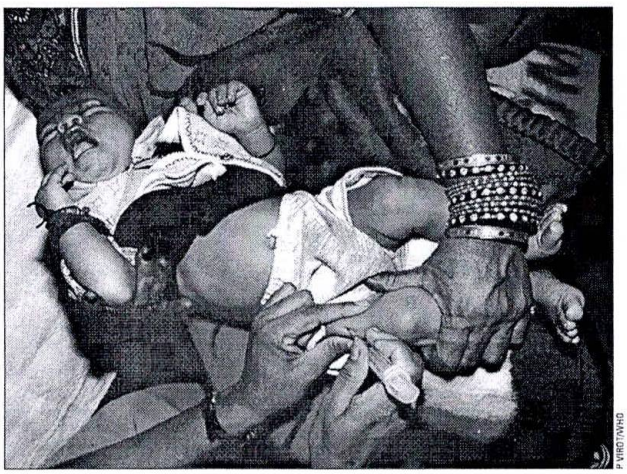
It has also cited national cancer registry data that show that the number of deaths from liver cancer from hepatitis B is only 5000 instead of previous estimates of more than 180 000.

"The decision to introduce the hepatitis B vaccine into universal immunisation appears to have been taken without thought to either the disease burden or the efficacy of the 6, 10 and 14 week schedule," said Jacob Puliyel, a paediatrician at the St Stephen's Hospital in New Delhi and author of the report released by the association.

"Nowhere in the world is there any study that has demonstrated the efficacy of the 6, 10, and 14 week schedule to reduce chronic carrier rates," Dr Puliyel said.

However, several doctors have expressed surprise at the association's report and have said that its recommendations spring from "mistaken notions of the true disease burden from hepatitis B."

"Neither the association nor paediatricians are in any position to appreciate the true disease burden caused by this virus," said Vivek Saraswat, a gastroenterologist at the Sanjay Gandhi Postgraduate Institute of Medical Sciences in Lucknow.



P VIRDTANAND

The Indian Medical Association says vaccinating babies against hepatitis B is wasteful as carrier status is often transmitted vertically

Negative dose for Bangalore's HIV+

Priyanjana Dutta
CNN-IBN
Posted Friday , September 08, 2006 at 07:55

REELING UNDER SIDE-EFFECTS: A city-based NGO has written to NACO about the side-effects of HIV drugs.

Bangalore: Karnataka has the fifth largest number of HIV-positive cases in the country.

The state government has been distributing anti-retro viral drugs free to the HIV-positive patients since 2004.

However, free doesn't necessarily mean good as many patients found out.

After nearly one year of taking the medication, several patients started developing severe side-effects like nausea, dizziness, headache and high fever.

It was then that Milana, an NGO supported by the ActionAid network in Bangalore, decided to take matters into their hands.

"We have more than 56 members from our network who take ART from Bangalore hospital. Initially when they started it was going smoothly the later 1/1 and half years there are lot of reactions started developing," says Project Coordinator, Milana Jyothi Kiran.

Among those affected is 30-year-old Amrita who started her anti-retro viral treatment nearly one year ago from Bangalore's Bowring hospital.

"In the beginning when I took ART it was fine. I used to take from outside. It was fine for six months. My CD-4 went from 14 to 136. It was Cipla company's Virulane-30. Now from the past seven to eight months, the company changed to Amcure. After that I started getting reactions - vomiting, giddiness, fever, stomach swelling," Amrita says.

After receiving complaints from Amrita and some others Milana wrote to the National AIDS Control Organisation (NACO).

"We started wondering why these reactions so we wrote a letter to NACO. Then we went into the details then saw why this reaction. The company brand had been changed from Cipla, Ranbaxy to Amcure drug. After that we realised these reactions were coming," says Jyothi Kiran.

However, NACO still hasn't replied and the state health minister R Ashok says he's not aware of the problem.

"I don't know but in the world tender we take the lowest bids. Now we are receiving the oral complains, so now we have to inform the Central Government," says Ashok.

Despite the side effects, many people like Amrita have been regular with their medicines because ART, once started, is a lifelong medication.

But there are others who just couldn't continue due to the extreme side-effects.

For those who were given the thin hope of prolonging their immunity, it's the very medicine that is turning out to be lethal.

Alerted Priyanjana abt the issue. She covered it for CNN-IBN
Naveen
10/10/06

Naveen

From: "leena menghaney" <leenamenghaney@gmail.com>
To: "Pawan Dhall" <pawan30@yahoo.com>; "gopa kumar" <gopa.kumar@centad.org>; "B. K. Keayla" <vgkeayla@del6.vsnl.net.in>; "delhi" <aidslaw1@lawyerscollective.org>; "Naveen_CHC" <naveen@sochara.org>
Cc: "Loongangte" <loon_gangte@yahoo.com>
Sent: 08 February 2007 12:37
Subject: Fwd: who will sign WHO letter and contact detail needed!

dear gopa, naveen, kajal, keaylaji, pawan,

thailand has issed compulsory licenses on AIDS drugs. the the new DG of WHO Cautioned Thailand Against Issuing Compulsory License for Abbott's Antiretroviral Kaletra

Access this story and related links online:
http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=42708

the delhi network of positive people has prepared a sign on letter addressed to WHO regarding its disturbing remarks of thailand s action of trying to save the lives of its people. please sign the letter on behalf of your organisation by tomorrow, 9th feb so that the thai grs advocating for the CL can make use of it.

warm regards,

Leena

letter is copied below,

To,

-WHO-SEARO

-WHO- India office

-UNAIDS - India.

Dear _____:

We write to express our dismay at some comments that Dr. Margaret Chan, the new Director General of the World Health Organization, was reported as having made during her recent visit to Thailand's National Health Security Office. In response to Thailand's recent decisions to improve its citizens' access to essential medicines by issuing compulsory licenses on three essential drugs, she allegedly stated, "I'd like to underline that we have to find a right balance for

OK HS 8/2/07

EP/RN/TN/SJC.

→ This is urgent. Shall we send CHC's support to this letter. Compulsory license is one of the only options left out of the TRIPS. trap which we have fallen into. 08/02/2007

8/2/07

compulsory licensing. We can't be naive about this. There is no perfect solution for accessing drugs in both quality and quantity."

These comments, if accurate, not only represent an attitude in contravention to WHO's mandate to attain, for all peoples, the highest possible level of health, but also refelect a deeply flawed understanding of the compulsory licensing mechanism and its indispensability in promoting access to essential medicines. As Dr. Chan's first public comments on this crucial topic, we harbour grave reservations about her ability to carry forward Dr. Lee Jong-wook's legacy of promoting access to treatment for those most in need.

Dr. Chan's observation that we have to find a "right balance" for compulsory licensing appears to imply that the financial concerns of the patent holding pharmaceutical companies must be given equal weight against the urgent need to provide lifesaving treatment to those who are unable to afford the exorbitant prices that these patent monopolies create. Such an attitude is in contravention to that of even the World Trade Organization, which stated through the Doha Declaration that the TRIPS agreement " *can and should be interpreted and implemented in a manner supportive of the WTO Members' right to protect public health, and in particular, to promote access to medicines for all.*"

This statement admits of no requirement for determining the "right balance" between patent rights and patients' rights. Rather, the Doha Declaration places the affirmative duty on member states to use all TRIPS-flexibilities available to it, including the compulsory licensing mechanism, to promote access to medicines for all. As the Director General of the organisation responsible for promoting global health, she should be applauding, rather than condemning, Thailand's actions to drastically reduce the costs of essential medicines for its people.

Furthermore, we would like to question who, exactly, is being "naive" about compulsory licensing. When Dr. Chan claims that "there is no perfect solution for accessing drugs in both quality and quantity," does she mean to imply that Thailand's decision to issue a compulsory license on clopidogrel, which will have the effect of lowering the price of this critical treatment for heart disease from 70 baht per day to 6 baht per day, was naive? Or that a 92% reduction in cost is not something close to a perfect solution? Or, perhaps, that switching to the Thai GPO's or Indian manufacturers' generic versions would be a sacrifice in quality? As these comments came without explanation or elaboration, we are left bewildered as to their meaning. At the very least, we feel that we are entitled to an explanation.

→ EP, RN, JN, SJC

We, along with DNP+, INP+ and AMTC had sent a letter to WHO (SEARO, India) & UNAIDS protesting Dr. Chan's statement on the use of compulsory licensing. The reply of the WHO (SEARO & India) is attached.

Naveen

RN
20/2/07

Could this be scanned and put on the PHA-NCC egroup

JN
20/2/07

World Health Organization
Regional Office for South-East Asia
WORLD HEALTH HOUSE, INDRAPRASTHA ESTATE, MAHATMA GANDHI MARG, NEW DELHI-110 002, INDIA WWW.SEARO.WHO.INT
TEL: 91-11-2337 0804, 2337 0809–11 FAX: 91-11-2337 0197, 2337 9395, 2337 9507

In reply please refer to: G2/27/2

Your reference:

Mr Loon Gangte
Regional Coordinator
Delhi Network of Positive People
Indian Network of People Living with HIV/AIDS
Affordable Medicines and Treatment Campaign
Community Health Cell
New Delhi

16 February 2007

Dear Mr Loon Gangte,

Thank you for your letter dated 9 February 2007 and for sharing your concerns with us.

First and foremost, we would like to assure you that WHO remains totally committed to promoting access to essential and life-saving treatment for all, and fully supports the use of the flexibilities within the TRIPS Agreement, including compulsory licensing, to facilitate access to affordable medicines. We consider Thailand's recent decision to issue compulsory licenses for three medicines to be in line with the TRIPS Agreement and the Doha Declaration.

We regret the confusion caused by the recent incident. We would like to inform you that the WHO Director General has since clarified that her statement was made in the context of ensuring a balance between the immediate and urgent need to provide affordable medicines to those who need them, and the need to provide continuous incentives for innovation. However, as requested, we will convey your concerns to our headquarters, while reconfirming our position on these issues, as stated above.

Finally, we would like to assure you that WHO remains committed to dialogue with all stakeholders, including people living with HIV/AIDS, civil society and NGOs, on policy issues related to access and equity.

We hope this clarifies the matter.

Yours sincerely

Samlee Plianbangchang, M.D., Dr.P.H.
Regional Director

Yours sincerely

Dr S.J. Habayeb
WHO Representative to India

Naveen

From: "Loongangte" <loon_gangte@yahoo.com>
To: <registry@searo.who.int>; <india@unaids.org>; <bround@unaids.org>; <india@unaids.org>
Cc: <naveen@sochara.org>; <k0b0@yahoo.com>; '"leena menghaney"' <leenamenghaney@gmail.com>; '"chan park"' <chansoobak@yahoo.com>
Sent: 10 February 2007 11:05
Subject: Open Letter to WHO/UNAIDS -India, on Margret Chan's remark on CL

Dr. Samlee Plianbangchang
World Health Organization
Regional Office for South-East Asia
World Health House
Indraprastha Estate
Mahatma Gandhi Marg
New Delhi 110 002, India
Fax: +91.11.23370197

Dr. S. J. Habayeb
World Health Organization
India Office
534, "A" Wing, Nirman Bhawan,
Maulana Azad Road,
New Delhi – 110 011
Fax: +91.11.2301.2450

Dr. Denis Broun
UNAIDS
A2/35 Safdarjung Enclave
New Delhi 110029
Fax: +91.11.4135.4534

9 February 2007

Dear Drs. Plianbangchang, Habayeb and Broun:

We write to express our dismay at some comments that Dr. Margaret Chan, the new Director General of the World Health Organization, was reported as having made during her recent visit to Thailand's National Health Security Office. In response to Thailand's recent decisions to improve its citizens' access to essential medicines by issuing compulsory licenses on three essential drugs, she allegedly stated, ''I'd like to underline that we have to find a right balance for compulsory licensing. We can't be naive about this. There is no perfect solution for accessing drugs in both quality and quantity."

These comments, if accurate, not only represent an attitude which is not in conformity with WHO's mandate to attain, for all peoples, the highest possible level of health, but also reflect a deeply flawed understanding of the compulsory licensing mechanism and its indispensability in promoting access to essential medicines. As Dr. Chan's first public comments on this crucial topic, we harbour grave reservations about her ability to carry forward Dr. Lee Jong-wook's legacy of promoting access to treatment for those most in need.

Dr. Chan's observation that we have to find a "right balance" for compulsory licensing appears to imply

that the financial concerns of the patent holding pharmaceutical companies must be given equal weight against the urgent need to provide lifesaving treatment to those who are unable to afford the exorbitant prices that these patent monopolies create. Such an attitude is not in conformity with that of even the World Trade Organization, which stated through the Doha Declaration that the TRIPS agreement "*can and **should** be interpreted and implemented in a manner supportive of the WTO Members' right to protect public health, and in particlular, **to promote access to medicines for all***."

The Doha Declaration admits of no requirement for determining the "right balance" between patent rights and patients' rights. Rather, the Doha Declaration places the affirmative duty on member states to use all TRIPS-flexibilities available to it, including the compulsory licensing mechanism, to promote access to medicines for all. As the Director General of the organisation responsible for promoting global health, she should be applauding, rather than condemning, Thailand's actions to drastically reduce the costs of essential medicines for its people.

Furthermore, we would like to question who, exactly, is being "naive" about compulsory licensing. When Dr. Chan claims that "there is no perfect solution for accessing drugs in both quality and quantity," does she mean to imply that Thailand's decision to issue a compulsory license on clopidogrel, which will have the effect of lowering the price of this critical treatment for heart disease from 70 baht per day to 6 baht per day, was naive? Or that a 92% reduction in cost is not something close to a perfect solution? Or, perhaps, that switching to the Thai GPO's or Indian manufacturers' generic versions would be a sacrifice in quality in exchange for quantity? As these comments came without explanation or elaboration, we are left bewildered as to their meaning. At the very least, we feel that we are entitled to an explanation.

In September of 2003 WHO and UNAIDS declared the lack of access to ART for HIV/AIDS a "global health emergency". Countries like Thailand and India are responding to this and other emergencies in access to affordable medication by using all means necessary to ensure that the right of every person to the highest attainable standard of health – an international law and human rights obligation higher than that of TRIPS – is not compromised by profiteering on life and death.

As the India office, we trust that you are aware of and understand the critical importance of measures like compulsory licensing in ensuring access to treatment. We urge you to communicate to WHO HQ the importance of prioritizing peoples' health over the monopoly and profits of pharmaceutical companies and the detrimental impact of Dr Chan's statements on treatment access.

Developing countries asserting the right to life and health of their people must be fully and publicly supported by the WHO and UNAIDS.

Sincerely,
Delhi Network of Positive People
Indian Network for People Living with HIV/AIDS
Affordable Medicines and Treatment Campaign
Community Health Cell

Reply Address:
Loon Gangte
Regional Coordinator
Collaborative Fund for HIV Treatment Prepapredness
South Asia

INP+

20/02/2007

The following edit will appear on February 28 issue of MIMS but is being released early in public interest:

New Maximum Retail Price (MRP) System:
Over Rs. 2,000 Crore Burden on Patients;
Bonanza for Retail Chemists.

When Suresh went to a chemist shop to buy Astymin-M manufactured by Tablets India, a shock was in store for him: the new price of 20 tablets pack had been printed as Rs. 172.38 while all along he had been paying Rs. 124. On enquiry, the drug store owner informed him that as per new rules, all medicines manufactured after October 2, 2006 are obliged to include all local taxes in the printed MRP. "But you never charged me local taxes in the past" countered an angry Suresh. "Due to competition, we were absorbing local taxes from our own trade margins" explained the shopkeeper and went on "we were earlier charging the printed MRP and even now we are charging the printed MRP. " Little consolation for Suresh who was already poorer by Rs. 50!

A survey done by MIMS covering a dozen retail chemists in Delhi and Mumbai found that all of them, without exception, were selling all old stock medicines at the printed MRP without adding local taxes.

Local taxes used to vary from state to state ranging from 8% (Delhi) to 14.3% (West Bengal). Except for one or two states, all others have replaced local taxes (such as sales tax) with uniform Value Added Tax (VAT) at the rate of 4%.

To make medicine prices uniform throughout the country, the Ministry of Chemicals and Fertilizers directed that henceforth MRP of medicines shall be inclusive of local taxes and permitted drug companies to increase the MRP accordingly on the basis of national average. The total burden on account of local taxes paid by private patients is just over Rs. 2,000 crores. This sum being earlier absorbed by retail chemists from their trade margins has now been effectively passed on to patients thus increasing their burden.

Taking advantage of the confusion, many drug

manufacturers have hiked the retail prices of their popular brands over and above the sum payable as local taxes. Some examples:

• Dr. Reddy's Lab: the price of Nise (nimesulide) has shot up from Rs. 27 to Rs. 32 - an increase of 18.5%. However the price of less popular Relant (cetirizine + ambroxol) has been increased by less than 9% - from Rs. 35.73 to Rs. 38.85. Surely local taxes cannot be less on one brand and more on another.

• Torrent: The price of Betacard (atenolol) has been increased from Rs. 32 to Rs. 38 i.e. by 18%. On the other hand, price of Alprax (alprazolam) has gone up by just 7% - from Rs. 34.90 to Rs. 37.35. If the local tax burden is 7%, why price of Betacard has been increased by 18%?

• Novartis: the price of Voveran SR (diclofenac) 100mg has been hiked from Rs. 49.30 to Rs. 57.50 i.e. by 16%. However the price of Otrivin (xylometazoline) has gone up by only 4% - from Rs. 37.50 to Rs. 39.

• Ranbaxy has increased the price of Storvas (simvastatin) from Rs. 80 to Rs. 84.84 i.e. by 6% but had no hesitation in hiking the price of Covance-50 (losartan) from Rs. 50 to Rs. 60.45 i.e. by more than 20%. Surely such hikes cannot be attributed to inclusion of local taxes only.

These are merely illustrative cases. Under the garb of including local taxes in the printed MRP, many other drug makers have indulged in similar unethical practices. "Ethics? There is nothing illegal about it," observed an old industry insider "companies are merely using the government-sanctioned opportunity to increase their profits." Can any one beat this?

AIDAN STATEMENT (FINAL) ON MASHELKAR COMMITTEE

----- Original Message -----
From: Mira Shiva
To: Naveen ; Ramya Sheshadri
Cc: aidanindia@yahoogroups.com ; Anant Phadke ; Gopa Kumar ; Gopal Dabade ; Mira Shiva ; sathya mala ; anurag ; Bhargava Anurag ; Prasanna Saligram
Sent: Tuesday, February 27, 2007 10:55 PM
Subject: Re: Mashelkar committee follow up

Dear Naveen ,
1 naveen please do what you think best about the statement .
2 I have been busy with the Consumer Education Task Force on Safety of FOOD & MEDICINE ,related work with the zonal organizations who are now engaged in the process
meeting here in Delhi today & tomorrow .
The Food safety & Standards Act implementation has been transferred to Health ministry from Food Processing Industry Ministry ,which is good news . .
3 Mashelkar Report
Tomorrow there is another meeting called by National Working Group on Patent Laws to discuss the Indo US MOU on training of our Patent authorities by American patent Authorities & Mashelkar Committee related Action plans . I will be going there .keayela ji is better & he will be there . Since the issue is sensitive & tricky I guess before issuing the 2nd Statement there was a need to have a consensus .
4 I met Asha Thomas briefed her about Mashelkar Issue , Drug Policy & Drugs & Cosmetics Amendment.

Regards
mira Shiva

Naveen <navthom@gmail.com> wrote:
Dear all,

Thanks Mira for that input. Shall we replace the JOINT PARLIAMENTARY COMMITTEE with PARLIAMENTARY STANDING COMMITTEE (but which one) in our statement and send it out to the contacts listed in my mail yesterday. Whom else should it sent to?

Naveen
28/2/07

----- Original Message -----
From: Mira Shiva
To: Ramya Sheshadri ; Naveen
Cc: aidanindia@yahoogroups.com ; Anant Phadke ; Gopa Kumar ; Gopal Dabade ; Mira Shiva ; sathya mala ; anurag ; Bhargava Anurag ; Prasanna Saligram
Sent: Monday, February 26, 2007 9:13 PM
Subject: Re: Explanation of Section 3d and Article 27

dear Ramya ,
I saw the explanation of the sections .3 d & Article 27 they are claryfying & very important ,but I think it would be better if these bits along with some other bits of info are sent to those who are engaged in this issue , &avoid info overload for those who would want to give ust a supportive statement .& not feel overawed with the complexity of the Excercize 7 disengage
Regarding the Mashelkar Committee report ,not landing back with Mashelkar Committee to be DEVERBATIZED we have to ask for it to be sent to THE PARLIAMENTARY STANDING COMMIITTEE NOT the JOINT PARLIAMENTARY Committee , since the latter will be chaired by Congress which is backing the Mashelkar Committee Report . The standing committee is chaired by opposition .i was told about claryfying Parliamentary Committee in our demand this evening only .
I think it is important that the stands & demands on the issue are well coordinated

With .regards
mira Shiva

----- Original Message -----
From: <policy.global@novartis.com>
To: "Naveen Thomas" <navthom@yahoo.co.uk>
Sent: Friday, December 01, 2006 4:02 PM
Subject: Response to your email to Dr Daniel Vasella at Novartis
>
> Dear Naveen,
>
> Thank you for contacting Dr Vasella. We share a common concern for the
> well-being of patients and we value hearing from you.
>
> Novartis' legal actions in India regarding our cancer treatment Glivec(c) /
> Gleevec(c) have generated public interest and inquiry, as well as raised
> concerns like yours about the reasons for the legal challenge and the
> potential impact of the case on access to medicines in general. We are
> happy to respond to these concerns.
>
> We too are deeply concerned about ensuring that patients throughout the
> world have access to the treatments they need. We strive through our many
> patient assistance (tiered-pricing or free of charge medicines to enable
> access) and other humanitarian and philanthropic programs to be a partner
> in finding and implementing solutions to help address the challenges of
> access to medicines throughout the world. Some of our programs with a wide
> reach in the developing world include providing treatments for malaria, TB
> and leprosy. For example, Novartis has partnered with the World Health
> Organization (WHO) to eradicate leprosy and has been donating the world's
> requirement for leprosy drugs absolutely free of any charge, and will
> continue to do so until leprosy is eradicated. India, with 70% of the
> world's leprosy patients, is the biggest beneficiary. Our commitment to
> improving healthcare in the developing world is also demonstrated through
> our continuing research into neglected tropical diseases, with a dedicated
> research centre in Singapore, one of the only of its kind in the world. We
> have committed to provide all medicines which are to be developed through
> this institution at no profit.
>
> More specifically, in India, Novartis provides Glivec totally free of
> charge to over 6,500 patients (99% of all patients receiving the medicine)
> as part of our Glivec International Patient Assistance Program (GIPAP).
> Therefore only 1% of patients pay for their treatment. Worldwide, we
> provide Glivec free of charge to more than 17,000 patients in 83 countries.
> On the other hand, the generic versions of Glivec in India are priced at
> approximately 4.5 times the average annual income, putting them out of
> reach for most patients needing Glivec in India. Clearly, generics do not,
> and will not sufficiently address the need for access to Glivec, or other
> life saving medicines in India.
>
> Helping patients and access to the proper medicines begins with bringing
> new and innovative medicines to market. Novartis' priority is to
> contribute what our skills enable us to do best - that is to continue to
> develop new and innovative treatments like Glivec. We will then do all we
> can, working with governments and non-governmental organizations, to ensure

> that these medicines reach the patients who need them. The best way to
> encourage innovation is via respect for intellectual property. We do not
> believe that denying patent protection for innovative medicines and
> promoting unlawful generic production and use within developing countries
> will help patients or increase their access to medical treatment. Indeed,
> the Indian case about which you wrote to us demonstrates the opposite.
> Such actions would most likely adversely affect patients by denying them
> continuous access to innovative new drugs or even, eventually, generic
> medicines too, since these are priced beyond the means of many patients in
> need. For example, companies who currently offer generic versions of
> Glivec in India do not offer any patient assistance support.
>
> You might also know that Novartis is the worlds 2nd largest producer of
> generic medicines, and as a result, we are more aware of the complexity of
> this issue than most of our competitors. Indeed, the intricate issues
> associated with access to medicines in developing countries have been
> intensively discussed in international bodies such as the World Trade
> Organization (WTO), with the active involvement of many development NGOs.
> These discussions have moved towards finding ways to increase access to
> medicines through, for example, making compulsory licensing possible where
> countries choose to take that path, not through denying patent protection
> for innovative drugs, as is the issue in India today. The tension between
> intellectual property rights and access to medicine is addressed by the
> Doha declaration offering the instrument of compulsory licenses to tackle
> public health problems, and Novartis supports the flexibilities offered in
> this declaration.
>
> Glivec is patented throughout the world, and we believe that our challenge
> to the denial of a patent for Glivec in India and to specific provisions in
> the Indian patent law are entirely legitimate and, indeed, in the public
> interest. India is a signatory to the WTO TRIPS (Trade-Related Aspects of
> Intellectual Property Rights) agreement and as an increasingly important
> industrial country and pharmaceutical power should be interested in
> promoting the development of innovative therapies. The Indian law creates
> new and unjustified hurdles in the way of pharmaceutical innovation. These
> shortcomings are likely not only to jeopardize further development of new
> medicines in many areas, but also to jeopardize continuous and reliable
> access to Glivec for patients in India today. That would be unacceptable
> to Novartis.
>
> For more information about Novartis and on our various patient assistance
> and other programs, we invite you to visit our website at
> http://www.novartis.com
>
> Thank you once again for raising your concerns with us. These are taken
> seriously, we are sincerely interested in your views and welcome the
> dialogue.
>
> Yours sincerely,
>
> Head of Global Public Affairs, Novartis AG

GETTING HEAT-STABLE LOPINAVIR/RITONAVIR (LPV/R) TO PATIENTS IN DEVELOPING COUNTRIES: THE EXPERIENCE OF MÉDECINS SANS FRONTIÈRES (MSF)

HOW TO ACCESS THE NEW FORMULATION

MSF Briefing Note
July 2006

An Essential Antiretroviral for Developing Countries

A new version of the fixed-dose combination lopinavir/ritonavir (LPV/r), marketed as Kaletra by Abbott Laboratories, was approved for use in the US in October 2005. This new formulation has several critically important advantages over the old version: lower pill burden (four pills per day instead of six), no dietary restrictions, and most important, storage without refrigeration. The WHO will recommend ritonavir boosted protease inhibitor combinations such as LPV/r in its revised HIV treatment guidelines[1] as part of a second-line therapy once first-line treatment failure has occurred. If made available and affordable, the new and improved version of LPV/r will be the first boosted protease inhibitor – the cornerstone of second-line therapy – that is practical to use in the hot climates of many developing countries, where refrigeration is not readily available.

So far, heat stable ritonavir is produced by Abbott only in combination with lopinavir and is thus not available for combination with other protease inhibitors. Abbott Laboratories is the sole producer of new LPV/r, as no generic versions are available. However, Abbott has failed to take steps to quickly make the drug widely available in developing countries, despite the new version's advantages for patients in these countries. In April, the company finally announced a price for the new formulation of $500 per patient per year for least-developed and African countries, which is still a very high price by developing country standards. Further, Abbott has been dragging its feet in filing for registration in developing countries, and although the company now has stated that it has begun filing in these, there is no further information available at this point as to which countries these are or the status of the filings. Furthermore, by limiting its $500 price to the poorest of developing countries, Abbott is adopting a policy that deliberately excludes people living with HIV/AIDS in other developing countries.

In recognition of the critical role of heat-stable LPV/r in second-line treatment and the lack of access to it in developing countries, leading HIV/AIDS researchers, physicians, policy-makers, and advocates around the world have called on Abbott to make the new version available to developing countries without further delay.

MSF's Efforts to Procure the Best Formulation for Patients

Some MSF projects have an urgent demand for this drug for patients who needed to be switched to an efficient, field-adapted second-line regimen. On 15 March 2006, MSF placed an order for the new formulation directly with Abbott headquarters in the US to use in MSF projects in nine countries (Cameroon, Guatemala, Kenya, Malawi, Nigeria, South Africa, Thailand, Uganda, Zimbabwe), requesting that the drug be priced no higher than the differential price for the older version of the drug ($500 per patient per year).

Initially, Abbott suggested to MSF that access to the old version of the drug should be sufficient until the new version was available in developing countries even though, in many settings, the old formulation cannot be refrigerated and, therefore, cannot be used Abbott no longer sells the old version of the drug in the US.

After weeks of written exchanges, Abbott agreed to fill MSF orders in Africa. However, the company refused to fulfil the orders for MSF's projects in Thailand and Guatemala, where the old formulation sells for between nearly $3000 and nearly $6000 per patient per year, respectively (see figure on p.2).

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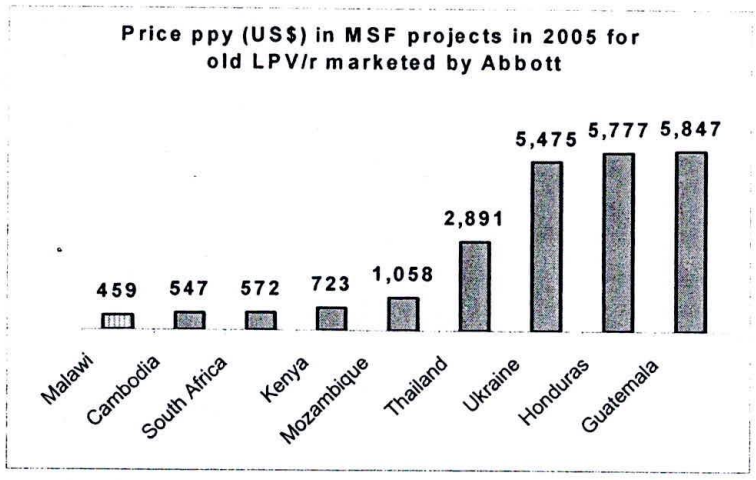
[1] Summary of the guideline committee meeting results is available at http://www.who.int/3by5/ARVmeetingreport_June2005.pdf



As the new version of the drug is not yet registered in any developing country, MSF sought and was granted special import authorisation from national drug regulatory authorities. To complete the orders, MSF provided Abbott with purchase orders for each project for which it needed new LPV/r, MSF's General Purchasing Conditions, and copies of the special authorizations to import and use new LPV/r received by MSF from each country. Shipments are made once MSF approves the proforma invoices and terms and conditions for each order. The first shipment of new LPV/r arrived in MSF's Cameroon project at the end of June 2006.

What Other Actors Can Do

MSF hopes that governments and generic manufacturers will take the necessary steps so that generic production of heat-stable ritonavir in fixed dose combination with lopinavir and other protease inhibitors like atazanavir can begin, in order to increase availability and decrease price of second-line regimens. Where Abbott is not registering, not filling demand or reducing prices sufficiently, countries will need to issue compulsory licenses to allow for generic production. But in the short-term, until there are more producers of new LPV/r, care providers will depend on Abbott as currently the sole source of the only existing field-adapted, corner-stone, second-line drug today. As a result, all actors should urge Abbott to take immediate measures to make the drug available in developing countries and to announce an affordable price for all developing countries.

Care Providers: Partners In Health has ordered heat-stable LPV/r for its clinic in Haiti and the National Drug Supply Organization (NDSO) in Lesotho has ordered the new formulation to meet the needs of the national program, including MSF-supported clinics, in Lesotho. (Both Partners In Health and NDSO submitted their orders via a letter of request and a purchase order, and must provide proof of import authorization to Abbott headquarters.) Other private and public care providers in need of LPV/r should order the new formulation of LPV/r and ask for their stocks to be replaced with the heat-stable version, as was done in the US.

National Drug Regulatory Agencies: National Drug Regulatory Agencies should invite Abbott Laboratories to submit the dossier for registration and should fast-track the review of the new LPV/r formulation, based on its approval by the US Food and Drug Administration, and on the dossier of the old formulation already registered in more than 70 developing countries, to ensure the drug's availability as soon as possible.

Procurement Agencies: Procurement agencies should push Abbott to supply programs with the new formulation and encourage regulatory agencies to accelerate the process of registration in developing countries.

Donors: Funding agencies including the Global Fund and the President's Emergency Plan for AIDS Relief (PEPFAR) should encourage the purchase of new LPV/r as the only adapted, boosted protease inhibitor for second-line existing today. Donors should also support the swift registration of the new formulation in developing countries and encourage generic competition.

For further information, please contact:
Carmen Perez, Head Pharmacist, MSF Campaign for Access to Essential Medicines
Carmen.Perez@paris.msf.org

The Hindu, Bangalore, Friday, November 26, 2004

Left warns against 'hasty passage' of amended Patents Act

By Our Special Correspondent

NEW DELHI, NOV. 25. The Left parties have cautioned the Government against "hasty passage" of amendments to the Indian Patents Act to make it Trade-Related Aspects of Intellectual Property Rights (TRIPS) compliant.

"We are strongly of the opinion that any hasty passage of the Bill (amendments 2003), without any informed discussion, will not be in the larger interests of the country. We give below a list of amendments that, we feel, need to be incorporated in the existing Indian Patents Act and the draft Bill 2003. These we believe are the minimum that need to be done to safeguard national interests," the parties said in a three-page note submitted to the Government on Wednesday.

The broad areas of concern of these parties include patentable subject matter; differentiating inventions; compulsory licensing; export by a licensee; transitional agreement and mailbox; royalty payment; and pre-grant opposition.

The Left parties said the Government must make full use of the "flexibilities" available in the TRIPS agreement and recounted the experience of many countries since the agreement came into force in 1995. They cited the instance of how an Indian pharmaceutical company was offering drugs for HIV-AIDS particularly in Africa at vastly reduced prices whereas global companies were selling them at 20-50 times their actual cost by seeking shelter under laws mandated by the agreement.

'Reserve term'

On patentable subject matter, the parties said that the term "invention" should be reserved for a 'new' product or process involving an inventive step and capable of industrial application. All three criteria of 'novelty,' 'inventive step' and the quality of being "capable of industrial application" must be insisted upon especially to limit the number of applications and discourage frivolous claims.

They said the Indian Patent Act allows patenting of "micro-organisms" and "non-biological and microbiological processes." Patenting of these inventions are under mandated review by the World Trade Organisation since 1999 and in the absence of any decision, patenting of these should not have been provided for. All life forms and research tolls for biotechnology should be excluded from the scope of patentability.

Compulsory licensing

Compulsory licensing, they said, was an instrument available in the TRIPS agreement to safeguard the legitimate interest of consumers by limiting the possibilities of monopolies being created in different sectors. "Unfortunately the Indian Act has not made full use" of such provisions unlike Brazil and China which have passed legislations allowing compulsory licensing in cases where the patentee does not respond within stipulated time the offer of reasonable commercial terms and conditions to the patent holder.

Similarly, the TRIPS agreement allows export by manufacturers who produce through a compulsory licence, and suggested that the same be incorporated in the amendment so that the Indian pharmaceutical companies could export drugs to developing countries at relatively lower prices to the mutual benefit of both.

The agreement also provided for receipt of patent applications through a mailbox between January 1995 and December 2004, which are to be examined after January 1. On being granted, the patent would remain effective for 20 years from the date of application. The parties said that in cases where production had been started by any enterprise during the transition period, it should be allowed to continue production on payment of a nominal royalty instead of being accused of violating the patent. The quantum of royalty payment should be explicitly stipulated if compulsory licensing was issued.

There was no justification in removing the existing pre-grant opposition from the Act in the proposed amendment Bill. They said countries such as Australia, Japan, Canada and the United Kingdom provide for pre-grant opposition in their laws.

The Prime Minister, Manmohan Singh, with the Bhutan King, Jigme Singye Wangchuk, at the former's residence in New Delhi on Thursday. — PTI

Kalam's plea to Aga Khan

By Our Special Correspondent

NEW DELHI, NOV. 25. The President, A.P.J. Abdul Kalam, today suggested that the Aga Khan Foundation extend its projects in social, education and health sectors beyond Maharashtra and Gujarat.

The President made this suggestion to Aga Khan, spiritual leader of Ismaili Khoja community, who called on him at Rashtrapati Bhavan.

Official sources said Mr. Kalam suggested that the foundation also take up work in Madhya Pradesh and Chhattisgarh, particularly in tribal areas.

He said the foundation should take up more projects in the field of girls' education.

The Aga Khan briefed the President on the foundation's activities in India.

The visiting King of Bhutan Jigme Singye Wankchuk and the crown prince Jigmi Khesar Namgyel Wanchuk also called on the President today.

They discussed the international situation and bilateral matters.

Goa DGP relieved of his duties

By Anil Sastry

PANAJI, NOV. 25. The Goa Government today relieved the Director-General of Police (DGP), Amod Kanth, of his duties while asking him to report to the Union Home Ministry.

Government sources said the Home Ministry had not requisitioned the services of Mr. Kanth, nor was there any communication to him in this regard. The State Cabinet on November 12 had decided to abolish the DGP post as the head of the State police and restore the post of Inspector-General of Police, while keeping the DGP's post in abeyance with immediate effect.

The State Government also wrote to the Union Home Ministry — the cadre controlling authority — on the subject.

Mr. Kanth, who then was in Delhi attending a DGPs' conference, reported back to duty on November 16 and was discharging his duties till today.

The incident comes when two major international events — the International Film Festival of India (November 29 to December 9) and the Exposition of the sacred relics of St. Francis Xavier (November 21 to January 2).

Supreme Court rejects plea for CBI probe into Acharya's arrest

By Our Legal Correspondent

NEW DELHI, NOV. 25. The Supreme Court today dismissed, at the admission stage, a public interest litigation (PIL) petition filed by a former BJP Rajya Sabha member, B.P. Singhal, seeking a CBI probe into the arrest of the Kanchi Sankaracharya, Sri Jayendra Saraswathi, by the Tamil Nadu police on November 11.

A Bench, comprising Chief Justice R.C. Lahoti and Justice [illegible] dismissed the petition *in* cused who would be the affected party by ordering a CBI probe into the matter had come to the court.

The decisions of the apex court cited by the petitioner to advance his case would not support him as in all these matters the petitions were filed either by the accused or by the affected persons and orders were passed in accordance with the facts and circumstances of those cases, the Bench said and against the treatment meted out to the seer. On the question of *locus standi*, he cited many earlier judgments to drive home the point that the court had entertained a PIL from third parties and granted relief by ordering a CBI probe.

Mr. Singhal, a retired Director General of Police, in his petition alleged that the State Government had deliberately and with *mala fide* intentions violated the human rights and the fundamental rights of the

Open letter from GSK regarding GSK patents and patent applications directed to a specific formulation of Combid/Combivir

GlaxoSmithKline (Thailand) Limited
12th Fl., Wave Place,
55 Wireless Road,
Lumpini, Patumwan,
Bangkok 10330, Thailand.

Tel. (66 2) 659-3000, 655-4557
Fax. (66 2) 655-4568

9 August 2006

GSK offices in Thailand and India have recently been subject to demonstrations against GSK's patents applications for Combid/Combivir in those countries. Prior to these demonstrations GSK decided to withdraw its patents and patent applications directed to a specific formulation of Combid/Combivir wherever they exist. This includes the patents applications which were the subject of the demonstrations in India and Thailand.

In June 2006 GSK instructed its agents in Thailand and India to withdraw this patent application. This means that GSK has no patent protection on Combid/Combivir in Thailand or India, and is not seeking any.

The patent and patent applications relating to this specific formulation of Combivir have been withdrawn, or are in the process of being withdrawn, in all countries where they have been filed. Other patents and patent applications relevant to Combivir and other GSK antiretrovirals are not affected.

GSK supports the World Trade Organisation's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, including the public health safeguards it contains. However, GSK believes that focus on patents in addressing the challenge of HIV/AIDS is misguided and counterproductive. New medicines and vaccines to address the challenge of HIV/AIDS are desperately needed and the patent system fundamentally stimulates the necessary research and development. The root cause of many countries' inability to address HIV/AIDS does not lie with the patent system but with the consequences of poverty, and lack of political will, leading to a lack of healthcare infrastructure and resources.

GSK recognises the challenge that HIV/AIDS has put on health systems and seeks to work in partnership with governments and NGOs to address this challenge. Dialogue with us on this issue prior to the recent demonstrations in Thailand and India would have made them unnecessary.

GSK's commitment and contribution to the fight against HIV/AIDS embraces four key areas - investment in research and development (R&D), preferential pricing of our antiretrovirals (ARVs), community investment activities, and partnerships that foster effective approaches against the disease and the challenges it presents. Details of our approach and progress can be found at: http://www.gsk.com/responsibility/cr_issues/dev_world_challenges.htm

For any additional queries on this statement please contact:

Khun Areerat Tanglertpaibul
Corporate Affairs Manager
GlaxoSmithKline (Thailand)
Telephone (Direct) 0 2659 3093 Mobile 0 1812 5915
Fax 0 2659 3197 E-mail: areerat.tanglertpaibul@gsk.com

3. Such a framework must recognize the principles of national sovereignty over genetic resources, prior informed consent of and benefit sharing with the countries in which the viruses originate.

4. The framework should ensure that the WHO collaborating centers and laboratories, as well as companies and other institutions do not patent the viruses or the gene sequences or parts of the sequences nor research tools and medical products that make use of the viruses or their parts or their sequences.

5. If there is intention that information contained in the virus, including gene sequences, are put in the public domain, the framework should require that any party that want to make use of the data should not seek proprietary rights over the data or parts of the data.

6. WHO must provide information on the viruses that have been provided to its Collaborating Centers and reference laboratories, what research has been done on these, whether the viruses or vaccine strains produced from them have been distributed to other organizations and if so to which ones, whether patent applications have been made and for what, the commercial activities being undertaken, and whether the countries contributing the viruses have been informed, their permission obtained and the benefit sharing arrangements, if any. There should be an inquiry and remedial action if collaborating centers or reference laboratories have not acted in good faith, or have not followed the relevant WHO guidelines, especially the WHO Guidance on sharing of influenza viruses (March 2005).

7. WHO should encourage and promote local pharmaceutical R&D and production activities in developing countries, including not-for-profit and public-owned organizations, and facilitate technology transfer and capacity building. WHO should build the capacity in developing countries for vaccine development and production, including the scientific research capacity to make this possible.

8. Prices of vaccines and other medical products should not be determined or influenced by monopolistic factors such as patenting. The products should be priced at levels that are at cost or non-profit for developing countries so as to assure their affordability.

9. The public health system should be strengthened to offer the best chances for prevention of avian flu pandemic, and to ensure an effective delivery of health services in the event of pandemic.

10. Governments should increase public investment in research and development for vaccine production in developing countries, and in building the capacity for local pharmaceutical production, particularly for production of affordable vaccines and other medical products.

11. We hope that the WHA can reach agreement on these points so that a framework for the sharing of viruses and vaccines and other medical products can be reached at this WHA.

Civil society groups endorsing this statement include:
People's Health Movement (PHM) - International,
Third World Network (TWN) – International,
Medico International - Germany,
noshasthaya Kendra (GK) - Bangladesh,
Association for Health and Environmental Development (AHED) - Egypt,
Health Unlimited - UK,
Asian Community Health Action Network (ACHAN) – Asia,
All India Drug Action Network - India,
Initiative for Health - International,
Equity and Society - India,
Consumers' Association of Penang - Malaysia,
Institute of Science in Society - UK,
Palestinian Medical Relief Society (PMRS) - Palestine,
National Front for People's Health – Ecuador,
Movimionto de Salud - Latin América,
Palestinian NGO Network (PNGONGT) - Palestine,
Arab Resource Collective (ARC) - Lebanon,
Global Health Watch - International,
Space Associative - Morocco,
International People's Health University (IPHU) - International,
Community Health Cell (CHC) - India,
Doctors for Global Health (DGH) - USA,
Hesperian Foundation - USA

JOINT CIVIL SOCIETY STATEMENT

WHA must establish Fair Framework for Sharing of Virus Samples as well as Vaccines

We the civil society organizations listed below call on member states of the World Health Assembly (WHA) as well as the WHO Secretariat to establish a fair and transparent mechanism and framework to govern the sharing of virus samples as well as the equitable distribution of vaccines and medical products relating to the avian influenza.

Early this year Indonesia suspended sending samples of avian influenza viruses to the WHO Laboratories, calling for the WHO set up a new framework for virus sharing that has better terms for developing countries.

Indonesia, a country severely affected by avian influenza thus far causing about 81 deaths, was offered by an vaccine manufacturer vaccines at an unaffordable cost of US$ 20 dollars per dose although the vaccine was produced using the Indonesian virus strain, and without the knowledge of the Indonesian authorities. We believe that this is an unfair situation which no country should be subjected to.

Developing countries simply cannot afford to pay high vaccine prices especially if entire or major parts of the populations have to be vaccinated. This highlights the inequities in current global health system.

Availability of vaccines in a timely manner and in sufficient quantities is also a major problem. Developed countries having financial and other resources are already booking in advance treatments including vaccines for pre pandemic and pandemic use. As supply capacity is less than demand, especially in the event of a pandemic, acute shortages are forseen.

In the event of a global pandemic, and in the absence of a fair global framework, there is a fear that it will be "each country for itself", with those countries that have stockpiled vaccines being reluctant or unwilling to share their stockpile of vaccines with other countries. Developing countries would likely face a situation of non-availability or acute shortage of badly-needed vaccines, including countries that have contributed their viruses.

Although developing countries voluntarily donate their viruses to the WHO collaborating centers and reference laboratories at present, these centers and laboratories have been passing on the virus or parts of it, or vaccine strains containing parts of the viruses, to companies, without the knowledge or permission of the countries. This is in violation of the WHO 2005 Guidance on sharing virus samples, which states that the viruses will not be distributed to parties outside the collaborating centers and laboratories without prior permission of the contributing countries.

Moreover, patents are already being sought by several companies and research institutes on products and materials containing parts of the viruses. The vaccine products are also to be patented. The resulting monopoly situation results in high profits for the companies holding patents, while health needs are sacrificed.

The current framework also disregards internationally recognized rights of affected developing countries. The Convention on Biological Diversity explicitly recognizes States' sovereign rights over their own biological resources, the right to grant access on agreed terms, the principle of prior informed consent and fair and equitable sharing of benefits arising from the commercialization and other utilization of the viruses.

Instead, the current framework favors the industry that already benefits from grants and subsidies by the developed governments for research and development of vaccines, and that will reap millions or billions of dollars from vaccine sales. It also favors the developed countries that have the financial resources to build up stockpiles of pre-pandemic vaccines and to purchase in advance pandemic vaccines.

The losers are the poorer countries that will not have vaccines and other necessary medical supplies in a timely manner in the event of a pandemic although they may have contributed their viruses leading to vaccine development and have rights under the CBD.

OUR ACTION PROPOSALS

1. Noting the existing inequitable framework for sharing viruses, we call on the WHA to immediately establish a new global framework on avian flu for the equitable sharing of both the viruses and the relevant medical products, including vaccines and diagnostics.
2. The highest priority and goal of the framework should be to meet public health needs, particularly in developing countries. As such the over-riding goal is to ensure that people in developing countries have access to vaccines and other medical products when they need these. The framework must establish systems by which scarce pandemic vaccines can be produced, stocked and distributed according to the principles of public health needs (where and when they are needed) and not according to financial and technological capacity and power (i.e. vaccines channeled to those who can pay for them).

Briefing Note
May 2006

OPPOSITION TO TENOFOVIR PATENT APPLICATION IN INDIA

The Indian Network for People Living with HIV/AIDS (INP+), the Delhi Network of Positive People are opposing a patent application filed by Gilead Sciences in India on tenofovir disoproxil fumarate (TDF), a key AIDS drug. The organizations represent people living with HIV/AIDS in developing countries, and officially registered their pre-grant patent opposition at the Delhi patent office on May 9th 2006.

Alternative law Forum, Bangalore providing the legal support to INP+ argues that forming a salt (fumaric acid) out of an existing compound (tenofovir disoproxil), is common practice within the pharmaceutical industry, and should not be considered a new invention.

Médecins Sans Frontières (MSF) supports Indian civil society groups in their legal battle of opposing the TDF patent application, as it wants to be able to access and use the drug in its HIV/ AIDS treatment projects around the world.

Tenofovir – A Crucial Drug for AIDS Treatment

TDF is clearly emerging as an important option for patients starting AIDS treatment for the first time, and those who have been on antiretroviral treatment therapy (ART) for some time and require access to newer drugs due to occurrence of toxic effects or as they develop resistance to first-line drug regimens. Because there are fewer known side effects associated with the use of TDF in adults, it is commonly prescribed in the US and Europe, where the drug is widely available at a priced of over USD 5,000 per patient per year.

In its HIV/AIDS treatment projects in South Africa, MSF has been trying to access TDF, as patients who experience long-term side effects from other drugs need to be switched to a TDF-based regimen. MSF would like to be able to provide TDF to its patients who urgently require the drug.

The updated World Health Organization (WHO) ART guidelines for HIV/AIDS treatment in developing countries recognize the importance of TDF and recommend the drug for first and second-line regimens.[1] It is ironic that at the same time as the WHO is underlining the importance of and recommending TDF, there is a risk that it may remain inaccessible to many patients in developing countries, if this patent were granted.

Very Limited Access to Gilead's tenofovir in Developing Countries

MSF has experienced serious difficulties in trying to access TDF in countries where it operates, due to the fact that the drug is not widely registered for use and marketed in developing countries. Gilead, the only producer of TDF until 2005, had announced greater availability of TDF in 2002 with a preferential price for low-income countries. So far Gilead has made limited progress in making the drug widely available.

Another barrier to TDF's use is its high cost in countries not eligible for the discounted price of $208 per patient per year. Gilead has made no offer to provide TDF at a discounted price to middle-income countries like Brazil, India, Thailand and China. In developed countries, Gilead's price for TDF is $ 5718 per patient per year.

If tenofovir is Patented in India, Generic Production is at Risk

Indian pharmaceutical companies have been working on developing generic versions of TDF. A generic version of TDF is already being marketed in India.Yet if Gilead were granted a patent on TDF, such generic production of the drug in India would be likely to stop, making prospects of accessing generic versions of the drug worldwide slim, as many developing countries rely on Indian generics. A TDF patent in India would lead to Indian drug manufacturers having to withdraw their generic TDF from the market, and any other generic production of the drug would be effectively blocked until 2018.

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[1] Summary is available for consultation at http://www.who.int/3by5/mediacentre/news51/en/

In addition, a patent on TDF would further compromise ART in developing countries as it would act as a barrier for developing fixed-dose combinations, or FDCs, which combine two or three drugs in a single pill, such as TDF/3TC and EFV. Because FDCs significantly reduce pill burden and increase adherence to treatment, they have become the backbone of scaling up AIDS treatment in developing countries. A patent on any of the drugs comprising the FDC makes it impossible for a generic company to produce the FDC. Despite the fact that antiretrovirals like lamivudine (3TC) and efavirenz (EFV) are not under patent in India, Gilead's patent on TDF would prevent Indian generic companies from developing this much-needed FDC.

AIDS treatment budgets are likely to be affected if TDF is patented. Developing countries scaling up AIDS treatment programs under the WHO 3 by 5 Initiative will be seriously affected. Currently 1.3 million people living with HIV/AIDS (PLHA) are accessing treatment under the 3 by 5 Initiative. In India, the National AIDS Control Organisation (NACO) provides 20,000 PLHAs with antiretroviral therapy. Unavailability of ARV drugs included in the WHO ART treatment guidelines for resource poor settings may impact the political will of developing countries to provide HIV/AIDS treatment.

The international medical humanitarian agency MSF began providing HIV/AIDS treatment in 2000 and is currently providing it to over 60,000 patients in nearly 30 countries including Thailand, South Africa and India. MSF hopes to source TDF from India in the near future, as Indian manufacturers are the source of 84% of antiretrovirals MSF uses in its AIDS treatment projects across the globe.

BACKGROUND ON INDIAN PATENT ACT AND PRE-GRANT OPPOSITIONS

Indian patents: one year on

About this time last year, the Indian Parliament approved the country's new Patent Act, thereby allowing pharmaceutical products to be patented in India. This new law put some serious constraints on generic competition but also included some potentially important features such as "automatic licensing" and the possibility for anyone to object to a patent before it is granted.

Although the law was not passed until last year, from as early as 1995, companies could start filing patent applications for pharmaceuticals in India with the patent offices. The Indian patent office started to examine these thousands of patent applications last year after the revision of the Indian patent law. Many patent applications for antiretroviral drugs (ARVs) such as tenofovir (tenofovir disoproxil fumarate – TDF) and Combivir (zidovudine/lamivudine, or AZT/3TC) are waiting to be approved or rejected.

First patent granted in India in March 2006

On March 3rd 2006, Roche announced it was "becoming the first pharmaceutical company in India to receive a product patent under the new patent regime". The patent was granted on peginterferon alfa-2a (Pegasys), a new generation hepatitis C therapy.

Because no generic versions of this product are being manufactured yet, any generic competition will be impossible until the new patent's term runs out in 2017 – unless the Indian government grants a compulsory license to another pharmaceutical company. Thus, this drug will only be available as a Roche product at about $5,000 per six-month treatment course, a price that obviously rules out the use of this drug in developing country settings.

Not all patent applications lead to patents

Not all patent applications are valid. Many of the applications do not claim real 'inventions' and therefore should not deserve a patent. Many patent applications are for a new use of old drugs, or simply for derivatives of old drugs or combinations of old drugs. The Indian Patent Act, if rigorously interpreted, provides several grounds for rejecting a patent, for instance if the pharmaceutical substance claimed is only a new form of a known substance.

→ Gleevac patent application was rejected

On January 25th 2006, the Indian patent office rejected Novartis' patent application for its anti-cancer drug imatinib mesylate (Gleevac) on the grounds that the application claims a 'new form of a known substance' (Novartis' patent application was related to a particular crystal form of the salt of imatinib mesylate). The

rejection was a major victory for the Cancer Patient Aid Association of India and some Indian generic companies, which had both submitted a pre-grant opposition to the patent office. The rejection of the Gleevac patent gives reason for optimism.

Essential drug patents in the "mailbox" waiting for examination

One of the next on the list for examination by the Indian Patent Office is Gilead's patent for tenofovir disoproxil fumarate (Viread), as the patent application was filed with the Delhi Patent office in 1998. The Lawyers Collective, in collaboration with the Alternative Law Forum, is currently drawing up an extensive list of drugs based on medical needs and for which patent applications are pending in India.

What is the pre-grant opposition system?

Due to the volume of patent applications, patent examiners often miss information related to the patent application under consideration about it being just an improvement of an old drug and not a 'new chemical entity'. If attention is brought to information that shows that the patent application is for a 'derivative' or a 'new use' of a known drug, the possibility of invalid patents being granted is reduced. Opposing patent applications in the case of ARV drugs is feasible, as research has indicated that most of the patent claims for patent protection are for known pharmaceutical substances like polymorphs, salts, and combinations.

Anyone can bring such information to the attention of the patent controller through the pre-grant opposition process (as provided under Section 25 of the Indian Patents Act), and generic companies have already filed a number of pre-grant oppositions. In addition to companies, patient groups (INP+ and other state networks) and public interest organisations are also working to oppose patent applications for essential drugs.

On March 30th 2006, The Indian Network for People Living with HIV/AIDS (INP+), the Manipur Network of Positive People (MNP+), represented by the Lawyers' Collective HIV/AIDS Unit officially submitted their opposition to a patent application filed in the Kolkata patent office by GlaxoSmithKline (GSK) for Combivir, a fixed-dose combination of two essential AIDS drugs zidovudine/lamivudine. The opposition is based on technical and health grounds. Clearly concerned that the granting of such a patent will increase the burden on developing countries already struggling to treat patients, INP+ objected to the Combivir patent application on the ground that it does not claim a new invention but instead simply the combination of two existing drugs.

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PHARMA PRODUCT PATENTS GRANTED BY MUMBAI PATENT OFFICE

SR.NO.	PATENT APPLICATION NO.	NO.OF THE PATENT GRANTED	PATENT HOLDER	TITLE OF THE PATENT GRANTED	DATE OF GRANT
1	83/MUM/2003	197696	DR. PATEL DINESH SHANTILAL, DR. PATEL SACHIN DINESH, KURANI SHASHIKANT PRABHUDAS.	ANTI FUNGAL PHARMA CEUTICAL COMPOSITIONS FOR THERAPEUTIC USE.	12/12/05
2	488/MUM/2000	198178	LUPIN LABORATORIES LTD.	ASYNERGISTIC AQUEOUS PHARMACEUTICAL COMPOSITION FOR PROPHYLACTIC TREATMENT OF MIGRAINE.	9/1/06
3	514/BOM/1998	197892	AJANTA PHARMA LIMITED.	A PROCESS FOR ISOLATION AND FORMULATIONS OF NUTRIENT - RICH CAROTENOIDS.	13/02/06
4	738/BOM/1999	198002	PATEL DINESH SHANTILAL AND KURANI SHASHIKANT PRABHUDAS.	NOVEL INJECTABLE ANTIMALERIAL COMPOSITIONS OF ARTEMISININ.	1/3/06
5	IN/PCT/2002/01001/MUM	200076	BOEHRINGER INGELHIEM INTERNATIONAL GMBH	A NEEDLE-LESS INJECTOR FOR A LIQUID	15/04/06
6	IN/PCT/2002/01296/MUM	200062	01. AMERICAN HOME PRODUCTS CORPORATION 02. LIGAND PHARMACEUTICALS INC.	THIO-OXINDOLE DERIVATIVES.	15/04/06
7	IN/PCT/2000/00497/MUM	200057	ASTRAZENICA AB	IMIDAZO PYRIDINE DERIVATIVES WHICH INHIBIT GASTRIC ACID SECRETION	17/04/2006
8	IN/PCT/2002/01000/MUM	200075	UCB S. A.	A 2 - OXO - 1 - PYRROLIDINE COMPOUND OR PHARMACEUTICAL SALTS THEREOF.	17/04/2006
9	132/MUM/2003	200334	GLENMARK PHARMACEUTICALS LIMITED.	CONTROLLED RELEASE PHARMACEUTICAL COMPOSITION CONTAINING ERYTHROMYCIN OR ITS DERIVATIVES AND A PROCESS FOR ITS PREPARATION.	5/5/06
10	684/MUM/2003	200339	GLENMARK PHARMACEUTICALS LIMITED.	TOPICAL PHARMACEUTICAL GEL COMPOSITION FOR VALDECOXIB.	5/5/06
11	IN/PCT/2002/01005/MUM	200890	NEW PHARMA RESEARCH SWEDEN AB	A MICELLAR COMPOSITION FOR THE TREATMENT OF PARASITIC DIASEASES IN ANIMALS	5/6/06
12	IN/PCT/2002/01890/MUM	200903	TULARIK INC & JAPAN TOBACO, INC	QUINOLINYL AND BENZOTHIAZALYL PPAR-GAMMA MODULATORS	5/6/06
13	540/MUMNP/2003	200906	RIBOPHARMA AG	METHOD FOR INHABITING THE EXPRESSION OF A TARGET EENE AND MEDICAMENT FOR TREATING A TUMOR DIEASE	5/6/06
14	IN/PCT/2001/00805/MUM	200884	AGOURON PHARMACEUTICALS,INC. & CANCER RESEARCH CAMPAIGN TECHNOLOGY LIMITED.	TRICYCLIC INHIBITORS OF POLY [ADP-RIBOSE]POLYMERASES.	8/6/06
15	IN/PCT/2002/00995/MUM	200889	WARNER-LAMBERT COMPANY	DUAL INHABITORS OF CHOLESTEROL ESTER AND WAX ESTER SYNTHESIS FOR SUBACEOUS GLAND DISORDERS	8/6/06
16	363/MUM/2003	201170	GLENMARK PHARMACEUTICALS LIMITED.	NOVEL TRICYCLIC COMPOUND AS PDO-4 INHABITORS	23/06/2006
17	228/MUM/2000	201137	PFIZER PRODUCTS INC	A TOPICAL PHARMACEUTICAL COMPOSITION	26/06/2006
18	IN/PCT/2002/00671/MUM	201241	ASTRAZENICA AB	ADMANTANE DERIVATIVES	17/07/2006
19	IN/PCT/2002/00745/MUM	201242	JANSEEN PHARMACEUTICAL N.V.	A COMPOUND OF HOMOPIPERIDINYL SUBSTITUTE BENZIMIDAZOLE DERIVATIVES	17/07/2006
20	IN/PCT/2002/00922/MUM	201243	ASTRAZENICA AB	CRYTELLINE SALTS OF 7-[4-(4-FLUOROPHENYL)-6-ISOPROPYL-2-METHYL(METHYLSULFONLY) AMINO] PYAMIDIN-5YL) (3r,5y)-3, 5-DIHYDROXYHEPT-6ENOIC ACID	17/07/2006
21	17/BOM/1995	202311	J.B. CHEMICALS & PHARMACEUTICALS LIMITED	CONTROLLER RELEASE FORMULATION OF RANITIDINE	5/8/06
22	IN/PCT/2001/01538/MUM	201237	JANSEEN PHARMACEUTICAL N.V.	A COMPOUND BENZIMIDAZOLES AND IMIDAZOPYNDINES	7/8/06
23	IN/PCT/2002/00604/MUM	201240	SOCIETE DE CONSEILS DE RECHCRCHES OF D'APPLICATION SCIENTIFIQUES (S.C.R.A.S.)	NEW HETEROCYELIC COMPOUNDS	7/8/06

24	IN/PCT/2002/01547/MUM	201254	JANSEEN PHARMACEUTICAL N.V.	A 2.3-DIHYDRO-[1,4] DIOXIDE-[2,3-B] PYRIDINE COMPOUND OF FORMOULA (1) AND PROCESS OF PREPARATION THEREOF	7/8/06
25	28/MUMNP/2003	201268	WARNER-LAMBERT COMPANY	AN IODO PHENYLAMINO BENZHYDROXAMIC COMPOUND	7/8/06
26	508/MUMNP/2003	201282	PFIZER PRODUCTS INC	N-METHYL-D-ASPARTIC ACID RECEPTOR ANTAGONIST PHARMACEUTICAL COMPOSITIONS	7/8/06
27	801/MUMNP/2003	201284	ASTRAZENICA AB	A METALLOPROTEINASE INHABITOR COMPOUND	7/8/06
28	802/MUMNP/2003	201285	ASTRAZENICA AB	A METALLOPROTEINASE INHABITOR COMPOUND	7/8/06
29	639/MUMNP/2003	200654	PFIZER PRODUCTS INC	PYRIDAINONE ALDOSE REDUCTASE INHABITORS	21/08/2006
30	141/MUM/2000	201976	PFIZER PRODUCTS INC	A NOVEL BIARYL ETHER COMPOUND	31/08/2006
31	472/MUM/2000	201982	PFIZER PRODUCTS INC	ZIPRASIDONE SUSPENSION	31/08/2006
32	IN/PCT/2002/00475/MUM	202295	PFIZER PRODUCTS INC	PHARMACEUTICAL COMPOSITION PROVIDING ENCHANCED DRUG CONCENTRATIONS.	11/9/06
33	IN/PCT/2001/00172/MUM	202299	ASTRAZENICA AB	AN ORAL IMMEDIATE RELEASE FORMULATION IN SOLID FORM	11/9/06
34	IN/PCT/2001/00039/MUM	201231	TEIJIN LIMITED	THIOBENZIMDAZOLC DERIVATIVES	13/09/2006

PUBLICATION UNDER SECTION 43(2) IN RESPECT OF THE GRANT OF PATENT

Notice is hereby given, that any person interested in opposing the following patents under Section 25(2) may, at any time within one year from the date of this issue, give notice to the Controller of Patents at the appropriate office on the prescribed Form 7.

S. NO	PATENT NO	PATENT APPLICATION NO	TITLE	NAME OF THE PATENTEE	APPROPRIATE OFFICE
1	188990	60/MAS/2000	A METHOD FOR OBTAINGING A HYDROLYSATE FROM A PROTEINACEOUS SUBSTRATE	(I) NOVOZYMES A/S (II) NOVOZYMES BIOTECH INC.	CHENNAI
2	191551	936/MAS/1995	RANDOM DUMPED PACKING ELEMENT	KOCH-GLITSCH, LP, A DELAWARE CORPORATION	CHENNAI
3	191967	1014/MAS/1995	AN APPARATUS RESPONSIVE TO A CONTROL SIGNAL FOR DEVELOPING A PRESSURE	FISHER CONTROLS INTERNATIONAL LLC, A DELAWARE CORPORATION	CHENNAI
4	192256	1393/MAS/1996	A PROCESS FOR MANUFACTURING STRONTIUM CARBONATE OF ABOVE 99% PURITY	TRAVANCORE CHEMICAL & MANUFACTURING CO. LTD., AN INDIAN COMPANY	CHENNAI
5	192259	819/MAS/2000	AN IMPROVED PROCESS FOR CONVERSION OF TRANS-N-METHYL-4-(3,4-DICHLOROPHENYL)-1,2,3,4-TETRAHYDRO-1-NAPHTHALENEAMINE TO ITS CIS-N-METHYL-4-(3,4-DICHLOROPHENYL)-1,2,3,4-TETRAHYDRO-1-NAPHTHALENEAMINE (AN INTERMEDIATE OF SERTRALINE HYDROCHLORIDE)	Dr. REDDY'S LABORATORIES LIMITED, AN INDIAN COMPANY	CHENNAI
6	192262	803/MAS/1995	A METHOD OF PRODUCING A CATALYST FOR REFORMING OR AROMATIZATION	CHEVRON PHILIPS CHEMICAL COMPANY LP, A CORPORATION ORGANIZED UNDER THE LAWS OF THE STATE OF DELAWARE, USA	CHENNAI
7	192264	33/MAS/1996	A DEPILATORY STRIP	RECKITT BENCKISER FRANCE, A FRENCH COMPANY	CHENNAI
8	192649	1249/MAS/1995	A CIRCULATING FLUIDIZED BED REACTOR	FOSTER WHEELER ENERGIA OY, A FINNISH COMPANY	CHENNAI
9	192889	410/MAS/2001	A PROCESS FOR THE PREPARATION OF DEEP FAT FRIED POTATO CHIPS	SURENDRA KUMAR SOOD, AN INDIAN NATIONAL	CHENNAI

LIST OF ~~PEC~~ PATENTS GRANTED BY CHENNAI PATENT OFFICE

511	198649	481/MAS/2003	A PROCESS FOR THE PREPARATION OF GABAPENTIN FORM-II	MATRIX LABORATORIES LTD, AN INDIAN COMPANY	CHENNAI
512	198650	5/MAS/2001	SELFCONTAINED AIR CONDITIONED ENCLOSURE	ASIR IYADURAI JEBARAJ, AN INDIAN CITIZEN	CHENNAI
513	198651	944/MAS/2001	DEVICE FOR GAS DYNAMIC DEPOSITION OF POWDER MATERIALS	INTERNATIONAL ADVANCED RESEARCH CENTRE FOR POWDER METALLURGY AND NEW MATERIALS (ARCI)	CHENNAI
514	198652	1391/MAS/1998	FLAT CABLE CONNECTOR FOR A BICYCLE	SHIMANO INC, A JAPANESE COMPANY	CHENNAI
515	198653	1881/MAS/1996	A PROCESS FOR PREPARING POLYMERS FROM OLEFINS	DOW GLOBAL TECHNOLOGIES INC., A US COMPANY	CHENNAI
516	198654	1450/MAS/1996	A COMPUTER IMPLEMENTED PROCESS AND A COMPUTER SYSTEM FOR DETECTING NETWORK FAILURE	INTERNATIONAL BUSINESS MACHINES CORPORATION (A COMPANY ORANGIZED AND EXISTING UNDER THE LAW OF THE STATE OF NEW YORK, USA	CHENNAI
517	198656	224/MAS/2001	A HANDHELD TYPE FOUR-CYCLE ENGINE	HONDA GIKEN KOGYO KABUSHIKI KAISHA, A CORPORATION OF JAPAN	CHENNAI
518	198686	853/CHE/2003	A METHOD FOR TRANSPORT BLOCK SIZE (TBS) SIGNALLING	NOKIA CORPORATION, A FINNISH CORPORATION	CHENNAI
519	198687	056/MAS/2002	INTERLEAVED ORTHOGONAL FREQUENCY DIVISION MULTIPLEXING (IOFDM) SYSTEM	INDIAN INSTITUTE OF SCIENCE	CHENNAI
520	198688	2295/MAS/1996	A HYDROFORMYLA-TION PROCESS IN THE PRESENCE OF A METAL-ORGANOPOLY PHOSPHINE LIGAND COMPLEX CATALYST	1 TAK WAI LEUNG, 2 DAVID ROBERT BRYANT BOTH ARE US CITIZENS 3 BERNARD LESLIE SHAW, A UK CITIZEN	CHENNAI
521	198726	622/MAS/2002	AN IMPROVED PROCESS FOR THE PREPARATION OF XANTHOPHYLL CRYSTALS	OMNIACTIVE HEALTH TECHNOLOGIES PVT. LTD, A COMPANY REGISTERED UNDER THE INDIAN COMPANIES ACT, 1956	CHENNAI
522	198952	1032/MAS/1997	A PHYSIOLOGICALLY ACTIVE BRANCHED PEG-IFNa CONJUGATE	F. HOFFMANN-LA ROCHE AG, A SWISS COMPANY	CHENNAI
523	198953	43/CHE/2005	REMOVAL OF COLOUR IN TEXTILE EFFLUENT USING CHEMICAL REACTANTS	SUDHAKAR MUNISWAMI, INDIAN NATIONAL	CHENNAI

The Mashelkar Report – vs – the INTERPAT funded IP Institute Report

Mashelkar Report	Interpat/ IP Institute Report
5.6 Granting patents only to NCEs or NMEs and thereby excluding other categories of pharmaceutical inventions is likely to contravene the mandate under Article 27 to grant patents to all 'inventions'. Neither Articles 7 and 8 of the TRIPS Agreement nor the Doha Declaration on TRIPS Agreement and Public Health can be used to derogate from this specific mandate under Article 27.	Section II, Part A 1. Limiting the grant of patents only to NCEs or NMEs and thereby excluding other categories of pharmaceutical inventions *('the proposed exclusion')* is likely to contravene the mandate under Article 27 to grant patents to all 'inventions'. Neither Articles 7 and 8 of the TRIPS Agreement nor the Doha Declaration on TRIPS Agreement and Public Health can be used to derogate from this specific mandate under Article 27.
5.9 If the aim of limiting patents to new chemical entities is to prevent a phenomenon loosely referred to as 'ever-greening', this can be done by a proper application of patentability criteria as present in the current patent regime.	Section II, Part A 3. If the aim of the *proposed exclusion* is to prevent a phenomenon loosely referred to as 'ever-greening', this can be done by a proper application of patentability criteria as present in the current patent regime.
5.10 It is important to distinguish 'ever-greening' from what is commonly referred to as 'incremental innovation'. While 'ever-greening' refers to an extension of a patent monopoly, achieved by executing trivial and insignificant changes to an already existing patented product, 'incremental innovations' are sequential developments that build on the original patented product and may be of tremendous value in a country like India.	Section II, Part A 4. Lastly, it is important to distinguish the phenomenon of 'ever-greening' from what is commonly referred to as 'incremental innovation'. While 'ever-greening' refers to an undue extension of a patent monopoly, achieved by executing trivial and insignificant changes to an already existing patented product, 'incremental innovations' are sequential developments that build on the original patented product and may be of tremendous value in a country like India.

Drug Information Centre -- A Profile and Activities

The Settings

The Drug Information Centre is a unit set up by the **Karnataka State Pharmacy Council**,a statutory body constituted by the Government of Karnataka under the provisions of the Pharmacy Act of 1948. The mission of Drug Information Centre is to improve patient care through dissemination of unbiased, well-referenced and critically evaluated drug information.

Location & Facilities

Drug Information Centre is situated in the heart of Vijayanagar area, a prime locality in the Bangalore City. The premises encloses spacious seminar hall equipped with modern amenities, Board Room to hold meetings and neatly designed office set up.

Drug Information Centre - Primary Objectives

- To provide in-depth and unbiased source of crucial **drug information in the Indian context** to meet the needs of the practicing pharmacists (chemists & druggists) and other health care professionals.
- To promote safe, effective, rational and economic use of drugs in patients by provision of drug information.
- To disseminate the latest advances in patient care through bulletins etc.

DRUG INFORMATION CENTER ACTIVITIES

Drug information center provides information for

- Hospitals
- All the pharmacy colleges
- Medical Colleges
- Health and allied professionals
- Governmental and regulatory agencies
- Non governmental organisations
- Mass media and other related bodies.
- Community pharmacists
- Members of the public

Our principle resources include

- Drug database from Micromedex includes Tomes, Poisoindex, Drugdex etc.,
- Drug database from Drug Facts and Comparison.
- A current collection of texts and files on various drug related information.
- Internet access for e-mail web searching and access to external databases.
- Clinical pharmacology on-line service.
- Online access to databases including medline, toxline , aidsline etc.,
- Several online subscriptions.

Bulletin

We are about to release our bulletin, designed for local use within our pharmacy and medical community. The council also has plans to prepare Bulletin in local language (Kannada).

Training

The center also provides continuing education for community pharmacists on many recent advancements in pharmacy field.

Drug Information Centre . its philosophy

Drug Information Center is a network of pharmacists producing comprehensive, up to date health information for all. We strive to bring a doctor's perspective to important medical issues. Our goal is to be comprehensive, easy to use and responsive to the patient's needs.

CONTACT

DEPUTY DIRECTOR-DRUG INFORMATION
DRUG INFORMATION CENTRE
KARNATAKA STATE PHARMACY COUNCIL
514/E, R.P.C. LAYOUT, I MAIN, II STAGE
VIJAYANAGAR CLUB ROAD
BANGALORE - 560 040.

E-MAIL: info@kspcdic.org ; kspcdic@blr.vsnl.net.in
TEL : 3404000; 3202345
FAX : 080-3202345
Visit us at http://www.kspcdic.org

Karnataka State Pharmacy Council – A Profile and Activities

Karnataka State Pharmacy Council is a Statutory body constituted by the Government of Karnataka under the provisions of the Pharmacy Act of 1948. The main function of the Karnataka State Pharmacy Council is to grant Registration to the eligible pharmacists possessing requisite qualification as enunciated in the Pharmacy Act and to enforce the provisions of the Pharmacy Act.

In addition to the main function of Registration, the Council has expanded it's activities into the following areas:

1. PHARMACIST SOCIAL SECURITY SCHEME :

The members of Karnataka State Pharmacy Council have constituted Karnataka registered Pharmacist Welfare Trust (KRKPWT) to provide financial security to the survivors of the Registered Pharmacist in the State of Karnataka. This is the first scheme of its kind in this country designed for the pharmacists by the pharmacists themselves.

2. CONTINUING EDUCATION :

CONTINUING EDUCATION for the Registered Pharmacists has been started by Karnataka State Pharmacy Council in 1998-99.

3. DRUG INFORMATION CENTRE :

Recognizing the growing need of up-to-date drug information by the healthcare professionals, the council has started Drug Information Centre, which can proudly say it is the first major venture in the country.

Drug Information Centre - Primary Objectives

- To provide in-depth and unbiased source of crucial drug information in the Indian context to meet the needs of the practicing pharmacists (chemists & druggists) and other health care professionals.
- To promote safe, effective, rational and economic use of drugs in patients by provision of drug information.
- To disseminate the latest advances in patient care through bulletins etc.

4. APPOINTMENT OF PHARMACY INSPECTORS:

Karnataka State Pharmacy Council has appointed Pharmacy Inspectors under section 26(A) of the Pharmacy Act, 1948. The Pharmacy Inspectors are instructed to inspect premises where dispensing is carried out.

ಸಮಂಜಸ ಔಷಧದ ಉಪಯೋಗ

ಔಷಧಗಳು ಆಧುನಿಕ ವೈದ್ಯ ಪದ್ಧತಿಯ ಹೆಗ್ಗುರುತು. ಯುಗಯುಗಗಳಿಂದಲೂ ವೈದ್ಯಕೀಯ ಶಾಸ್ತ್ರದಲ್ಲಿ ರೋಗಿಗಳ ಉಪಚಾರಕ್ಕಾಗಿ ನಿಸರ್ಗದತ್ತ ಅಥವಾ ಮಾನವ ನಿರ್ಮಿತ ಔಷಧಿಗಳನ್ನು ಅವುಗಳ ವೈದ್ಯಕೀಯ ಗುಣಗಳಿಂದಾಗಿ ಉಪಯೋಗಿಸಲ್ಪಟ್ಟಿದೆ. ಆದಾಗ್ಯೂ ಔಷಧಗಳೂ ಈ ಶತಮಾನದ ಪೂರ್ವಾರ್ಧಕ್ಕಿಂತಾ ಉತ್ತರಾರ್ಧದಲ್ಲಿ ವೈದ್ಯ ಶಾಸ್ತ್ರವನ್ನು ಹಿಂದೆ ಹಾಕಿದೆ. ಈಗ ಪ್ರತಿಯೊಂದು ಕಾಯಿಲೆಗೂ ಒಂದು ಗುಳಿಗೆ ಸಂಸ್ಕೃತಿ ಚೆನ್ನಾಗಿ ಬೆಳೆದಿದೆ. ಇದು ಸರ್ವಕಾಲಕ್ಕೂ ನಮ್ಮ ಪೀಳಿಗೆ ಅತೀ ಔಷಧಿ ಉಪಯೋಗಿಸಿದ್ದ ಪೀಳಿಗೆ ಎಂದು ಸಾಬೀತು ಮಾಡುತ್ತದೆ. ಇದು ಆರೋಗ್ಯಕರ ಬೆಳವಣಿಗೆ ಅಲ್ಲದಿದ್ದರೂ ಸಹ!

ಶತಶತಮಾನಗಳಿಂದಲೂ ತತ್ವಜ್ಞಾನಿಗಳು, ಸಾಮಾಜಿಕ ಕಾರ್ಯಕರ್ತರು ಮತ್ತು ವೈದ್ಯರು ಔಷಧದ ಅತೀ ಉಪಯೋಗದ ಹಾಗೂ ದುರ್ಬಳಕೆಗಳ ಅಪಾಯ ಹಾಗೂ ತೊಂದರೆಗಳ ಬಗ್ಗೆ ಜನರಿಗೆ ಎಚ್ಚರಿಕೆ ಕೊಡುತ್ತಲೇ ಇದ್ದಾರೆ.

ದೌರ್ಭಾಗ್ಯದ ಸಂಗತಿ ಎಂದರೆ ಈಗಿನ ಭಾರತದ ಆರೋಗ್ಯ ಪರಿಸ್ಥಿತಿಗಳಲ್ಲಿ ವೈದ್ಯರುಗಳು ರೋಗಿಗಳಿಗೆ ಹೆಚ್ಚು ಬೆಲೆಯ, ಬೆಡಗಿನ ಕಡಿಮೆ ಗುಣಕಾರೀ ಅಂಶಗಳನ್ನೊಳಗೊಂಡ ಔಷಧಗಳನ್ನು ಹೆಚ್ಚು-ಹೆಚ್ಚು ಶಿಫಾರಸ್ಸು ಮಾಡುತ್ತಿದ್ದಾರೆ. ಹಾಗೆಯೇ ಔಷಧ ಉತ್ಪಾದಕರೂ ಕೂಡ ತಮ್ಮ ಉತ್ಪಾದನೆಗಳನ್ನು ವೈದ್ಯರಿಂದ ಶಿಫಾರಸ್ಸು ಮಾಡಿಸಲು ಸರಿ-ತಪ್ಪುಗಳ ಗಣನೆ ಇಲ್ಲದೆ ಎಲ್ಲ ರೀತಿಯ ಮಾರ್ಗಗಳಿಂದ ಪ್ರಯತ್ನಿಸುತ್ತಿದ್ದಾರೆ. ಇದು ಬೇರಾವುದೇ ಕಾರಣಗಳಿಗಿಂತ ಗಂಭೀರವಾದವುಗಳು.

ಅಸಮಂಜಸ ಔಷಧದ ಬಳಕೆ : ಕೆಲವು ದೃಷ್ಟಿಕೋನಗಳು

ಸಮಂಜಸ ಔಷಧದ ಬಳಕೆಯ ತತ್ವವನ್ನು ಅರಿಯಲು ಮೊದಲು ನಾವು ಆ ಸಂದರ್ಭದಲ್ಲಿ ಔಷಧದ ಅಸಮಂಜಸ ಬಳಕೆಯನ್ನು ಮೊದಲು ಗುರುತಿಸ ಬೇಕಾಗುತ್ತದೆ. ವೃತ್ತ ಪತ್ರಿಕೆ ಹಾಗೂ ನಿಯತಕಾಲಿಕೆಗಳಲ್ಲಿನ ವರದಿಗಳು ಈ ಸಂಗತಿಗಳ ಬಗ್ಗೆ ಬೆಳಕು ಚೆಲ್ಲುತ್ತವೆ. ಅವುಗಳೆಲ್ಲೆಲ್ಲ ಲೆಂಟಿನ್ ಕಮಿಷನ್ ನ ಇತ್ತೀಚಿನ ವರದಿಗಳು ದಿಗ್ಭ್ರಮೆಗೊಳಿಸುವಂತಿದೆ.

ಅಸಮಂಜಸ ಔಷಧ ಬಳಕೆ ಮೂರು ಸಂಗತಿಗಳಿಂದ ಉಂಟಾಗುತ್ತವೆ:

(ಅ) ಅಸಮಂಜಸ ಔಷಧ ಉತ್ಪಾದನೆ, ಮಾರಾಟ ಹಾಗೂ ದೊರೆಯುವಿಕೆ.

(ಆ) ವೃತ್ತಿನಿರತ ವೈದ್ಯರು ಹಾಗೂ ಆರೋಗ್ಯ ಕಾರ್ಯಕರ್ತರಿಂದ ಅಸಮಂಜಸ ಶಿಫಾರಸ್ಸು

(ಇ) ಗ್ರಾಹಕರಿಂದ ಅಸಮಂಜಸ ಔಷಧಗಳ ಬಳಕೆ

ಈ ಎಲ್ಲಾ ಮೂರು ಕಾರಣಗಳೂ ಒಟ್ಟು ಸೇರಿ ನಾವಿರುವ ಇಂದಿನ ಪರಿಸ್ಥಿತಿಗೆ ಕಾರಣವಾಗಿದೆ.

ಅ. ಅಸಮಂಜಸ ಔಷಧಿಗಳ ಉತ್ಪಾದನೆ, ಮಾರಾಟ ಹಾಗೂ ಲಭ್ಯತೆ:

ಔದ್ಯೋಗಿಕ ನೀತಿ : ಔಷಧ ನೀತಿ ಆರೋಗ್ಯ ನೀತಿಯ ಭಾಗವಾಗಿರದೇ, ಔದ್ಯೋಗಿಕ ನೀತಿಯ ಭಾಗವಾಗಿ ಮುಂದುವರಿದಿದೆ. ಔದ್ಯೋಗಿಕ ಪ್ರಗತಿ ಹಾಗೂ ಲಾಭ, ಲಾಭಾಂಶಗಳು ಔಷಧ ನೀತಿಯನ್ನು ನಿರ್ಧರಿಸುತ್ತವೆಯೇ ಹೊರತು ಜನರ ಆರೋಗ್ಯದ ಅಗತ್ಯತೆಗಳನ್ನಲ್ಲ.

ವಿಪುಲವಾಗಿ ದೊರೆಯುವಿಕೆ : ದೇಶದಲ್ಲಿ ಅಸಂಖ್ಯಾತ ಔಷಧಗಳ ಉತ್ಪಾದನೆಯಾಗಿದೆ. ಹಾಥಿ ಕಮಿಟಿಯು 116 ಔಷಧಗಳು ಅವಶ್ಯವಾಗಿವೆ ಎಂದೂ ಮತ್ತು ವಿಶ್ವ ಸಂಸ್ಥೆಯು 200 ಔಷಧಗಳು ಅವಶ್ಯವೆಂದೂ ಶಿಫಾರಸ್ಸು ಮಾಡಿದೆ. ಈಗ 70,000ಕ್ಕೂ ಹೆಚ್ಚು ಔಷಧಗಳು ದೇಶದಲ್ಲಿ ಲಭ್ಯವಿದೆ.

ಔಷಧದ ಗುಣಮಟ್ಟ : ಈಗ ಲಭ್ಯವಿರುವ ಔಷಧಗಳಲ್ಲಿ ಶೇಕಡಾ 20ರಷ್ಟು ಔಷಧಗಳೂ ಕಡಿಮೆ ದರ್ಜೆಯವು ಮತ್ತು ಕಲಬೆರಕೆಯವು. ಕೆಲವು ಹಳೆಯ ಮತ್ತು ಅವಧಿ ತೀರಿದ ದಿನಾಂಕದವು.

ಟೆಟ್ರಾಸೈಕ್ಲಿನ್ ನಲ್ಲಿ ಅರಿಶಿನ ಪುಡಿಯ ಕೆಳದರ್ಜೆಯ ಅಂತರ್ ಧಮನಿ ದ್ರವವೆಂದು ವರದಿಯಾಗಿವೆ. ಕಡಿಮೆ ದರ್ಜೆಯ ಗ್ಲಿಸಿರಾಲ್ ಬಳಕೆ ಆಸ್ಪತ್ರೆಯಲ್ಲಿ ಎಂಬ ಲೆಂಟಿನ್ ವರದಿ ಇದಕ್ಕೊಂದು ಉದಾಹರಣೆ.

ಬೇಡವಾದ ಔಷಧಗಳು : ದೊರಕುವ ಔಷಧಗಳಲ್ಲಿ ಬೇಡವಾದ ಔಷಧಗಳು ಈ ಕೆಳವು :

ನಿಷೇಧಿಸಲ್ಪಟ್ಟ ಔಷಧಿಗಳು : ಹಲವು ದೇಶಗಳಲ್ಲಿ ನಿಷೇಧಿಸಲ್ಪಟ್ಟ ಔಷಧಿಗಳಾದ ಲೋಮೋಟಿಲ್ ಹಾಗೂ ಕ್ಲಿಯೋಕ್ವಿನಾಲ್

ಬಿ. ಅಸಮಂಜಸ ಮಿಶ್ರಣಗಳು : ಅಸಮಂಜಸ ಮಿಶ್ರಿತ ಆಂಟಿಗೊನೆಸ್ಟಕ್ ಅಥವಾ ಅಸಮಂಜಸ. ಹಾಥಿ ಕಮಿಟಿಯು ಕಡಿಮೆ ಎಂದರೆ 23 ಅಸಮಂಜಸ ಔಷಧ ಮಿಶ್ರಣವನ್ನು ತೆಗೆದೆಸೆಯಬೇಕೆಂದು ಸಲಹೆ ಮಾಡಿದೆ. ಇವುಗಳನ್ನು ಜುಲೈ 1983ರ ಗೆಜೆಟ್ ಪ್ರಕಾರ ನಿಷೇಧಿಸಲ್ಪಟ್ಟದೆಯಾದರೂ ಕೆಲವು ದೇಶದಲ್ಲಿ ದೊರೆಯುತ್ತಿವೆ.

ಸಿ. ಹಾನಿಕರಕ/ ಬಹಿಷ್ಕರಿಸಬೇಕಾದ ಔಷಧಗಳು : ಹಾನಿಕರಕ ಔಷಧಗಳು ಸರಿಯಾದ ವೈದ್ಯ ಸಲಹೆ ಅಥವಾ ಮೇಲ್ವಿಚಾರಣೆ ಇಲ್ಲದೆ ದೊರೆಯಕೂಡದು. ಅನಾಲ್ಜಿನ್, ಆಕ್ಸಿಫಿನ್ ಬ್ಯೂಟಜೋನ್ ಮತ್ತು ಕಾರ್ಟಿಕೊ - ಉತ್ತೇಜನಗಳನ್ನೊಳಗೊಂಡ ಔಷಧಗಳು ಕೆಲವು ಸಾಮಾನ್ಯ ಉದಾಹರಣೆಗಳು (ಔಷಧದ ಆಮೂಲಾಗ್ರ ಬಳಕೆಯ ಪುಟ 31ನ್ನು ನೋಡಿ)

ಡಿ. ಆಸ್ಪತ್ರೆಗಳಲ್ಲಿ ಸಾಬೀತಾಗಿಲ್ಲದ ಔಷಧಗಳನ್ನು ಮಾರಾಟ ಮಾಡಲು ಉತ್ತೇಜಿಸುವುದು ಬಹಳ ಅಪಾಯಕಾರಿ. ಉದಾಹರಣೆಗೆ ಗರ್ಭ ಪರೀಕ್ಷೆ ಮಾಡುವ ಮತ್ತು ಗರ್ಭಪಾತವನ್ನು ಅನುವು ಮಾಡುವ ಇ.ಪಿ. ಪೋರ್ಟೆ ಔಷಧಿಯನ್ನು ಬಳಸುವುದರಿಂದ ಅಪಾಯವಿದೆಯೆಂದು ಆಧಾರವಿದ್ಯಾಗ್ಯೂ ಉಪಯೋಗಿಸುವುದು. (30-6-1998 ರಿಂದ ನಿಷೇಧಿಸಲ್ಪಟ್ಟದೆ)

ಇ. ಅಧಿಕ ಬೆಲೆಯ ಔಷಧ : ಔಷಧಗಳ ಬೆಲೆಯನ್ನು ಏರಿಸಲು ಅಧಿಕ ಬೆಲೆಯ ಹೆಚ್ಚು ವರಿ ಅಥವಾ ಕೆಲವು ಬಾರಿ ಅನಾವಶ್ಯವಾದ ಪದಾರ್ಥವನ್ನು ಸೇರಿಸುವುದು. ಉತ್ಪಾದನೆಯಲ್ಲಿ ಹಾಗೂ ಪ್ಯಾಕಿಂಗ್ ಹಂತದಲ್ಲಿ ಹಾಗೂ ಹೆಚ್ಚು ಜೀವಸತ್ವವುಳ್ಳ ಟಾನಿಕ್‌ಗಳು, ವಿಶೇಷವಾಗಿ ಶಿಶು ಆಹಾರ ಇದಕ್ಕೆ ಒಳ್ಳೆಯ ಉದಾಹರಣೆಗಳು.

ತಪ್ಪು ಆದ್ಯತೆ : ಮುಖ್ಯವಲ್ಲದ ಔಷಧಿಗಳು ಶ್ರೀಮಂತರಿಗಾಗಿ ಅಧಿಕ ಉತ್ಪಾದನೆಯಾಗುತ್ತಿದೆ. ಆದರೆ ಕೆಲವು ಸಾಮಾನ್ಯ ಆರೋಗ್ಯ ತೊಂದರೆಗಳಿಗೆ ಬೇಕಾದವು ಸರಿಯಾಗಿ ಪೂರೈಕೆಯಾಗುತ್ತಿಲ್ಲ. ತ್ರಾಣಕಗಳು (ಟಾನಿಕ್) ವಿಟಮಿನ್‌ಗಳು, ಜೀವರಸಾಯನಿಕಗಳು ಹಾಗೂ ಹೆಚ್ಚು ಜೀವಸತ್ವಗಳ ಬದಲಿ ಉಪಯೋಗಿಸುವ ಔಷಧಗಳು ನಿರರ್ಥಕವಾಗಿ ಹೆಚ್ಚು ಉತ್ಪಾದನೆಯಾಗುತ್ತಿದೆ. ಹಾಗೆಯೇ ಕುಷ್ಠ ಮತ್ತು ಕ್ಷಯ (ಇವೆರಡೂ ದೊಡ್ಡ ಆರೋಗ್ಯ ಸಮಸ್ಯೆ) ರೋಗದ ಔಷಧಗಳು ಅವಶ್ಯಕತೆಗಿಂತಾ 1/3 ಹಾಗೂ 1/4 ಭಾಗ ಮಾತ್ರ ಉತ್ಪಾದಿಸಲಾಗುತ್ತಿದೆ.

ವಿಟಮಿನ್ ಎ ಮತ್ತು ಮಕ್ಕಳ ಆರೋಗ್ಯಕ್ಕಾಗಿ ತುರ್ತಾಗಿ ಹಾಗೂ ಅವಶ್ಯವಾಗಿ ಬೇಕಾದ ಔಷಧಗಳು, ಚುಚ್ಚುಮದ್ದುಗಳು, ವ್ಯಾಕ್ಸಿನ್‌ಗಳು ಉಪಲಬ್ಧವಿರುವುದಿಲ್ಲ.

ಅಂಗಡಿಗಳಿಂದ ನೇರ ಮಾರಾಟ : ಅರ್ಹ ವೈದ್ಯರಿಂದ ಶಿಫಾರಸ್ಸು ಮಾಡಲ್ಪಡದೆಯೇ ಹಲವಾರು ಔಷಧಗಳು ಅಂಗಡಿಗಳಿಂದ ಮಾರಾಟ

ಮಾಡಲ್ಪಡುತ್ತಿವೆ. ಇದಕ್ಕೆ ಶಾಸನ ಬದ್ದ ಅಡೆತಡೆ ಇಲ್ಲ. ಇದು ಸರಿಯಾದ ಔಷಧ ಕಾನೂನು ಮತ್ತು ಔಷಧ ನಿಯಂತ್ರಣವಿಲ್ಲದಿದುರ ಪರಿಣಾಮ. ಹೀಗೆ ಶಿಫಾರಸ್ಸಿಲ್ಲದೇ ನೇರ ಅನಧಿಕೃತ ಮಾರಾಟದ ಔಷಧಗಳ ಮೇಲೆ ಮುನ್ನೆಚ್ಚರಿಕೆ ಮತ್ತು ಔಷಧದ ಬಗೆಗಿನ ಮಾಹಿತಿ ಕೂಡ ಇಲ್ಲದಿರುವುದು ಪರಿಸ್ಥಿತಿಯನ್ನು ಮತ್ತಷ್ಟು ಅಪಾಯಕಾರಿಯಾಗಿಸಿದೆ.

ಏರುವ ಬೆಲೆಗಳು : ಔಷಧ ಬೆಲೆ ನಿಯಂತ್ರಣ ನಿಯಮಗಳು ಸಾಕಷ್ಟಿಲ್ಲ ಹಾಗೂ ಇದ್ದರು ನಿಷ್ಕ್ರಿಯವಾಗಿದೆ. ಆದ್ದರಿಂದ ಔಷಧದ ಬೆಲೆಗಳು ಒಂದೇ ಸಮನೇ ಏರುತ್ತಿವೆ. ಇಂದಿನ ಸರ್ಕಾರದ ಮುಕ್ತ ನಿಯಮಗಳಿಂದ ಬೆಲೆಗಳು ಮತ್ತಷ್ಟು ಏರುತ್ತಿವೆ. ಬಹುತೇಕ ರೋಗಿಗಳು ಕೊಳ್ಳುವ ಶಕ್ತಿಯು ಕಡಿಮೆ ಇದೆ. ಈ ರೀತಿ ಬೆಲೆ ಏರಿಕೆಯಿಂದ ರೋಗಿಗಳು ಶಿಫಾರಸ್ಸು ಮಾಡಲ್ಪಟ್ಟ ಔಷಧಕ್ಕಿಂತ ಕಡಿಮೆ ಅಥವಾ ಕಡಿಮೆ ದರ್ಜೆಯ, ಔಷಧ ಅಂಗಡಿಗಳವು ಕೊಡುವ ಪರ್ಯಾಯ ಔಷಧಿಯನ್ನು ಕೊಳ್ಳಲು ಪ್ರೇರೇಪಿಸುತ್ತದೆ.

ಬಿ. ಅಸಮಂಜಸ ಔಷಧಗಳ ಶಿಫಾರಸ್ಸು :

ವೈದ್ಯರು, ದಾದಿಗಳು ಹಾಗೂ ಆರೋಗ್ಯ ಕಾರ್ಯಕರ್ತರು ಮೇಲಿಂದ ಮೇಲೆ ಅಸಮಂಜಸ ಔಷಧಗಳನ್ನು ಶಿಫಾರಸ್ಸು ಮಾಡುತ್ತಾರೆ ಅಥವಾ ಕೊಡುತ್ತಾರೆ.

ಅಸಮಂಜಸ ಔಷಧ ಶಿಫಾರಸ್ಸಿನ ಬಗೆಗಳನ್ನು ಈ ರೀತಿ ವರ್ಗೀಕರಿಸಬಹುದು.

ಅಸಮಂಜಸ ಔಷಧದ ಉಪಯೋಗ ಈ ಕೆಳಕಂಡ ಕಾರಣಗಳಿಂದ ಉಂಟಾಗುತ್ತದೆ.

1. ಅತಿರೇಕದ ಶಿಫಾರಸ್ಸು : ಕಡಿಮೆ ಬೆಲೆಯ ಔಷಧ ಕೂಡ ತುಲನಾತ್ಮಕವಾಗಿ ಗುಣಕಾರಿ ಹಾಗೂ ಕ್ಷೇಮವಾಗಿರಬಲ್ಲದು.

ಕಡಿಮೆ ಬೆಲೆಯ ಪರ್ಯಾಯ ಮತ್ತು ಸಮಾನ ಗುಣಕಾರಿ ಅಂಶಗಳನ್ನೊಳಗೊಂಡ ಔಷಧಿಗಳಿದ್ದಾಗ ಹೆಸರಾಂತ ಔಷಧಿಗಳನ್ನು ಉಪಯೋಗಿಸಲಾಗುತ್ತಿದೆ.

2. ಅತೀ ಶಿಫಾರಸ್ಸು : ಔಷಧವು ಬೇಡವಾಗಿದ್ದರೂ ಕೂಡ ಅತಿ ಹೆಚ್ಚಿನ ಪರಿಮಾಣ.

ರೋಗೋಪಚಾರದ ಅವಧಿ ದೀರ್ಘವಾಗಿದ್ದಾಗ ನಡೆಸಿರುವ ರೋಗೋಪಚಾರಕ್ಕೆ ಹೋಲಿಸಿದರೆ ಕೊಟ್ಟ ಔಷಧದ ಪ್ರಮಾಣ ವಿಪರೀತ ಹೆಚ್ಚಿದಾಗ

3. ಸರಿಯಲ್ಲದ ಶಿಫಾರಸ್ಸು : ತಪ್ಪು ಪರೀಕ್ಷಿತ ರೋಗ ವಿಧಾನದಿಂದ ಕೊಟ್ಟ ಔಷಧ

ರೋಗ-ಲಕ್ಷಣಗಳಿಗೆ ತಪ್ಪಾದ ಔಷಧಿ ಕೊಟ್ಟಾಗ. ಔಷಧ ಶಿಫಾರಸ್ಸು ಸರಿಯಾಗಿ ಮಾಡದಿದ್ದಾಗ ಜೊತೆಗಿರುವ ಔಷಧ, ತಳ, ಪರಿಸರ ಹಾಗೂ ಇತರೆ ಕಾರಣಗಳನ್ನು ಸರಿಯಾಗಿ ಹೊಂದಿಸಿಕೊಳ್ಳದಿದ್ದಾಗ

4. ಬಹು ಶಿಫಾರಸ್ಸು : ಒಂದೆರಡು ಔಷಧಿಗಳು ಪರಿಣಾಮಕಾರಿಯಾಗಿದ್ದಾಗ್ಯೂ ಎರಡು ಮತ್ತು ಅದಕ್ಕೂ ಹೆಚ್ಚಿನ ಔಷಧಿಗಳನ್ನು ಶಿಫಾರಸ್ಸು ಮಾಡುವುದು.

ಖಾಯಿಲೆಯ ಇತರೇ ಲಕ್ಷಣಗಳಿಗೂ ಉಪಚರಿಸುವುದು.

ಮುಖ್ಯವಾದ ಖಾಯಿಲೆ ಲಕ್ಷಣಗಳ ಸ್ಥಿತಿ ಸುಧಾರಿಸುತ್ತಿರುವಾಗ ಇತರೇ ಖಾಯಿಲೇ ಲಕ್ಷಣಗಳು ಸುಧಾರಿಸುತ್ತದೆ.

5. ಕಡಿಮೆ ಶಿಫಾರಸ್ಸು : ಅವಶ್ಯಕತೆ ಇರುವಷ್ಟು ಔಷಧವನ್ನು ಶಿಫಾರಸ್ಸು ಮಾಡದಿರುವುದು

ಔಷಧದ ಪ್ರಮಾಣವನ್ನು ಸರಿಯಾಗಿ ಗುರುತಿಸದಿರುವುದು.

ರೋಗೋಪಚಾರದ ಅವಧಿ ಕಡಿಮೆ ಇರುವುದು.

ಇನ್ನೂ ಹಲವಾರು ಹಿನ್ನೆಲೆ ಕಾರಣಗಳು ಈ ರೀತಿಯ ಔಷಧ ಶಿಫಾರಸ್ಸಿಗೆ ಅವಕಾಶ ಮಾಡಿಕೊಡುತ್ತದೆ.

(ಅ) ತರಬೇತಿಯ ಕೊರತೆ : ವೈದ್ಯರು, ದಾದಿಗಳು, ಔಷಧ ಪರಿಣಿತರು ಹಾಗೂ ಆರೋಗ್ಯ ಕಾರ್ಯಕರ್ತರುಗಳಿಗೆ ಔಷಧ ಉಪಯೋಗದಲ್ಲಿ ಸಾಕಷ್ಟು ತರಬೇತಿ ಪಡೆದಿಲ್ಲದಿರಬಹುದು. ಅಂತಹ ತರಬೇತಿಗಳು ಪಠ್ಯ ವಿಷಯವಾಗಿರುತ್ತದೆಯೇ ವಿನಹ ನಿಜ ಜೀವನದಲ್ಲಿನ ಪ್ರತ್ಯಕ್ಷ ಸಂದರ್ಭಗಳಲ್ಲಿ ಶಿಫಾರಸ್ಸು ಮಾಡುವ ತರಬೇತಿ ಕೊಡುವುದಿಲ್ಲ. ತಾಂತ್ರಿಕವಾಗಿ ಸಣ್ಣ ವಿಷಯಗಳಿಗೂ ಒತ್ತು ಕೊಟ್ಟಾಗ ಬೆಲೆ ಬಗ್ಗೆ ಮಾಹಿತಿ, ಸಾಮಾಜಿಕ ಪರಿಸ್ಥಿತಿ ಹಾಗೂ ಅಪಾಯವನ್ನು ತಡೆಯಬಹುದು.

(ಆ) ಮುಂದುವರೆದ ಶಿಕ್ಷಣದ ಅಭಾವ : ವೃತ್ತಿನಿರತ ವೈದ್ಯರು, ದಾದಿಗಳು, ಔಷಧ ಪರಿಣಿತರು ಮತ್ತು ಆರೋಗ್ಯ ಕಾರ್ಯಕರ್ತರುಗಳು ಅವರ ಸಂಸ್ಥೆಗಳು ಸರಿಯಾದ ಸಾಕಷ್ಟು ಮುಂದುವರೆದ ಶಿಕ್ಷಣಕ್ಕೆ ಒತ್ತು ಬೆಂಬಲವಿಲ್ಲದಿರುವುದು. ತರಬೇತಿ ಶಿಬಿರಗಳ ಕೊರತೆ. ಒಮ್ಮೆ ಪದವಿ ಪಡೆದ ನಂತರ ಔಷಧ ಮತ್ತು ವೈದ್ಯಕೀಯ ವಿಷಯಗಳಲ್ಲಿ ಜ್ಞಾನಾಭಿವೃದ್ಧಿಗೆ ಸರಿಯಾದ ಅವಕಾಶಗಳಿಲ್ಲದೇ ಇರುವುದು ಮತ್ತು ಸರಿಯಾದ ಆಕರಗಳಿಂತ ಮಾಹಿತಿ ಇಲ್ಲದಿರುವುದು.

(ಇ) ವೈದ್ಯಕೀಯ ಔಷಧಗಳ ಜಾಹೀರಾತುಗಳು ಬಹಳಷ್ಟು ಬಾರಿ ಔಷಧದ ಸಾಮರ್ಥ್ಯ ಸಾಬೀತು ಪಡಿಸಿಲ್ಲದವಾಗಿರುತ್ತದೆ. ಇದರ ಜೊತೆ ಔಷಧ ಮಾರಾಟವನ್ನು ಉತ್ತೇಜಿಸುವ ಮಾಹಿತಿಗಳು ಒಂದೇ ಕಂಪನಿಯದಾಗಿದ್ರೂ ಒಂದು ದೇಶದಿಂದ ಇನ್ನೊಂದು ದೇಶಕ್ಕೆ ಬಹಳ ವ್ಯತ್ಯಾಸವಿರುತ್ತದೆ. ನಿಜ ಸಂಗತಿಗಳು ಮರಮಾಚಲ್ಪಟ್ಟಿರುತ್ತದೆ. ಸಂಖ್ಯಾ ಶಾಸ್ತ್ರವು ಸರಿಯಾದ ರೀತಿಯಲ್ಲಿ ಉಪಯೋಗಿಸಲ್ಪಟ್ಟಿರುವುದಿಲ್ಲ. ಔಷಧ ಸಂಸ್ಥೆಗಳ ಪ್ರಾಯೋಜಿತ ಜಾಹೀರಾತಿನಲ್ಲಿ ತಪ್ಪು ಮಾಹಿತಿಗಳು ಇಲ್ಲದಿಲ್ಲ.

(ಈ) ಹೆಚ್ಚುಗಾರಿಕೆಗಾಗಿ ಔಷಧ ಶಿಫಾರಸ್ಸು : ವೈದ್ಯರು ಪದೇ ಪದೇ ದೊಡ್ಡಸ್ಥಿಕೆಗಾಗಿ ವಿಪರೀತ ಔಷಧಿಗಳನ್ನು ಶಿಫಾರಸ್ಸು ಮಾಡುತ್ತಾರೆ. ಭಾರತದಲ್ಲಿ ಹೆಚ್ಚು ಉದ್ದವಾದ, ಬಹಳ ಬೆಲೆಯುಳ್ಳ ಔಷಧಗಳನ್ನು ಶಿಫಾರಸ್ಸು ಮಾಡುವ ಬಹು ಪದವಿ ಹೊಂದಿದ ವೈದ್ಯ ಉತ್ತಮ ವೈದ್ಯ ನೆನೆಸಿಕೊಳ್ಳುತ್ತಾನೆ. ಹೆಚ್ಚಿನ ವೈದ್ಯರುಗಳು ಈ ರೀತಿಯ ಸಂಸ್ಕೃತಿಗೆ ಬಲಿಯಾಗಿದ್ದಾರೆ. ಹೀಗಾಗಿ ಒಂದು ವಿಷ ವೃತ್ತವೇ ಸೃಷ್ಟಿಯಾಗಿದೆ.

(ಉ) ಬಿಡುವಿಲ್ಲದ ಹೊರ ರೋಗಿಗಳು : ವಿಶೇಷವಾಗಿ ಸರ್ಕಾರಿ ವೈದ್ಯಕೀಯ ಸಂಸ್ಥೆಗಳಲ್ಲಿ ಸಾಕಷ್ಟು ಸಿಬ್ಬಂದಿ ಇಲ್ಲ. ಹೊರ ರೋಗಿಗಳ ವಿಭಾಗದ ಮುಂದೆ ವಿಪರೀತ ನೂಕುನುಗ್ಗಲು ಹಾಗೂ ಉದ್ದವಾದ ಸರತಿಯ ಸಾಲು ಇರುತ್ತದೆ. ಸಮಯದ ಅಭಾವದಿಂದ ಸರಿಯಾದ ಸಮಂಜಸ ಔಷಧದ ಆಯ್ಕೆ ಬದಲು ಅಸಮಂಜಸ ಔಷಧ ಶಿಫಾರಸ್ಸು ಮಾಡುವ ಪರಿಸ್ಥಿತಿ ನಿರ್ಮಾಣವಾಗುತ್ತದೆ.

(ಊ) ಔಷದ ಸಂಸ್ಥೆಗಳ ಪ್ರಲೋಭನೆ : ಔಷಧ ಸಂಸ್ಥೆಗಳ ತಪ್ಪು ಮಾಹಿತಿಯೊಂದೇ ವೈದ್ಯರುಗಳ ಅಸಮಂಜಸ ಔಷಧ ಶಿಫಾರಸ್ಸು ಮಾಡುವಂತೆ ಮಾಡುವುದಿಲ್ಲ. ಮಾರಾಟ ಉತ್ತೇಜನ ಮಾಡುವ ನೆಪದಲ್ಲಿ ನೀತಿಬಾಹಿರ ವಾಣಿಜ್ಯ ಸೋಡಿಗಳು, ಲಂಚ, ಉಡುಗೊರೆ, ಪ್ರಾಯೋಜಿತ ಕಾರ್ಯ ಏಬರ ಮತ್ತು ಪ್ರವಾಸ. ಈ ವಾಣಿಜ್ಯ ಉದ್ದೇಶಗಳು ವೈದ್ಯರು ನೀತಿ-ಬಾಹಿರವಾಗಿ ಶಿಫಾರಸ್ಸು ಮಾಡುವುದನ್ನು ಪಳಗಿಸಿಕೊಳ್ಳುತ್ತದೆ.

(ಋ) ಅನಧಿಕೃತ ಶಿಫಾರಸ್ಸು : ಆರೋಗ್ಯ ಕಾರ್ಯಕರ್ತರು ಹಾಗೂ ಆಲೋಪತಿ ವೈದ್ಯರಲ್ಲದ ಇತರ ವೈದ್ಯ ವೃತ್ತಿನಿರತರು ತಮ್ಮ ಪರಿಮಿತ ತರಬೇತಿಯಿಂದ ಅನಧಿಕೃತವಾಗಿ ಆಲೋಪತಿ ಔಷಧಗಳನ್ನು ಶಿಫಾರಸ್ಸು ಮಾಡುತ್ತಾರೆ. ಆರೋಗ್ಯ ಕಾರ್ಯಕರ್ತರಿಗೆ ಕೆಲವೇ ಔಷಧಗಳನ್ನು ಮಾತ್ರ ಶಿಫಾರಸ್ಸು ಮಾಡಲು ತರಬೇತಿ ನೀಡಬಹುದು. ಬಹಳಷ್ಟು ಸಲ ಅವರು ಸಾಮಾಜಿಕ ಮನ್ನಣೆ ಹಾಗೂ ದೊಡ್ಡಸ್ಥಿಕೆ ಪಡೆಯಲು ವಿವಿಧ ಔಷಧಗಳ ಶಿಫಾರಸ್ಸು ಹಾಗೂ ಉಪಯೋಗ ಮಾಡುವರು. ಕೆಲವು ಸಂಪ್ರಾದಾಯಿಕ ಆಲೋಪತಿ ವೈದ್ಯರು, ಔಷಧದ ಬಗೆಗಿನ ಕಡಿಮೆ ತರಬೇತಿ ಮತ್ತು ಜ್ಞಾನದಿಂದ ಔಷಧಗಳನ್ನು ಉಪಯೋಗಿಸುವರು.

(ಎ) ಪಾಲನೆಗೆ ಪರ್ಯಾಯ ಔಷಧಗಳು : ಔಷಧಗಳು ನವ

ವೈದ್ಯಕೀಯ ಸಂಸ್ಕೃತಿಯ ಕರುಹಾಗಿದೆ. ಇಲ್ಲಿ ರೋಗಿಗಳ ಉಪಚಾರಕ್ಕೆ ಔಷಧಿಗಳು ಮುಖ್ಯವಾಗಿ ಇನ್ನಿತರ ಪಾಲನೆ ಹಾಗೂ ಶುಶ್ರೂಷೆ ಹಿಂದೆ ಸರಿದಿದೆ. ಕೆಲವು'ಬಾರಿ ಕೇವಲ ಬಿಸಿನೀರಿನಿಂದ ಬಾಯಿ ಮುಕ್ಕಳಿಸುವ ಅಥವಾ ಸಾಮಾನ್ಯ ಶೂಶ್ರೂಷೆಯಿಂದ ರೋಗ ಲಕ್ಷಣಗಳನ್ನು ಗುಣಪಡಿಸ ಬಹುದಾಗಿದಾಗ್ಯೂ ವೈದ್ಯರು ಔಷಧಗಳನ್ನು ಶಿಫಾರಸ್ಸು ಮಾಡಿ ಅಸಮಂಜಸ ಔಷಧ ಉಪಯೋಗಕ್ಕೆ ಕಾರಣರಾಗುತ್ತಾರೆ.

(೯) ಗ್ರಾಹಕರಿಂದ ಔಷಧ ಉಪಯೋಗ - ಅಸಮಂಜಸ ದೃಷ್ಟಿಕೋನ

(ಅ) ಸ್ವಯಂ ವೈದ್ಯ : ರೋಗಿಗಳು ಸ್ವಯಂ ವೈದ್ಯರಾಗುವುದು, ಔಷಧ ಮಾರಾಟಗಾರರಿಂದ ಸುಲಭ ಲಭ್ಯವಾದ ಔಷಧಿಗಳಿಂದ, ಜಾಹೀರಾತುಗಳಿಂದ, ಹತ್ತಿರದವರ ಅಥವಾ ಮನೆಯ ಇತರ ಸದಸ್ಯರ ಸಲಹೆ ಸ್ವಯಂ ವೈದ್ಯಕ್ಕೆ ಕಾರಣಗಳು. ಅವಳಿ ನಗರಗಳಾದ ಹೈದರಾಬಾದ್ - ಸಿಕಿಂದರಬಾದ್‌ನಲ್ಲಿ ರಾಷ್ಟ್ರೀಯ ಪೌಷ್ಠಿಕತಾ ಸಂಸ್ಥೆಯವರು ನಡೆಸಿದ ಸಮೀಕ್ಷೆಯಲ್ಲಿ ಶೇಕಡ 10ರಷ್ಟಿದ್ದ 330 ಔಷಧ ಮಾರಾಟಗಾರರನ್ನು ಸಮೀಕ್ಷಿಸಿದಾಗ ಗೊತ್ತಾದ ಅಂಶಗಳು ಎಚ್ಚರಿಕೆ ಮೊಳಗಿಸುವಂಥೆ ಮಾಡುತ್ತದೆ. ಸ್ವಯಂ ವೈದ್ಯ ಶೇಕಡವಾರು 46.

ಉಳಿಕೆ ಔಷಧಗಳ ಉಪಯೋಗ : ರೋಗಿಗಳು ಬಹಳಷ್ಟು ಸಲ ವೈದ್ಯರು ರೋಗ ಸರಿಯಾಗಲು ಹೇಳಿದಷ್ಟು ಔಷಧ ತೆಗೆದುಕೊಳ್ಳುವುದಿಲ್ಲ. ಇದು ಶಿಶು ಔಷಧಗಳು ಹಾಗೂ ಆಂಟಿಬಯೋಟಿಕ್ ಔಷಧಗಳಲ್ಲಿ ಸಾಮಾನ್ಯ. ಈ ರೀತಿ ಬಳಸದ ಔಷಧಗಳನ್ನು ಮನೆಯಲ್ಲಿಟ್ಟು ಮನೆಯ ಬೇರಾವುದೇ ಸದಸ್ಯನಿಗಾಗಲೀ ಮಕ್ಕಳಿಗಾಗಲಿ ಅದೇ ರೀತಿಯ ರೋಗ ಲಕ್ಷಣ ಕಂಡು ಬಂದಲ್ಲಿ ಉಪಯೋಗಿಸುವರು. ನಂತರ ಉಳಿಕೆ ಔಷಧವನ್ನು ಅವಧಿ ತೀರಿದ ನಂತರವೂ ಮನೆಯಲ್ಲಿಟ್ಟಿರುತ್ತಾರೆ. ಸರಿಯಾದ ರೀತಿಯಲ್ಲಿ ಸಂರಕ್ಷಿಸಿದಿದ್ದರೆ ಔಷಧವು ತನ್ನ ಗುಣ ಕಳೆದು ಕೊಳ್ಳಬಹುದು ಅಥವಾ ಉಪಯೋಗಿಸಿದಾಗ ವ್ಯತಿರಿಕ್ತ ಪರಿಣಾಮ ಬೀರಬಹುದು.

3. ಸಾಕಷ್ಟು ಮಾಹಿತಿಯಿಲ್ಲದ ಹಣೆಪಟ್ಟಿ ಅಥವಾ ಔಷಧ ಕಾಪಾಡುವಿಕೆ : ವೈದ್ಯರು ಶಿಫಾರಸ್ಸು ಮಾಡಲ್ಪಟ್ಟ ಔಷಧಗಳು ಬಹಳವಾಗಿ ಔಷಧ ವ್ಯಾಪಾರಿಗಳಿಂದ ಸರಿಯಾಗಿ ಹಣೆಪಟ್ಟಿ ಹೆಚ್ಚಿಲ್ಲದಿರಬಹುದು. ಔಷಧ ಕಾದಿಡುವ ಮಾರ್ಗಸೂಚಿಗಳನ್ನು ರೋಗಿಗೆ ಸರಿಯಾಗಿ ತಿಳಿಸಿರುವುದಿಲ್ಲ. ಔಷಧ ಕಪಾಟು ಅಸಮಂಜಸ ಔಷಧ ಉಪಯೋಗದ ಒಂದು ಮೂಲ. ಮಕ್ಕಳ ಕೈಗೆ ಸಿಕ್ಕಿ ಈ ಔಷಧ ಆಕಸ್ಮಿಕವಾಗಿ ವಿಷಪ್ರಶಾನಕ್ಕೆ ಕಾರಣವಾಗ ಬಲ್ಲದು.

4. ಗುಂಪಿನಲ್ಲಿ ಮಾಹಿತಿ ವಿನಿಮಯ : ಔಷಧ ಉಪಯೋಗಿಸಿದವರು ಅದರ ಪರಿಣಾಮ ಹಾಗೂ ಪ್ರಯೋಜನಗಳ ಬಗ್ಗೆ ತಮ್ಮ ಮಿತ್ರರಿಗೆ ಹಾಗೂ ಬಂಧುಗಳಿಗೆ ಸಲಹೆ ನೀಡುತ್ತಾರೆ. ಹಾಗೂ ತಮಗಾದಂತಹ ರೋಗ ಚಿಹ್ನೆಗಳೆಂದು ತಿಳಿದೂ ಅವರಿಗೂ ಔಷಧ ತೆಗೆದುಕೊಳ್ಳಲು ಸೂಚಿಸುತ್ತಾರೆ. ಈ ರೀತಿಯ ಮಾಹಿತಿ ವಿನಿಮಯ ಅಸಮಂಜಸ ಔಷಧ ಉಪಯೋಗಕ್ಕೆ ಕಾರಣವಾಗುತ್ತದೆ.

5. ಅಂತಸ್ತು ಚಿನ್ಹೆಯ ಔಷಧಗಳು : ಚುಚ್ಚುಮದ್ದು, ತ್ರಾಣಕ ಹಾಗೂ ಕೆಲವು ಮಾತ್ರೆಗಳು ಅಂತಸ್ತು ಚಿನ್ಹೆಗಳಾಗಿದೆ. ಅವುಗಳ ಬೆಲ ಹೆಚ್ಚಿರುವುದರಿಂದ ಹೆಚ್ಚು ಪರಿಣಾಮಕಾರೀ ಹಾಗೂ ದೊಡ್ಡಸ್ತಿಕೆ ಎನಿಸಿಕೊಳ್ಳುತ್ತವೆ. ರೋಗಿಗಳು ವೈದ್ಯರನ್ನು ಅಂತಹ ಒಂದೆರಡು ಔಷಧಗಳನ್ನು ಶಿಫಾರಸ್ಸು ಮಾಡಲು ಒತ್ತಡ ತರುತ್ತಾರೆ. ಹಾಗೂ ವೈದ್ಯರುಗಳೂ ಅವರ ವೃತ್ತಿಯ ದೃಷ್ಟಿಯಿಂದ ಅಂತಹ ಒತ್ತಡಗಳಿಗೆ ಮನ್ನಣೆ ನೀಡುತ್ತಾರೆ.

6. ಬಹು ವೈದ್ಯಕೀಯ ಸಲಹೆ : ರೋಗಿಗಳು ತಮ್ಮ ರೋಗಲಕ್ಷಣಗಳಿಗೆ ತಕ್ಷಣದ ಉಪಶಮನಕ್ಕಾಗಿ ಹಲವು ವೈದ್ಯರ ಸಲಹೆ ಪಡೆಯುತ್ತಾರೆ. ವೈದ್ಯರಿಗೂ ಈ ರೀತಿಯ ಭೇಟಿ ಹಲವರಲ್ಲೊಂದು ಎಂದು ತಿಳಿದಿರುವುದಿಲ್ಲ. ಈ ರೀತಿಯ ವೈದ್ಯರು ಮತ್ತು ಪರಿಣಿತ ವೈದ್ಯರಿರಬಹುದು. ಬೇರೆ ಬೇರೆ ವೈದ್ಯ ಪದ್ದತಿಯ ವೈದ್ಯರ ಸಲಹೆ ಪಡೆದಿರಬಹುದು. ಬೇರೆ ಬೇರೆ ವೈದ್ಯ ಪದ್ದತಿಯ ವೈದ್ಯರ ಸಲಹೆ ಪಡೆದಿರಬಹುದು. ಬೇರೆ ಬೇರೆ ವೈದ್ಯರು ಕೊಟ್ಟ ಬೇರೆ ಬೇರೆ ಔಷಧಗಳನ್ನು ಬೇಗನೆ ಉಪಶಮನ ಪಡೆಯಲು ಉಪಯೋಗಿಸುವರು. ರೋಗೋಪಶಮನದ ನಂತರ ಯಾವ ಔಷಧ ಉಪಶಮನಕಾರಿ ಎಂದು ತಿಳಿದು ಬರುವುದಿಲ್ಲ. ಹೀಗಾಗಿ ಪ್ರತೀ ಬಾರಿಯೂ ಈ ರೀತಿಯ ಅಭ್ಯಾಸ ಅಂಟಿಕೊಳ್ಳುತ್ತದೆ. ಕೆಲವು ಔಷಧಗಳು ಪೂರಕವಾಗಿ ಮತ್ತೆ ಕೆಲವು ಒಂದಕ್ಕೊಂದು ವ್ಯತಿರಕ್ತವಾಗಿ ಪರಿಣಾಮ ಬೀರಬಹುದು. ಬಹು ವೈದ್ಯಕೀಯ ಪದ್ದತಿಯಿಂದ ಸಲಹೆ ಪಡೆದಿದ್ದರೆ ವಿಪರೀತ ಗೊಂದಲಕ್ಕೆ ಈಡಾಗಬಹುದು.

7. ಸಾಕಷ್ಟಿಲ್ಲದ ಗ್ರಾಹಕ ತಿಳುವಳಿಕೆ : ಬಹಳಷ್ಟು ಅಸಮಂಜಸ ಔಷಧ ಉಪಯೋಗಕ್ಕೆ ಭಾರತದ ಗ್ರಾಹಕರಲ್ಲಿನ ಔಷಧ ಉಪಯೋಗದ ಬಗ್ಗೆ ತಿಳುವಳಿಕೆ ಇಲ್ಲದಿರುವುದು, ತಪ್ಪು ಉಪಯೋಗಿ ಮತ್ತು ಹೆಚ್ಚು ಉಪಯೋಗದ ಪರಿಣಾಮಗಳು ಮುಖ್ಯಕಾರಣಗಳು. ಭಾರತದಲ್ಲಿ ಗ್ರಾಹಕ ತಿಳುವಳಿಕೆಯನ್ನು ಬಳಸಿಕೊಂಡಿಲ್ಲ. ಕಾನೂನಿನಲ್ಲಿನ ಒಳದಾರಿಗಳಿಂದಾ ಮುಂಜಾತರೂಕತಾ ತಿಳುವಳಿಕೆಗಳೂ ಔಷಧಿಗಳ ಜೊತೆ ಸರಬರಾಜಾಗುತ್ತಿಲ್ಲ. ಮಾಧ್ಯಮಗಳು, ವೈದ್ಯಕೀಯ ವೃತ್ತಿ, ಶಿಕ್ಷಣ ಪದ್ದತಿ ಮತ್ತು ಸಾಮಾಜಿಕ ಹಿತ ಸಂಸ್ಥೆಗಳು ಔಷಧ ವ್ಯಸನಿಗಳ ಬಗ್ಗೆ ಗಮನ ಹರಿಸುತ್ತಿವೆ.

ಶಿಫಾರಿತ ಔಷಧದ ದುರ್ಬಳಕೆ, ಅತಿಬಳಕೆಯನ್ನು ಗ್ರಾಹಕ ತಿಳಿವಳಿಕೆ ಬಗ್ಗೆ ಗಂಭೀರವಾದ ತೊಂದರೆ ಎಂದು ಪರಿಗಣಿಸಿಲ್ಲ. ಈ ತೊಂದರೆ ಅವಿದ್ಯಾವಂತರಿಂದ ಮತ್ತಷ್ಟು ಜಟಿಲಗೊಂಡಿದೆ. ಅವುಗಳನ್ನು ನೀಗಿಸಲು ಬಹುಭಾಷೆಗಳಲ್ಲಿನ ಪರಿಶ್ರಮದ ಅಗತ್ಯತೆ ಇದೆ.

ಸಮಂಜಸ ಔಷಧ ಬಳಕೆ

ಎಂದರೆ ಸಾಮಾಜಿಕ ಕಳಕಳಿಯುಳ್ಳ, ಸಂಬಂಧಪಟ್ಟ ಮತ್ತು ವೈಜ್ಞಾನಿಕವಾಗಿ ಸರಿಯಾದ ಔಷಧ.

ಔಷಧಗಳನ್ನು ಕೆಳಕಂಡ ಆಧಾರದ ಮೇಲೆ ಆಯ್ದು ಕೊಳ್ಳಬೇಕಾಗುತ್ತದೆ.

ಅಗತ್ಯತೆ

ಕಾರ್ಯದಕ್ಷತೆ

ಸುರಕ್ಷಿತ

ಸುಲಭ ಲಭ್ಯತೆ

ಕಡಿಮೆ ದರ

ಉಪಯೋಗಿಸಲು ಸುಲಭವಾದ

ಅಗತ್ಯ ಗುಣಮಟ್ಟ

ಸ್ವದೇಶಿ ತಯಾರಿಕೆ

ಅಗತ್ಯ ಔಷಧಗಳ ಗುರುತಿಸುವಿಕೆ ಹಾಗೂ ಆರೋಗ್ಯ ಕಾರ್ಯಕರ್ತರ ವಿವಿಧ ಸ್ತರಗಳ ವರ್ಗಿಕರಣ

ಕೆಲವು ಪರಿಸ್ಥಿತಿಗಳಲ್ಲಿ ಔಷಧಿಗಳ ಪಾತ್ರ ಹಾಗೂ ಕೆಲವು ಪರಿಸ್ಥಿತಿಗಳಲ್ಲಿ ಪರ್ಯಾಯ ವೈದ್ಯ ಪದ್ದತಿಗಳ ಪಾತ್ರವನ್ನು ಗುರುತಿಸುತ್ತದೆ.

ಮನಃ ಪೂರ್ವಕವಾಗಿ ತೀರ್ಮಾನಿಸಿ ಕೆಲವು ಹಾನಿಕರಕ ಔಷಧಿಯನ್ನು ಬಹಿಷ್ಕೃತಗೊಳಿಸುವುದು, ಅಥವಾ ಬಹಿಷ್ಕೃತಗೊಂಡ ಔಷಧಿಯನ್ನು ಉಪಯೋಗಿಸದಿರುವುದು. ಮತ್ತು ಇನ್ನಿತರ ಔಷಧಿಗಳನ್ನು ಅಗತ್ಯಬಿದ್ದಾಗ ಮಾತ್ರ ಉಪಯೋಗಿಸುವುದು. ಎಂದರೆ ಪೂರ್ಣ ತಿಳುವಳಿಕೆಯಿಂದ ಶಿಫಾರಸ್ಸು ಮಾಡಲ್ಪಟ್ಟ ಮತ್ತು ಸಾಧ್ಯವಾದ ಮಟ್ಟಿಗೆ ಈ ಕೆಲವನ್ನು ತಪ್ಪಿಸುವುದು.

ಔಷಧ ಪರಿಣಾಮದಿಂದ ತೊಂದರೆಗಳು

ಔಷಧದ ವ್ಯತಿರಿತ್ತ ಪರಿಣಾಮಗಳು

ಔಷಧದ ಪರಸ್ಪರ ಪರಿಣಾಮಗಳು

ಮುಂದುವರೆಯುತ್ತಿರುವ ಔಷಧ ನಿರೋಧಕ ಗುಣ

ಆರೋಗ್ಯ ಕಾರ್ಯಕರ್ತರ ಮತ್ತು ಗ್ರಾಹಕರ ಔಷಧದ ಬಗೆಗಿನ ಸರಿಯಾದ ತಿಳುವಳಿಕೆ ಮತ್ತು ಮಾಹಿತಿ ಮತ್ತದರ ಸರಿಯಾದ ತಿಳಿಸುವಿಕೆಯನ್ನು ಗುರುತಿಸುತ್ತದೆ.

ಶತಮಾನಗಳಿಂದಲೂ ಔಷಧಗಳು ನೋವು ಹಾಗೂ ನರಳುವಿಕೆಯನ್ನು ತಪ್ಪಿಸಿವೆ. ಅವು ಜೀವನವನ್ನು ಹೆಚ್ಚು ಸುಖಕರವಾಗಿ, ಉತ್ಪಾದಕರವಾಗಿ ಹಾಗೂ ಅರ್ಥಪೂರ್ಣವಾದ ಜೀವಿಗಳನ್ನಾಗಿಸಿದೆ. ನಾವೆಲ್ಲರೂ, ಆರೋಗ್ಯ ಚಳುವಳಿಯಲ್ಲಿ ಬದ್ದರಾಗಿರುವವರು ಔಷಧಗಳು ತಮ್ಮ ಹಿತ-ಮಿತ ಹಾಗೂ ಉಪಯುಕ್ತ ಪಾತ್ರವನ್ನು ವೈದ್ಯೋಪಚಾರದಲ್ಲಿರುವಂತೆ ನೋಡಿಕೊಳ್ಳಬೇಕು.

ಸಾರ್ವಜನಿಕರು

ಸರ್ಕಾರಗಳು

ಔಷಧ ಉದ್ಯಮ

ಯೋಜನೆದಾರರು

ವೈದ್ಯ ವೃತ್ತಿಯಲ್ಲಿರುವವರು

ವೈದ್ಯ ಮಹಾ ವಿದ್ಯಾಲಯದವರುಗಳು

ಔಷಧ ಮಹಾ ವಿದ್ಯಾಲಯದವರು

ಶುಶ್ರೂಷ ನಿಯಂತ್ರಕರು

ಔಷಧ ವ್ಯಾಪಾರಿಗಳು

ಪತ್ರಕರ್ತರು ಮತ್ತು ಇನ್ನಿತರ ಮಾಧ್ಯಮದಲ್ಲಿರುವವರು

ಉಪಾಧ್ಯಾಯರು ಹಾಗೂ ಶಿಕ್ಷಕರು

ಇವರೆಲ್ಲರು ಔಷಧಿಗಳ ಸಮಂಜಸ ಉಪಯೋಗವನ್ನು ಉತ್ತೇಜಿಸಲು ಬದ್ದರಾದಾಗ ಮಾತ್ರ ಇದು ಸಾಧ್ಯವಾಗುತ್ತದೆ.

ಔಷಧ ಮತ್ತು ಸೌಂದರ್ಯವರ್ಧಕ ಕಾಯ್ದೆ (1940)

ಆಹಾರ ಪದಾರ್ಥಗಳು ಮತ್ತು ದಿನಬಳಕೆಯ ವಸ್ತುಗಳನ್ನು ಬಿಟ್ಟರೆ ಬಳಕೆದಾರರ ಜನಜೀವನವನ್ನು ತಟ್ಟುವ ಮುಖ್ಯ ವಸ್ತುಗಳೆಂದರೆ ಔಷಧಿಗಳು ಮತ್ತು ಸೌಂದರ್ಯ ಸಾಧನಗಳು. ಆಹಾರ ಪದಾರ್ಥಗಳು ಎಷ್ಟು ಪರಿಶುದ್ಧವಾಗಿ ಇರಬೇಕೋ ಔಷಧಿಗಳು ಅದಕ್ಕಿಂತ ಹೆಚ್ಚು ಪರಿಶುದ್ಧವಾಗಿರಬೇಕು. ಜನರ ಆರೋಗ್ಯ ಮತ್ತು ಜೀವ ಈ ಔಷಧಿಗಳನ್ನು ಅವಲಂಭಿಸಿದೆ. ಈ ಕಾರಣದಿಂದ ಜನರಿಗೆ ಉಪಯುಕ್ತವಾದ ಔಷಧಿಗಳನ್ನು ಸಮರ್ಪಕವಾಗಿ ವಿತರಣೆ ಮಾಡುವುದಲ್ಲದೆ, ಗುಣಮಟ್ಟವೂ ಉತ್ತಮವಾಗಿರಬೇಕೆಂಬ ಉದ್ದೇಶದಿಂದ ಸರ್ಕಾರ, ಆರೋಗ್ಯಕ್ಕೆ ಸಂಬಂಧ ಪಟ್ಟಂತೆ ಕೆಲವು ಕಾಯ್ದೆಗಳನ್ನು ಹೊರಡಿಸಿದೆ.

ಬಳಕೆದಾರರ ಆರೋಗ್ಯಕ್ಕೆ ಸಂಬಂಧಿಸಿದ ಮುಖ್ಯ ಕಾಯ್ದೆಗಳು, ಔಷಧಿ ಮತ್ತು ಸೌಂದರ್ಯವರ್ಧಕ ಕಾಯ್ದೆ 1940, ಔಷಧಿ ಮತ್ತು ಮಂತ್ರ ಪರಿಹಾರ (ಆಕ್ಷೇಪಣಾರ್ಹ ಜಾಹಿರಾತು) ಕಾಯ್ದೆ 1954, ಔಷಧಿ (ನಿಯಂತ್ರಣ) ಕಾಯ್ದೆ 1950, ಮತ್ತು ಆಪಾಯಕಾರಿ ಔಷಧಿ ಕಾಯ್ದೆ 1930. ಈ ಕಾಯ್ದೆಗಳು ಬೇರೆ ಬೇರೆ ವಿಷಯಗಳಿಗೆ ಸಂಬಂಧಿಸಿದ್ದರೂ ಆವುಗಳೆಲ್ಲದರ ಉದ್ದೇಶ ಬಳಕೆದಾರರ ಆರೋಗ್ಯ ಮತ್ತು ಹಿತರಕ್ಷಣೆ ಒಂದೇ.

ಔಷಧ ಮತ್ತು ಸೌಂಧರ್ಯವರ್ಧಕ ಕಾಯ್ದೆಯ ಉದ್ದೇಶ ಕಳಪೆ ಔಷಧಿಗಳನ್ನು ತಡೆಗಟ್ಟುವುದು ಮತ್ತು ವೈದ್ಯಕೀಯ ಶುಶ್ರೂಶೆಯಲ್ಲಿ ಉತ್ತಮ ಗುಣಮಟ್ಟವನ್ನು ಉಂಟುಮಾಡುವುದು. ಈ ಕಾಯ್ದೆ ದೇಶದಲ್ಲಿ ತಯಾರಾಗುವ, ವಿತರಣೆಗೊಳ್ಳುವ ಮತ್ತು ಮಾರಾಟಗೊಳ್ಳುವ ಔಷಧಿಗಳ ಗುಣಮಟ್ಟ ಮತ್ತು ನಿಯಂತ್ರಣವನ್ನು ನೋಡಿಕೊಳ್ಳುತ್ತದೆ. ಇದನ್ನು ಕಾರ್ಯಗತಗೊಳಿಸಲು ಕಾಯ್ದೆಯಲ್ಲಿ ಮೂರು ಸಮಿತಿ ಅಥವಾ ಸಂಸ್ಥೆಗಳನ್ನು ಸ್ಥಾಪಿಸಲಾಗಿದೆ. ಆವು :

೧. ಔಷಧ ತಾಂತ್ರಿಕ ಸಲಹಾ ಮಂಡಳಿ

೨. ಕೇಂದ್ರಿಯ ಔಷಧಿ ಪ್ರಯೋಗಾಲಯಗಳು

೩. ಔಷದ ಸಲಹಾ ಸಮಿತಿ.

ಈ ಕಾಯ್ದೆಯ ಅನುಷ್ಠಾನದಲ್ಲಿ ಬರಬಹುದಾದ ತಾಂತ್ರಿಕ ವಿಷಯಗಳನ್ನು ಮತ್ತು ಸಮಸ್ಯೆಗಳನ್ನು ಪರಿಶೀಲಿಸಲು ಔಷಧ ತಾಂತ್ರಿಕ ಸಲಹಾ ಮಂಡಳಿಯನ್ನು ಸ್ಥಾಪಿಸಲಾಗಿದೆ. ಈ ಮಂಡಳಿಯಲ್ಲಿ 15 ಸದಸ್ಯರಿರುತ್ತಾರೆ. ಅವರುಗಳಲ್ಲಿ ಮುಖ್ಯವಾದವರು ದೇಶದ ಔಷಧ ನಿಯಂತ್ರಣಾಧಿಕಾರಿಗಳು, ಕಲ್ಕತ್ತಾ, ಕಸೌಲಿ ಮತ್ತು ಇಜತ್‌ನಗರದಲ್ಲಿರುವ ಔಷಧಿ ಪ್ರಯೋಗಾಲಯಗಳ ಮುಖ್ಯಸ್ಥರು ಮತ್ತು ಭಾರತೀಯ ವೈದ್ಯಕೀಯ ಮಂಡಳಿಯ ಅಧ್ಯಕ್ಷರು.

ಜನರಿಗೆ ಉತ್ತಮ ಗುಣಮಟ್ಟದ ಔಷಧಿ ಒದಗಿಸಲು ಈ ಕಾಯ್ದೆಯ ಅನುಸಾರವಾಗಿ ಹಲವಾರು ಕ್ರಮಗಳನ್ನು ಕೈಗೊಳ್ಳಲಾಗಿದೆ. ಯಾವುದಾದರು ಔಷಧಿ ಅಥವಾ ಸೌಂದರ್ಯ ಸಾಮಗ್ರಿಗಳು ಉಪಯೋಗಿಸುವವರಿಗೆ ಯಾವುದೇ ರೀತಿಯ ಆಘಾತ ಅಥವಾ ನೋವು ಉಂಟುಮಾಡುತ್ತವೆ ಎಂದು ತಿಳಿದು ಬಂದಲ್ಲಿ ಆ ಔಷಧಿಗಳನ್ನು ನಿಷೇಧಿಸಲಾಗುತ್ತದೆ. ಅಲ್ಲದೆ, ಔಷಧಿಗಳು ಯಾವ ಪರಿಹಾರ ನೀಡುತ್ತವೆ ಎಂದು ಹೇಳಲಾಗುತ್ತದೋ, ಆ ಪರಿಹಾರ ನೀಡದಿದ್ದರೆ, ಅಂತಹವುಗಳನ್ನು ಬಹಿಷ್ಕರಿಸಲಾಗುತ್ತದೆ.

ಜನರಿಗೆ ಅಥವಾ ಜಾನುವಾರುಗಳಿಗೆ ಹಾನಿ ಉಂಟು ಮಾಡುವ ಔಷಧಿಗಳನ್ನು ಬಹಿಷ್ಕರಿಸುವುದಲ್ಲದೆ, ಆದರ ಆಮದು ನಿಷೇದಕ್ಕೆ ಒಳಪಡಿಸುವ ಅವಕಾಶ ಇದೆ. ಇದಕ್ಕೆ ತಕ್ಕ ಕಾನೂನು ರೂಪಿಸಲು ಸರ್ಕಾರ ಈ ಕಾಯ್ದೆಯಲ್ಲಿ ಅಧಿಕಾರ ನೀಡಿದೆ.

ಔಷಧಿ ಮತ್ತು ಸೌಂದರ್ಯವರ್ಧಕ ಕಾಯ್ದೆಯಲ್ಲಿ ಖೋಟಾ ಔಷಧಿಗಳಿಗೆ ಸಂಬಂಧಪಟ್ಟ ಹಲವಾರು ನೀತಿ ನಿಯಮುಗಳನ್ನು ರೂಪಿಸಲಾಗಿದೆ. ಈ ಕಾಯ್ದೆಯ ಪ್ರಕಾರ ಖೋಟಾ ಔಷಧಿ ಎಂದರೆ :-

೧. ಸಂಬಂಧಪಡದ ಹೆಸರಿನಲ್ಲಿ ಆಮದು ಮಾಡಿಕೊಂಡಿರುವುದು.

೨. ಬೇರೊಂದು ಔಷಧಿಯಂತೆ ಮೇಲ್ನೋಟಕ್ಕೆ ಕಂಡರೂ, ಅದು ಆ ಔಷಧಿ ಆಗಿರದೆ ಇರುವುದು.

೩. ಔಷಧಿಯ ಪೊಟ್ಟಣ ಅಥವಾ ಕವಚದ ಮೇಲೆ ಮುದ್ರಿತವಾಗಿರುವ ತಯಾರಕರು ಅಥವಾ ವಿತರಕರು ವಾಸ್ತವವಾಗಿ ಅಸ್ತಿತ್ವದಲ್ಲಿ ಇರದಿರುವುದು.

೪. ಬೇರೊಂದು ಔಷಧಿಯಿಂದ ಬೆರಕೆ ಆಗಿರುವುದು.

ಇದೇ ರೀತಿ ಕಲಬೆರಕೆಯಿಂದ ಕೂಡಿದ ಔಷಧಿಗಳ ಬಗ್ಗೆಯೂ ಕಾಯ್ದೆಯಲ್ಲಿ ಕೆಲವು ನಿಯಮಗಳನ್ನು ರೂಪಿಸಲಾಗಿದೆ. ಈ ಕಾಯ್ದೆಯ ಪ್ರಕಾರ ಕಲಬೆರಕೆ ಔಷಧಿ ಎಂದರೆ

೧. ಔಷಧಿ ಕುಲಗೆಟ್ಟ ದ್ರವ್ಯಗಳಿಂದ ಕೂಡಿರುವುದು

೨. ಅನಾರೋಗ್ಯಕರ ವಾತಾವರಣದಲ್ಲಿ ತಯಾರಿಸರುವ ಔಷಧಿಗಳು

೩. ಔಷಧಿಯಲ್ಲಿ ಬಹಿಷ್ಕರಿಸಿದ ಘಟಕ, ವರ್ಣಗಳಿಂದ ಕೂಡಿರುವುದು.

೪. ಬೇರಾವುದೇ ರೀತಿಯಲ್ಲಿ ಉಪಯೋಗಿಸುವವರಿಗೆ ಹಾನಿಯುಂಟು ಮಾಡುವುದು

ಯಾವುದಾದರೂ ಔಷಧಿ ಅಥವಾ ಸೌಂದರ್ಯವರ್ಧಕ ಈ ಮೇಲೆ ಸೂಚಿಸಿರುವ ಗುಂಪಿಗೆ ಸೇರಿದರೆ, ಅವುಗಳನ್ನು ಬಹಿಷ್ಕರಿಸಲಾಗುವುದಲ್ಲದೆ, ತಯಾರಕರನ್ನು ಮತ್ತು ವಿತರಕರನ್ನು ಶಿಕ್ಷೆಗೆ ಗುರಿಪಡಿಸಲಾಗುವುದು.

ಕೇಂದ್ರ ಹಾಗೂ ರಾಜ್ಯ ಸರ್ಕಾರಗಳು, ಔಷಧಿಗಳ ಗುಣಮಟ್ಟ ನಿಯಂತ್ರಿಸಲು ಪರಿವೀಕ್ಷಕರನ್ನು (Inspectors) ನೇಮಕ ಮಾಡಿದೆ. ರಾಜ್ಯ ಔಷಧಿ ನಿಯಂತ್ರಣಾಧಿಕಾರಿಗಳ ವ್ಯಾಪ್ತಿಗೆ ಬರುವ ಈ ಪರಿವೀಕ್ಷಕರ ಮುಖ್ಯ ಕರ್ತವ್ಯ ಔಷಧಿಗಳನ್ನು ಪರೀಕ್ಷಿಸುವುದು ಮತ್ತು ಸೂಕ್ತ ಕ್ರಮ ಕೈಗೊಳ್ಳವುದು. ಈ ಪರಿವೀಕ್ಷಕರಿಗೆ ತಮ್ಮ ಕಾರ್ಯನಿರ್ವಹಿಸಲು ಅನುಕೂಲವಾಗುವಂತೆ ಕೆಲವು ಅಧಿಕಾರ ನೀಡಲಾಗಿದೆ. ಅದರ ಪ್ರಕಾರ ಪರಿವೀಕ್ಷಕರು ತಮ್ಮ ವ್ಯಾಪ್ತಿಗೆ ಬರುವ ಯಾವುದೇ ಔಷಧಿ ಅಥವ ಸೌಂದರ್ಯವರ್ಧಕಗಳನ್ನು ತಯಾರಿಸುವ ಸಂಸ್ಥೆಗೆ ಭೇಟಿ ನೀಡಬಹುದು. ಆ ತಯಾರಿಕ ಘಟಕದಲ್ಲಿ ಗುಣಮಟ್ಟ ಕಾಪಾಡಲು ಅಳವಡಿಸಿರುವ ಉಪಕರಣಗಳನ್ನು ಪರೀಕ್ಷಿಸಬಹುದು.

ಈ ಪರಿವೀಕ್ಷಕರು, ಔಷಧಿ ಮತ್ತು ಸೌಂದರ್ಯ ಸಾಮಗ್ರಿಗಳ ಮಾರಾಟಗಾರರನ್ನು, ವಿತರಕರನ್ನು, ದಾಸ್ತಾನುದಾರರನ್ನು, ದಾಸ್ತಾನನ್ನು ಪರೀಕ್ಷಿಸಬಹುದಾಗಿದೆ. ಅವರಿಂದ ಔಷಧಿ ಮತ್ತು ಸೌಂದರ್ಯ ಸಾಮಗ್ರಿಗಳನ್ನು ಪಡೆದು, ಅದನ್ನು ಪ್ರಯೋಗಾಲಯದಲ್ಲಿ ಪರೀಕ್ಷೆಗೆ ಒಳಪಡಿಸಬಹುದು. ಅಲ್ಲದೆ ನಿರ್ಬಂಧಿತ ಔಷಧಿಗಳನ್ನು ಮತ್ತು ಸೌಂದರ್ಯ ಸಾಮಗ್ರಿಗಳನ್ನು ರವಾನಿಸಲಾಗುತ್ತಿದೆ ಎಂದು ತಿಳಿದು ಬಂದಲ್ಲಿ ಆ ವಾಹನಗಳನ್ನು ನಿಲ್ಲಿಸಿ ಪರೀಕ್ಷಿಸುವ ಅಧಿಕಾರ ಪರಿವೀಕ್ಷಕರಿಗೆ ಇದೆ.

ಪರಿವೀಕ್ಷಕರು ತಯಾರಕರಿಂದ ಪಡೆದ ಔಷಧಿಯ ನಮೂನೆಯನ್ನು ಪರೀಕ್ಷೆಗೆ ಒಳಪಡಿಸಬಹುದು. ಹೀಗೆ ಪಡೆದ ಔಷಧಿಗೆ ತಗಲುವ ವೆಚ್ಚವನ್ನು (ಔಷಧಿಯ ಬೆಲೆಯನ್ನು) ಮಾರಾಟಗಾರನಿಗೆ ನೀಡತಕ್ಕದ್ದು. ತಾವು ಪರೀಕ್ಷೆಗಾಗಿ ಔಷಧಿಯನ್ನು ಪಡೆಯುತ್ತಿರುವುದಾಗಿ ತಯಾರಕರಿಗೆ ತಿಳಿಸಬೇಕಾದದ್ದು ಪರಿವೀಕ್ಷಕರ ಜವಾಬ್ದಾರಿ. ಹಾಗೆ ಪಡೆದ ಔಷಧಿಯನ್ನು

ಮೂರು ಭಾಗವಾಗಿ ವಿಂಗಡಿಸಬೇಕು. ಒಂದು ಭಾಗವನ್ನು ಸರ್ಕಾರಿ ವಿಶ್ಲೇಷಕರಿಗೆ ಪರೀಕ್ಷೆಗಾಗಿ ನೀಡಬೇಕು. ಎರಡನೇ ಭಾಗವನ್ನು ನ್ಯಾಯಾಲಕ್ಕೆ ಒಪ್ಪಿಸಬೇಕು. (ಯಾವುದಾದರೂ ವಾದ ವಿವಾದ ಇದ್ದ ಪಕ್ಷದಲ್ಲಿ ಈ ನಿಯಮ ಅನ್ವಯವಾಗುತ್ತದೆ) ಮೂರನೆ ಭಾಗವನ್ನು ಯಾರಿಂದ ಪಡೆಯಲಾಯಿತೋ ಅವರಿಗೆ ನೀಡಬೇಕು.

ಸರ್ಕಾರಿ ವಿಶ್ಲೇಷಕರು ತಮಗೆ ಬಂದ ಔಷಧಿಯನ್ನು ವಿಶ್ಲೇಷಿಸಿ ವರದಿಯೊಂದನ್ನು ಸಿದ್ಧಪಡಿಸಬೇಕು. ಈ ವರದಿಯ ಪ್ರತಿಯೊಂದನ್ನು ಪರಿವೀಕ್ಷಕರಿಗೆ ನೀಡಿ, ಮತ್ತೊಂದು ಪ್ರತಿಯನ್ನು ತಯಾರಕರಿಗೆ ಅಥವಾ ವಿತರಿಕರಿಗೆ ನೀಡಬೇಕು. ಯಾವುದೇ ವಾದ ವಿವಾದ ಅಥವಾ ವ್ಯಾಜ್ಯಕ್ಕೂ, ಸರ್ಕಾರಿ ವಿಶ್ಲೇಷಕರ ವರದಿಯೇ ಅಂತಿಮವಾದುದ್ದು. ಇದಕ್ಕೆ ಯಾವ ಸಾಕ್ಷಿಯೂ ಬೇಕಾಗುವುದಿಲ್ಲ.

ಬಳಕೆದಾರರ ಹಕ್ಕು

ಔಷಧಿ ಕೊಳ್ಳುವ ಯಾವುದೇ ಬಳಕೆದಾರನಾಗಲಿ ಅಥವಾ ಬಳಕೆದಾರ ಸಂಸ್ಥೆಯಾಗಲಿ, ಔಷಧಿಯನ್ನು ಸರ್ಕಾರಿ ವಿಶ್ಲೇಷಕರಿಗೆ ನೀಡಿ, ಪರೀಕ್ಷಿಸುವಂತೆ ವಿನಂತಿಸಿಕೊಳ್ಳಬಹುದು. ಇದಕ್ಕೆ ನಿಗದಿತ ಪ್ರಮಾಣದ ಶುಲ್ಕ ನೀಡಿ, ನಿಗದಿತ ಪತ್ರದಲ್ಲಿ, ಸರ್ಕಾರಿ ವಿಶ್ಲೇಷಕರಿಗೆ ಔಷಧಿಯನ್ನು ಸಲ್ಲಿಸಬೇಕು. ಹಾಗೆ ಪಡೆದ ಔಷಧಿಯನ್ನು ವಿಶ್ಲೇಷಿಸಿ, ಆದರ ಪರೀಕ್ಷಾ ವರದಿಯನ್ನು ಬಳಕೆದಾರನಿಗೆ ನೀಡುವುದು ಸರ್ಕಾರಿ ವಿಶ್ಲೇಷಕರ ಕರ್ತವ್ಯ.

ಔಷಧಿಯ ಗುಣಮಟ್ಟದ ನಿಯಂತ್ರಣದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವ ಇನ್ನೊಬ್ಬ ಮುಖ್ಯ ಅಧಿಕಾರಿ ಸರ್ಕಾರಿ ವಿಶ್ಲೇಷಕರು. ರಾಜ್ಯ ಅಥವ ಕೇಂದ್ರ ಸರ್ಕಾರಗಳು ಸರ್ಕಾರಿ ವಿಶ್ಲೇಷಕರನ್ನು ನೇಮಿಸಬಹುದು. ಈ ಹುದ್ದೆಗೆ ಬೇಕಾದ ವಿದ್ಯಾರ್ಹತೆ, ಅನುಭವ ಇತ್ಯಾದಿಗಳನ್ನು ರಾಜ್ಯ ಸರ್ಕಾರ ಅಥವಾ ಕೇಂದ್ರ ಸರ್ಕಾರ ನಿಗದಿಪಡಿಸಬಹುದು. ಯಾವುದೇ ಔಷಧಿ ತಯಾರಿಕಾ ಸಂಸ್ಥೆಯಲ್ಲಿ ಆರ್ಥಿಕವಾಗಿ ಆಸಕ್ತಿ ಹೊಂದಿರುವವರನ್ನು ಸರ್ಕಾರಿ ವಿಶ್ಲೇಷಕರನ್ನಾಗಿ ನೇಮಿಸಲಾಗುವುದಿಲ್ಲ.

ಆಕ್ಷೇಪಣಾರ್ಹ ಜಾಹಿರಾತು

ಬಡತನ ಮತ್ತು ಅನಕ್ಷರತೆಯ ಸಮಸ್ಯೆಗಳ ಜೊತೆ ನಮ್ಮ ದೇಶದ ಇನ್ನೊಂದು ಅಷ್ಟೇ ದೊಡ್ಡ ಸಮಸ್ಯೆ ಮೂಢನಂಬಿಕೆ. ಜನರಲ್ಲಿ ಬೇರು ಬಿಟ್ಟಿರುವ ಈ ಮೂಢನಂಬಿಕೆ ಹಲವಾರು ಕ್ಷೇತ್ರಗಳಲ್ಲಿ ಕಾಣಿಸಿಕೊಂಡಿವೆ. ಅನಕ್ಷರಸ್ಥರನ್ನು ಮಾತ್ರವಲ್ಲದೆ ವಿದ್ಯಾವಂತರನ್ನೂ ಈ ಮೂಢನಂಬಿಕೆ ಆವರಿಸಿಕೊಂಡಿದೆ. ಮೂಢನಂಬಿಕೆಗಳು ಕೇವಲ ದೇವರು, ಧರ್ಮ, ಪ್ರತಗಳಿಗೆ ಸೀಮಿತವಾಗಿರದೆ, ಆರೋಗ್ಯಕ್ಕೂ ಲಗ್ಗೆ ಇಟ್ಟಿದೆ. ಯಾವುದೇ ಮಂತ್ರ, ತಂತ್ರ ಮಾಡಿದರೆ ರೋಗ, ಹುಣ್ಣು ಇತ್ಯಾದಿ ಗುಣಂವಾಗುತ್ತದೆ ಎಂದು ಬಹಳಷ್ಟು ಜನ ನಂಬಿದ್ದಾರೆ. ಇದರಿಂದ ಖೋಟಾ ವೈದ್ಯರ ಸಂಖ್ಯೆ ಬೆಳೆದು ಅವರು ಜನರನ್ನು ದಾರಿ ತಪ್ಪಿಸುತ್ತಿದ್ದಾರೆ.

ಮಂತ್ರ, ಯಂತ್ರ, ಕವಚ, ಬೂದಿ ಇತ್ಯಾದಿಗಳ ಮೂಲಕ ರೋಗವನ್ನು ಗುಣಮಾಡುವುದಾಗಿ ನಂಬಿಸಿ ಜನರನ್ನು ವಂಚಿಸುವುದನ್ನು ತಪ್ಪಿಸಲು ಸರ್ಕಾರ ಔಷಧಿ ಮತ್ತು ಮಂತ್ರ ಪರಿಹಾರ (ಆಕ್ಷೇಪಣಾರ್ಹ ಜಾಹಿರಾತು) ಕಾಯ್ದೆ 1954 ಅನ್ನು ಅನುಷ್ಠಾನಗೊಳಿಸಿದೆ. ಈ ಕಾಯ್ದೆಯ ಉದ್ದೇಶ ಜಾಹಿರಾತುಗಳ್ನು ನೀಡಿ ಜನರನ್ನು ಆಕರ್ಷಿಸಿ ವಾಸಿಯಾಗದ ರೋಗಗಳನ್ನು ಮಂತ್ರ, ಯಂತ್ರಗಳ ಮೂಲಕ ಗುಣಪಡಿಸುತ್ತೇವೆ ಎಂದು ಸಾರುವುದನ್ನು ತಡೆಗಟ್ಟುವುದು.

ಉದಾಹರಣೆಗೆ ಈಗಿರುವ ವೈದ್ಯಕೀಯ ಜ್ಞಾನ ಮತ್ತು ಅಭಿವೃದ್ಧಿಯ ಮಟ್ಟದಿಂದ ಕೆಲವು ರೋಗಗಳನ್ನು ಸಂಪೂರ್ಣ ಗುಣಪಡಿಸಲು ಸಾಧ್ಯವಿಲ್ಲ ಎಂದು ಸ್ಥಿರಪಟ್ಟಿದೆ. ಈ ರೋಗಗಳನ್ನು ವಾಸಿಮಾಡುತ್ತೇವೆ ಎಂದು ಸಾರುವ ಜಾಹಿರಾತು ಆಕ್ಷೇಪಣಾರ್ಹ. ಅಲ್ಲದೆ ಕೆಲವು ವಿಷಯಗಳಿಗೆ ಸಂಬಂಧಿಸಿದಂತೆ ಜಾಹಿರಾತು ನೀಡುವುದನ್ನು ಈ ಕಾಯ್ದೆಯು ಕಟ್ಟುನಿಟ್ಟಾಗಿ ನಿರ್ಬಂಧಿಸಿದೆ. ಅವುಗಳೆಂದರೆ :

೧. ಗರ್ಭಪಾತ ಮಾಡಿಸುವ ಇಲ್ಲವೇ ಮಕ್ಕಳಾಗದಂತೆ ತಡೆಯುವ ಔಷಧಿಗಳ ಬಗ್ಗೆ ಜಾಹಿರಾತು

೨. ಜನರಲ್ಲಿ ಸಂಭೋಗಾಸಕ್ತಿ ಅಥವಾ ಕಾಮೋದ್ರೇಕ ಹೆಚ್ಚಿಸುತ್ತದೆ ಎಂದು ಸಾರುವ ಜಾಹಿರಾತು.

೩. ಖಿತುಚಕ್ರ ಸರಿಪಡಿಸುತ್ತದೆ ಎಂದು ಹೇಳುವ ಜಾಹಿರಾತು.

೪. ಈ ಕಾಯ್ದೆಗೆ ಸೇರಿಸಿರುವ ಅನುಬಂಧದಲ್ಲಿ ಸೂಚಿಸಲಾಗಿರುವ ರೋಗಗಳಿಗೆ ಔಷಧಿ ನೀಡಲಾಗುವುದು ಎಂದು ತಿಳಿಸುವ ಜಾಹಿರಾತು.

ಔಷಧಿ ಮತ್ತು ಮಂತ್ರ ಪರಿಹಾರ (ಆಕ್ಷೇಪಣಾರ್ಹ ಜಾಹಿರಾತು) ಕಾಯ್ದೆಗೆ ಸೇರಿಸುವ ಅನುಬಂಧದಲ್ಲಿ ಉಲ್ಲೇಖಿಸಿರುವ ಕೆಲವು ಕಾಯಿಲೆಗಳನ್ನು ಇಲ್ಲಿ ನೀಡಲಾಗಿದೆ.

೧. ಅಪೆಂಡಿಸೈಟಿಸ್

೨. ಕುರುಡುತನ

೩. ರಕ್ತದಲ್ಲಿ ವಿಷ ಬೆರಕೆ

೪. ಕ್ಯಾನ್ಸರ್

೫. ಕಣ್ಣಿನ ಪೊರೆ

೬. ಸಕ್ಕರೆ ಕಾಯಿಲೆ

೭. ಖಿತುಚಕ್ರದ ತೊಂದರೆ

೮. ಸ್ತನದ ಗಾತ್ರ ಮತ್ತು ರೂಪವನ್ನು ವೃದ್ಧಿಗೊಳಿಸುವುದು

೯. ತೊನ್ನು

೧೦. ಪ್ಲೇಗ್

ಕಾಯ್ದೆಯಂತೆ ಯಾವ ವ್ಯಕ್ತಿಯಾಗಲಿ ಈ ರೀತಿಯ ಜಾಹಿರಾತು ನೀಡಿದರೆ ಅವರನ್ನು ಪ್ರಥಮ ಬಾರಿ ಆರು ತಿಂಗಳ ಸಜೆ ಅಥವಾ ದಂಡ ವಿಧಿಸಲಾಗುವುದು. ಇನ್ನೊಂದು ಬಾರಿ ಇದೇ ಅಕ್ರಮದಲ್ಲಿ ಭಾಗವಹಿಸಿದರೆ, ಒಂದು ವರ್ಷ ಸಜೆಗೆ ಗುರಿಪಡಿಸಲಾಗುವುದು.

ಔಷಧಿಗಳ ನಿಯಂತ್ರಣ ಕಾಯ್ದೆ

ಬಳಕೆದಾರರಿಗೆ ಬಹಳ ಉಪಯುಕ್ತವಾದ ಕಾಯ್ದೆಗಳಲ್ಲಿ ಔಷಧಿಗಳ ನಿಯಂತ್ರಣ ಕಾಯ್ದೆ-1950 ಮುಖ್ಯವಾದದ್ದು. ಕಾರಣ ಈ ಕಾಯ್ದೆ ಔಷಧಿಗಳ ಬೆಲೆಯನ್ನು ನಿಯಂತ್ರಿಸುವಲ್ಲಿ ಕೆಲವು ನೀತಿ ನಿಯಮಗಳನ್ನು ರೂಢಿಸಿದೆ. 1952 ರಲ್ಲಿ ಜಾರಿಗೆ ಬಂದ ಈ ಕಾಯ್ದೆ ಔಷಧಿಗಳ ಮಾರಾಟ ಮತ್ತು ವಿತರಣೆಯನ್ನು ನಿಯಂತ್ರಿಸುತ್ತದೆ.

ಬಳಕೆದಾರರು ಈ ಕಾಯ್ದೆಯಲ್ಲಿ ಗಮನಿಸಬೇಕಾದ ಅಂಶವೆಂದರೆ, ಔಷಧಿಗಳ ಬೆಲೆ ಮತ್ತು ದಾಸ್ತಾನು. ಈ ಕಾಯ್ದೆಯು, ಔಷಧಿಗಳ ತಯಾರಕ ಅಥವಾ ದಾಸ್ತಾನುಗಾರ ಎಷ್ಟು ಬೆಲೆಗೆ ಮಾರಬಹುದು ಎಂಬುದನ್ನು ನಿಗದಿಪಡಿಸುತ್ತದೆ. ಅಲ್ಲದೆ ಒಂದು ನಿಗದಿತ ಸಮಯದಲ್ಲಿ ದಾಸ್ತಾನುಗಾರ ಎಷ್ಟು ಔಷಧಿಗಳನ್ನು ಶೇಖರಿಸಿ ಇಡಬಹುದು ಎಂಬುದನ್ನು ನಿರ್ದೇಶಿಸುತ್ತದೆ.

ಎರಡನೆಯದಾಗಿ ಪ್ರತಿಯೊಬ್ಬ ಔಷಧಿ ಮಾರಾಟಗಾರನು ಐದು ರೂಪಾಯಿಗೆ ಮೇಲ್ಪಟ್ಟು ಔಷಧಿ ಮಾರಾಟ ಮಾಡಿದರೆ, ಕೊಳ್ಳುವವರಿಗೆ ರಸೀದಿಯನ್ನು ನೀಡಬೇಕು. ಐದು ರೂಪಾಯಿಗಿಂತ ಕಡಿಮೆ ಇದ್ದ ಸಂದರ್ಭದಲ್ಲಿ ಔಷಧಿ ಕೊಂಡವರು ಕೇಳಿದ ಪಕ್ಷದಲ್ಲಿ ರಸೀದಿ ನೀಡಬೇಕು. ಮುಖ್ಯ ಆಯುಕ್ತರು ರಸೀದಿಯಲ್ಲಿ ಯಾವ ಯಾವ ವಿಷಯಗಳು ಮತ್ತು ವಿವರಣೆಗಳು ಇರಬೇಕು ಎಂಬುದನ್ನು ಗೆಜೆಟ್ ಪ್ರಕಟಣೆಯ ಮೂಲಕ ತಿಳಿಯಪಡಿಸಬಹುದು. ಮಾರಾಟವಾಗದೆ ಉಳಿದ ಔಷಧಿಗಳನ್ನು ಹೇಗೆ ವಿಲೇವಾರಿ ಮಾಡಬಹುದು ಎಂಬುದನ್ನು ಸಹ ವಿಶೇಷ ಅಥವ ಮುಖ್ಯ ಆಯುಕ್ತರು ಸೂಚಿಸಬಹುದು.

ಬಳಕೆದಾರರ ಹಿತದೃಷ್ಟಿಯಿಂದ ಹಲವಾರು ಕಾಯ್ದೆಗಳಿದ್ದರೂ, ಮಾರುಕಟ್ಟೆಯಲ್ಲಿ ಖೋಟಾ ಔಷಧಿಗಳನ್ನು ಮಾರಲಾಗುತ್ತಿದೆ. ಮುಗ್ಧ ಜನರನ್ನು ವಂಚಿಸಿ ಅವರ ಆರೋಗ್ಯ ಮತ್ತು ಹಣವನ್ನು ದೋಚುವ ಪ್ರಯತ್ನಗಳು ನಡೆಯುತ್ತಿವೆ. ಈ ಕಾರಣದಿಂದ ಬಳಕೆದಾರರು ಔಷಧಿಗಳ ವಿಚಾರದಲ್ಲಿ ಜಾಗರೂಕತೆ ವಹಿಸಬೇಕಾಗಿದೆ. ಅವರಿಗೆ ಸಹಾಯಕವಾಗುವಂತೆ ಕರ್ನಾಟಕ ರಾಜ್ಯದ ಔಷಧಿ ನಿಯಂತ್ರಣ ಅಧಿಕಾರಿಗಳು ಕೆಲವು ಸೂಚನೆಗಳನ್ನು ನೀಡಿದ್ದಾರೆ. ಬಳಕೆದಾರರ ಯೋಗಕ್ಷೇಮವನ್ನು ದೃಷ್ಟಿಯಲ್ಲಿಟ್ಟುಕೊಂಡು ಸಿದ್ಧ ಪಡಿಸಿರುವ ಸೂಚನೆಗಳು ಈ ಕೆಳಕಂಡಂತಿವೆ:

೧. ಅಧಿಕೃತ ಅನುಮತಿ (ಲೈಸನ್ಸ್) ಹೊಂದಿರುವ ಔಷಧಿ ಮಾರಾಟಗಾರರಿಂದ ಮಾತ್ರ ಔಷಧಿ ಖರೀದಿಸಿರಿ. ಈ ಅನುಮತಿ ಪತ್ರವನ್ನು ಅಂಗಡಿಯವರು ಪ್ರಮುಖವಾದ ಜಾಗದಲ್ಲಿ ಪ್ರದರ್ಶಿಸಿರುತ್ತಾರೆ.

೨. ಪ್ರತಿ ಬಾರಿ ಔಷಧಿ ಕೊಂಡಾಗಲೂ ರಸೀದಿ ಕೇಳಿ ಪಡೆಯಿರಿ.

೩. ಔಷಧಿಯ ಪೊಟ್ಟಣ ಅಥವ ಸೀಸೆಯ ಮೇಲೆ ಮುದ್ರಿಸಿರುವ ದಿನಾಂಕವನ್ನು ನೋಡಲು ಮರೆಯದಿರಿ. ಔಷಧಿಯನ್ನು ಸೇವಿಸಲು ಮುದ್ರಿತ ದಿನಾಂಕದಂತೆ ಕಾಲಾವಕಾಶ ಇದೆಯೇ ಎಂಬುದನ್ನು ಖಚಿತಪಡಿಸಿಕೊಳ್ಳಿರಿ.

೪. ಯಾವಾಗಲೂ ವೈದ್ಯರು ನೀಡಿರುವ ಚೀಟಿಯನ್ನು ತೋರಿಸಿಯೇ ಔಷಧಿಕೊಳ್ಳಿರಿ.

೫. ಕೆಲವು ಔಷಧಿಗಳನ್ನು ವೈದ್ಯರು ಚೀಟಿ ತೋರಿಸಿದಲ್ಲಿ ಮಾತ್ರ ಮಾರಲಾಗುತ್ತದೆ. ಇದನ್ನು ತಪ್ಪದೆ ಗಮನಿಸಿ.

೬. ಕೆಲವು ಔಷಧಿಗಳನ್ನು ಸೂಚಿಸಿ, ತೆಗೆದುಕೊಳ್ಳಬೇಡಿ. ವೈದ್ಯರ ಬಳಿ ಹೋಗಿ ಪರೀಕ್ಷೆ ಮಾಡಿಸಿಕೊಳ್ಳಿ. ಅವರು ಹೇಳಿದ ಔಷಧಿ ಸೇವಿಸಿರಿ.

೭. ಔಷಧಿಯ ಪೊಟ್ಟಣ, ಸೀಸೆ ಇತ್ಯಾದಿಗಳನ್ನು ಅವುಗಳ ಮೇಲಿನ ಚೀಟಿಯನ್ನು ನಾಶಪಡಿಸಿಯೇ ಎಸೆಯಿರಿ.

೮. ಸಂದೇಹವಿದ್ದಲ್ಲಿ ಔಷಧಿ ನಿಯಂತ್ರಣಾಧಿಕಾರಿಗಳ ಕಛೇರಿಗೆ ದೂರು ಸಲ್ಲಿಸಿ. ವಿಳಾಸ : ಅಂಚೆ ಪಟ್ಟಿಗೆ 5377, ಪ್ಯಾಲೇಸ್ (ಅರಮನೆ) ರಸ್ತೆ, ಬೆಂಗಳೂರು-560 001. ಇದಲ್ಲದೆ ಆಯಾ ವ್ಯಾಪ್ತಿಯಲ್ಲಿ ಔಷಧಿ ಪರಿವೀಕ್ಷಕ (Drug Inspector) ರಿರುತ್ತಾರೆ. ಇವರಿಗೂ ದೂರಬಹುದು.

ಔಷಧವನ್ನು ವಿಶ್ಲೇಷಕರಿಗೆ ಕಳುಹಿಸುವ ಕ್ರಮ

Drugs and Cosmetics Rulesನಲ್ಲಿ ಇದಕ್ಕೆ ಸಂಬಂಧಪಟ್ಟ ಒಂದೇ ಒಂದು ನಿಯಮ ಇದೆ. ಅದೇನೆಂದರೆ, ಔಷಧವನ್ನು ಪರೀಕ್ಷಿಸಬೇಕಾದರೆ, ಆ ಔಷಧದ ನಾಲ್ಕ ಪಟ್ಟು ಹಣವನ್ನು Drugs Controler ಅವರಲ್ಲಿ ಸಲ್ಲಸಬೇಕು. ಇದು ಮಾರಾಟಗಾರನಿಂದ ಔಷದ ಪಡೆದಿದ್ದರೆ, ತಯಾರಕರಿಂದ ಔಷಧ ಪಡೆದಿದ್ದರೆ, ಔಷಧದ ಮೂರು ಪಟ್ಟು ಬೆಲೆಯನ್ನು ಪಾವತಿ ಮಾಡಬೇಕು. ಇದಕ್ಕೆ ಯಾವುದೇ ಮಾದರಿ ಅರ್ಜಿ ನಮೂನೆ ಇಲ್ಲ.

ಜನರಿಕ್ ಮತ್ತು ಬ್ರಾಂಡ್ ಹೆಸರುಗಳು

ಜನರಿಕ್ ಮತ್ತು ಬ್ರಾಂಡ್ ಹೆಸರುಗಳ ಬಗ್ಗೆ ನಿಷೇಧಿತ ಔಷಧಗಳ ಪುಸ್ತಕದಲ್ಲಿ ಒಂದು ಅಧ್ಯಾಯ ಬರೆಯಲು ಕಾರಣವಿದೆ. ಇಂದು ಗ್ರಾಹಕನಿಗೆ ಅತಿ ಹೆಚ್ಚು ವಂಚನೆ ಆಗುತ್ತಿರುವುದೇ ಈ ಬ್ರಾಂಡ್ ಹೆಸರುಗಳಿಂದಾಗಿ ಇಷ್ಟೊಂದು ಬೇರೆ ಬೇರೆ ಬ್ರಾಂಡ್‌ಗಳಿರುವುದರಿಂದಲೇ ಇಂದು ಔಷಧ ಮಾರುಕಟ್ಟೆ 70,000 ಕ್ಕಿಂತಲೂ ಹೆಚ್ಚು ಔಷಧಗಳಿಂದ ತುಂಬಿ ತುಳುಕುತ್ತಿದೆ.

ಸರಕಾರದ ಗೆಜೆಟ್ ನೋಟೀಸಿನಲ್ಲಾಗಲೀ, ಔಷಧ ನಿಷೇಧವಾಗಿದೆಯೆಂದು ಪತ್ರಿಕೆಯಲ್ಲಿ ಬಂದಾಗಲಾಗಲೀ, ಜನರಿಕ್ ಹೆಸರುಗಳೇ ನಮೂದಿತವಾಗಿರುತ್ತವೆ. ಆದರೆ ನಮಗೆಲ್ಲ ಪರಿಚಯ ಇರುವುದು ಬ್ರಾಂಡ್ ಹೆಸರುಗಳು. ಇಂಥ ವೇಳೆಯಲ್ಲಿ ಗ್ರಾಹಕರಿಗೆ ಗೊಂದಲ ಆಗಬಾರದೆಂದು ಈ ವಿವರವಾದ ಅಧ್ಯಾಯ.

ಯಾವುದೇ ಒಂದು ಔಷಧಕ್ಕೆ ಮೂರು ಹೆಸರುಗಳಿರುತ್ತವೆ. ಒಂದು : ಪ್ರಯೋಗ ಶಾಲೆಯಲ್ಲಿ ಕರೆಸಿಕೊಳ್ಳುವ ವೈಜ್ಞಾನಿಕ ಹೆಸರು ಎರಡು : ಕಂಪನಿಗಳಲ್ಲಿ ಔಷಧ ಎಂದು ತಯಾರಾಗುವಾಗಿನ ಹೆಸರು - ಜನರಿಕ್ ಹೆಸರು. ಮೂರು : ಕಂಪನಿಯಿಂದ ಹೊರಬರುವಾಗ ಆಯಾ ಕಂಪನಿಯವರು ಅಂಕಿತಮಾಡುವ - ಬ್ರಾಂಡ್ ಹೆಸರು. ನಮಗೆಲ್ಲ ಅತಿ ಹೆಚ್ಚು ಪರಿಚಯ ಇರುವುದು ಈ ಬ್ರಾಂಡ್ ಹೆಸರುಗಳು ಮಾತ್ರ.

ಉದಾ: ಕ್ರೋಸಿನ್ (Crocin) ಮಾತ್ರೆ ನಮಗೆಲ್ಲರಿಗೂ ಪರಿಚಿತ. ಇದು ಬ್ರಾಂಡ್ ಹೆಸರು. ಇದರ ಜನರಿಕ್ ಹೆಸರು ಪ್ಯಾರಾಸಿಟಮಾಲ್ (Para-cetamol) ಎಂದು ವೈಜ್ಞಾನಿಕವಾಗಿ (ಎನ್- ಆಸಿಟೈ-ಪ್ಯಾರಾ-ಆಮಿನೋಫೆನಾಲ್) (n-acethy-Oara amino-phenol). Paracetamol - ಬೇರೆ ಬೇರೆ ಕಂಪನಿಗಳು ತಯಾರಿಸಿ ನಿರಾಮೋಲ್, ಕ್ಯಾಲ್ಪಾಲ್, ಪೆನೋಡಿನ್ ಮುಂತಾದ ಹೆಸರುಗಳನ್ನಿಟ್ಟು ಮಾರುತ್ತಾರೆ.

ಔಷಧದ ಸ್ಟ್ರಿಪ್ ಮೇಲೆ ದೊಡ್ಡದಾಗಿ ಎದ್ದು ತೋರುವಂತೆ ಬರೆದಿರುವುದು ಬ್ರಾಂಡ್ ಹೆಸರು. ಈ ಹೆಸರಿನ ಕೆಳಗೇ ಕಂಡೂ ಕಾಣದಂತೆ ಚಿಕ್ಕದಾಗಿ ಜನರಿಕ್ ಹೆಸರನ್ನು ಬರೆದಿರುತ್ತಾರೆ. ಜಾಹೀರಾತು - ಪ್ರಚಾರಗಳೆಲ್ಲ ನಡೆಯುವುದು ಬ್ರಾಂಡ್ ಹೆಸರುಗಳ ಮೇಲೆಯೇ. ವೈದ್ಯರು ಬರೆದುಕೊಡುವುದು ಬ್ರಾಂಡ್ ಹೆಸರುಗಳನ್ನೇ. ಹೀಗಾಗಿ ಜನರೆಲ್ಲ ಪರಿಚಿತರಾಗಿರುವುದು ಬ್ರಾಂಡ್ ಹೆಸರುಗಳಿಗೇ. ಜನರಿಕ್ ಹೆಸರಿನಲ್ಲಿ ಔಷಧಗಳ ಬಗ್ಗೆ ಮಾತನಾಡಿದರೆ ಜನಕ್ಕೆ ಯಾವುದೆಂದು ತಿಳಿಯುವುದಿಲ್ಲ.

ಬ್ರಾಂಡ್ ಹೆಸರುಗಳು ವೈಜ್ಞಾನಿಕ ಔಷಧಗಳೆಲ್ಲ ಜನರಿಕ್ ಹೆಸರುಗಳಲ್ಲೇ ಸಿಗಬೇಕು ಎಂಬ ಬೇಡಿಕೆ ಬಹಳ ಹಿಂದಿನದು. ಮುಂದುವರೆದ ದೇಶಗಳಲೆಲ್ಲ ಈಗಾಗಲೇ ಜನರಿಕ್ ಹೆಸರುಗಳಲ್ಲಿ ಮಾತ್ರ ಔಷಧಗಳು ಸಿಗುವಂತಾಗಿವೆ. ಜನರಿಕ್ ಹೆಸರುಗಳಿದ್ದರೆ ಔಷಧಗಳ ಬಗೆಗಿನ ಅನೇಕ ಗೊಂದಲಗಳು ನಿವಾರಣೆಯಾಗುತ್ತವೆ. ಉದಾ: ಡೈಜಿಪಾಮ್ (Diaz-epam) ನೈಟ್ರಾಜೆಪಾಮ್ (Nitrazepam) ಒಂದೇ ಗುಂಪಿನವು. ಆದರೆ ಇವೇ ಬ್ರಾಂಡ್ ಹೆಸರಿನಲ್ಲಿದ್ದಾಗ ಕಾಂಪೋಸ್ (Calmpose) ಮತ್ತು ನೈಟ್ರಾವಿಟ್ (Nitravit) ಒಂದೇ ಗುಂಪಿನವೆಂದು ಗುರುತಿಸುವುದು ಕಷ್ಟ. ಸ್ವತಃ ವೈದ್ಯರಿಗೇ ಗೊಂದಲವಾಗಬಹುದು.

ವೈದ್ಯ ಸರಿಯಾಗಿ ಬರೆದುಕೊಟ್ಟರೂ ಅಂಗಡಿಯಾತನಿಗೆ ಹೆಚ್ಚು ಕಮ್ಮಿಯಾಗುವ ಸಾಧ್ಯತೆಗಳೂ ಇರುತ್ತವೆ. ಬೇರೆ ಬೇರೆ ಔಷಧಗಳ ಹೆಸರುಗಳು ಒಂದೇ ರೀತಿಯಲ್ಲಿದ್ದಾಗ, ಅಂಗಡಿಯಾತ ಒಂದರ ಬದಲು ಮತ್ತೊಂದು ಕೊಟ್ಟುಬಿಟ್ಟನೆಂದರೆ ಕೆಲಸ ಕೆಟ್ಟಂತೆಯೇ. ಇದರಿಂದ ರೋಗಿಗೆ ತೀವ್ರ ಅಪಾಯವಾಗುವ ಸಂಭವವಿದೆ.

ಉದಾ : ಅಮಿಲೀನ್ (Amiline) - ಮನೋರೋಗದ ಔಷಧ ಅಮಿಕ್ಲೀನ್ (Amicline) - ಹೊಟ್ಟೆ ಝಾಡಿಸುವುದಕ್ಕೆ ಔಷಧ ಹಾಗೆಯೇ, ಸೆಲಿನ್ (Celin) - ವಿಟಮಿನ್ ಸಿ ; ಸಿಪ್ಲಿನ್ (Ciplin) - ಸೋಂಕು ರೋಗದ ಔಷಧ.

ಒಂದೇ ಔಷಧಕ್ಕೆ ಬೇರೆ ಬೇರೆ ಹೆಸರು ಕೊಡುವ ಉದ್ದೇಶ ಹಣ ಮಾಡುವುದು ಮಾತ್ರ. ಕಂಪನಿಗಳು ತಮ್ಮ ಬ್ರಾಂಡಿನ ಅತಿಯಾದ ಪ್ರಚಾರ ಮಾಡಿ ಜನರು, ವೈದ್ಯರು ಅದಕ್ಕೇ ಅಂಟಿಕೊಳ್ಳುವಂತೆ ಮೋಡಿ ಹಾಕುತ್ತಾರೆ. ಫಲವಾಗಿ ಆ ಬ್ರಾಂಡಿನ ಬೆಲೆ ಎಷ್ಟು ಹೆಚ್ಚಾದರೂ ಗ್ರಾಹಕರು ಅದಕ್ಕೇ ಜೋತುಬೀಳುತ್ತಾರೆ. ಇದರಿಂದ ಲಾಭವಾಗುವುದು ಔಷಧ ಕಂಪನಿಗಳಿಗೆ ಮಾತ್ರ. ಉದಾ : ಮೆಂಬಿಂಡ್‌ಜೋಲ್ (Mebenodozole) ನ್ನು ಒಂದೊಂದು ಕಂಪನಿ ಒಂದೊಂದು ಬೆಲೆಗೆ ಮಾರುತ್ತದೆ. 10 ಮಾತ್ರೆಗಳ ಬೆಲೆ 1.80 ರೂ. ನಿಂದ 5.50 ರೂ. ವರೆಗೂ ವ್ಯತ್ಯಾಸವಾಗುತ್ತದೆ.

ಟಿನಿಡಾಝೋಲ್ (Tinidazole) ನ್ನು ಒಂದು ಕಂಪನಿ ತಯಾರಿಸಿ ನಾಲ್ಕು ಬೇರೆ ಬೇರೆ ಕಂಪನಿಗಳಿಗೆ ಕೊಡುತ್ತದೆ. ಅವು ತಮ್ಮ ಬ್ರಾಂಡ್ ಹಾಕಿಕೊಂಡು ಅದೇ ಔಷಧವನ್ನು ಬೇರೆ ಬೇರೆ ಬೆಲೆಗೆ ಮಾರುತ್ತವೆ.

ಒಂದೇ ಔಷಧವನ್ನು ಬೇರೆ ಬೇರೆ ಕಂಪನಿಗಳು ಬೇರೆ ಬೇರೆ ಬ್ರಾಂಡ್ ಹೆಸರು ಹಾಕಿ ಮಾರುವುದು ಒಂದು ವಿಷಯವಾದರೆ ಒಂದೇ ಕಂಪನಿ ಒಂದೇ ಔಷಧವನ್ನು ಬೇರೆ ಬೇರೆ ಹೆಸರುಗಳಲ್ಲಿ ಬೇರೆ ಬೇರೆ ಬೆಲೆಗೆ ಮಾರಿ ಹಣ ಮಾಡುವುದು ಉಂಟು. ಉದಾ : Wellcome ಕಂಪನಿ, ಪ್ಯಾರಾಸಿಟ್‌ಮಾಲ್ (Paracetamol) ನ್ನು Redake ಮತ್ತು Caplpol ಎಂಬ ಎರಡು ಹೆಸರಲ್ಲಿ ಮಾರುತ್ತದೆ. ಅದೇ ರೀತಿ ಗ್ಲಾಕ್ಸೋ ಕಂಪನಿಯವರು ಬೆಟ್ನಲಾಮ್ (Beetnelom) ಮತ್ತು ಬೆಟ್ನಸೋಲ್ (Betnesol) ಎಂಬ ಎರಡು ಬ್ರಾಂಡ್‌ಗಳಲ್ಲಿ ಒಂದೇ ಔಷಧವನ್ನು ಮಾರುತ್ತಾರೆ.

ಬ್ರಿಟನ್ನಿನಲ್ಲಿ ರಾಷ್ಟ್ರೀಯ ಆರೋಗ್ಯ ಯೋಜನೆಯ ಅಡಿಯಲ್ಲಿ ಎಲ್ಲಾ ಔಷಧಗಳನ್ನು ಜನರಿಕ್ ಹೆಸರಿನಲ್ಲಿ ಮಾರಬೇಕೆಂದು ಕಡ್ಡಾಯ ಮಾಡಿದಾಗ ಒಮ್ಮೆಗೇ ಎಲ್ಲ ಔಷಧಗಳ ಬೆಲೆಯೂ ಇಳಿದುಬಿಟ್ಟಿತು. ಜನರಿಕ್ ಹೆಸರಿನಲ್ಲಿ ಔಷಧ ಸಿಗುತ್ತಿದ್ದರೆ ಆಯಾ ಔಷಧ, ಅದು ಯಾವ ಕಂಪನಿಯದೇ ಆಗಲಿ ಒಂದೇ ಹೆಸರಿನಲ್ಲಿ ಇರಬೇಕಾಗುತ್ತದೆ. ಪ್ಯಾರಾಸಿಟಮಾಲ್‌ನ್ನು ಯಾವ ಕಂಪನಿಯೇ ಮಾಡಲಿ ಅದು ಪ್ಯಾರಸಿಟಮಾಲ್ ಮಾತ್ರ. ಆದಕ್ಕೆ ಬೇರೆ ಬೇರೆ ಬೆಲೆ ಇಟ್ಟರೆ ಸಹಜವಾಗಿ ಜನರು ಕಡಿಮೆ ಬೆಲೆಯದನ್ನು ಕೊಳ್ಳುತ್ತಾರೆ. ಆಗ ಬೆಲೆ ತಾನೇ ತಾನಾಗಿ ಒಂದೇ ಮಟ್ಟಕ್ಕೆ ಬಂದು ನಿಲ್ಲುತ್ತದೆ.

ವೈದ್ಯರೆಲ್ಲ ಕಾಲೇಜಿನಲ್ಲಿ ಓದುವಾಗ ಔಷಧಗಳ ಬಗ್ಗೆ ಕಲಿಯುವುದು ಸಂಪೂರ್ಣ ಜನರಿಕ್ ಹೆಸರುಗಳಲ್ಲಿಯೇ. ಎಲ್ಲಾ ವೈದ್ಯಕೀಯ ಪುಸ್ತಕಗಳಲ್ಲಿ ಕೊಟ್ಟಿರುವುದು ಜನರಿಕ್ ಹೆಸರುಗಳನ್ನೇ. ವಿದ್ಯಾರ್ಥಿ ವೈದ್ಯನಾಗುತ್ತಲೇ ಒಮ್ಮೆಗೇ ಜನರಿಕ್ ಹೆಸರು ಬಿಟ್ಟು ಬ್ರಾಂಡ್ ಹೆಸರುಗಳಲ್ಲಿ ಔಷಧಿಗಳನ್ನು ನೋಡಬೇಕಾಗುತ್ತದೆ. ಬರೆದು ಕೊಡಬೇಕಾಗುತ್ತದೆ. ಅದೂ ನಮ್ಮಲ್ಲಿರುವುದು ಒಂದೇ ಎರಡೇ ? 70,000 ಕ್ಕೂ ಮಿಕ್ಕ ಬ್ರಾಂಡ್‌ಗಳು ಅವನ್ನೆಲ್ಲ ಕಲಿಸುವವರಾದರೂ ಯಾರು ? ಔಷಧ ಕಂಪನಿಗಳ ಜಾಹೀರಾತುದಾರರು ಮಾತ್ರ. ತಮಗೇ ಗೊತ್ತಿಲ್ಲದ ಹೆಸರುಗಳನ್ನು ತಮಗೇ ಗೊತ್ತಿಲ್ಲದ ಅಳತೆಯಲ್ಲಿ ಈ ಹೊಸ ವೈದ್ಯರು ಬರೆದು ಕೊಡಬೇಕಾಗುತ್ತದೆ.

ಅದಾಗ್ಯೂ ಬ್ರಾಂಡ್ ಹೆಸರುಗಳೇ ಇರಲಿ ಎಂದು ವಾದಮಾಡುವವರೇ ವೈದ್ಯರು. ಬ್ರಾಂಡ್ ಇವರಿಗೆ ಅದೆಷ್ಟು ರೂಢಿಯಾಗಿ ಹೋಗಿದೆಯೆಂದರೆ ಜನರಿಕ್ ಹೆಸರುಗಳು ಇವರಿಗೆ ಮರೆತೇ ಹೋಗಿರಬಹುದು. ಎಂಥ ವಿಪರ್ಯಾಸ! ವಿಜ್ಞಾನದ ಮಂದಿ ಎಂದು ಹೇಳಿಕೊಳ್ಳುವ ವೈದ್ಯರು ಏನೂ

ಗೊತ್ತಿಲ್ಲದ ಜಾಹೀರಾತುದಾರ ಹೇಳಿದ್ದನ್ನೇ ನಂಬಿ ಬರೆದು ಕೊಡುವಂಥ ಪರಿಸ್ಥಿತಿ! ಔಷಧ ಕಂಪನಿಗಳು ಸೃಷ್ಟಿಮಾಡಿರುವ ವಿಷ ವರ್ತುಲವಿದು.

ಬ್ರಾಂಡ್ ಹೆಸರುಗಳಲ್ಲಿ ಔಷಧಗಳಿದ್ದರೆ ಮಾತ್ರ ಮಿಶ್ರ ಸಂಯುಕ್ತ (Fixed dose combination) ಗಳನ್ನು ತಯಾರಿಸಲು ಸಾಧ್ಯ. ಆದ್ದರಿಂದ ಜನೆರಿಕ್ ಹೆಸರುಗಳು ಬೇಡ ಎಂದು ಕಂಪನಿಗಳು ವಾದಿಸುತ್ತೆ. ಅಪ್ಪಟ ಸತ್ಯ. ಇದರಲ್ಲಿ ಸಂಶಯವೇ ಇಲ್ಲ. ಆದರೆ ಈ ಮಿಶ್ರ ಸಂಯುಕ್ತಗಳು ನಮಗೆ ಬೇಡವೇ ಬೇಡ. ಅವುಗಳಿಂದ ಯಾವುದೇ ಉಪಯೋಗವಿಲ್ಲ. ಬದಲಿಗೆ ಹಾನಿಯೇ ಹೆಚ್ಚು. ಹಾಗಾಗಿ ಜನೆರಿಕ್ ಹೆಸರು ಬೇಕೆನ್ನವವರು ಹೇಳುವ ಮಾತೂ ಇದೇ ಬ್ರಾಂಡ್ ಹೆಸರುಗಳು ಹೋದರೆ ಮಿಶ್ರ ಸಂಯುಕ್ತಗಳು ಪೇಟೆಯಿಂದ ಮರೆಯಾಗುತ್ತವೆ ಎಂದು.

ಜೆನರಿಕ್ ಹೆಸರು ಬಂದರೆ ಔಷಧಗಳ ಗುಣಮಟ್ಟ ಕಡಿಮೆ ಆಗುತ್ತದೆ. ತಮ್ಮ ಬ್ರಾಂಡ್‌ಗಳು ಉತ್ತಮವಾದವುಗಳು. ಯಾವುದೋ ಸಾಧಾರಣ ಕಂಪನಿಯ ಕಡಿಮೆ ಗುಣಮಟ್ಟದ ಔಷಧದೊಂದಿಗೆ ಸರಿಯಾಗಿ ಪರಿಗಣಿತವಾಗುತ್ತವೆ. ಬ್ರಾಂಡ್ ಹೆಸರುಗಳಲ್ಲಿ ನಾವು ನಮ್ಮ ಔಷಧದ ಗುಣಮಟ್ಟದ ಬಗ್ಗೆ ಭರವಸೆ ನೀಡುತ್ತೇವೆ ಎಂದು ದೊಡ್ಡ ದೊಡ್ಡ ಕಂಪನಿಗಳು ಹೇಳುತ್ತವೆ. ವಿಪರ್ಯಾಸವೆಂದರೆ ಇತ್ತೀಚೆಗೆ ನಡೆದ ಒಂದು ಶೋಧನೆಯಲ್ಲಿ ಬೆಳಕಿಗೆ ಬಂದ ಕಡಿಮೆ ಗುಣಮಟ್ಟದ ಔಷಧಗಳಲ್ಲಿ 50% ನಷ್ಟು ಇಂಥ ದೊಡ್ಡ ಪ್ರತಿಷ್ಠಿತ ಕಂಪನಿಗಳಿಂದ ತಯಾರಾದವುಗಳೇ. ಅಂದ ಮೇಲೆ ಇವರ ಭರವಸೆಯನ್ನು ಎಷ್ಟರ ಮಟ್ಟಿಗೆ ನಂಬಬಹುದು?

ಈ ಮುಂದೆ ನಿಷೇಧಿತ – ನಿಷೇಧ ಆಗಬೇಕಾದ ಔಷಧಗಳ ಹೆಸರು ಕೊಡುವಾಗ ಜನರಿಗೆ ಅರ್ಥವಾಗಲೆಂದು ಕೆಲವು ಜನಪ್ರಿಯ ಬ್ರಾಂಡ್ ಹೆಸರುಗಳನ್ನೂ ಕೊಟ್ಟಿದೆ.

ಔಷಧ ಮತ್ತು ಬಳಕೆದಾರರ ಹಕ್ಕುಗಳು

ಆರೋಗ್ಯ ಪ್ರತಿಯೊಂದು ಜೀವಿಯನ್ನು ಕಾಡುತ್ತದೆ. ಇದಕ್ಕೆ ಬಳಕೆದಾರರ ಹೊರತಲ್ಲ. ತನ್ನ ಜೀವಿತದ ಒಂದಲ್ಲ ಮತ್ತೊಂದು ಹಂತದಲ್ಲಿ ಬಳಕೆದಾರರು ರೋಗಿಗಳಾಗುತ್ತಾರೆ. ಈ ಕಾರಣದಿಂದಲೆ ಬಳಕೆದಾರರನ್ನು ಪೊಟೆನ್‌ಶಿಯಲ್ ರೋಗಿ ಎಂದು ಕರೆಯಲಾಗಿದೆ. ವಿಶ್ವ ಆರೋಗ್ಯ ಸಂಸ್ಥೆಯ ಪ್ರಕಾರ ಯಾರು ಆರೋಗ್ಯ ಸೇವೆಯನ್ನು ಪಡೆಯುತ್ತಾರೊ ಅವರೆಲ್ಲರೂ ರೋಗಿಗಳೆ. ಅವರು ಆರೋಗ್ಯವಂತರಾಗಿರ ಬಹುದು ಇಲ್ಲವೆ ಕಾಯಿಲೆಯಿಂದ ನರಳುತ್ತಿರಬಹುದು.

ನಾನಾ ರೀತಿಯ ರೋಗಗಳು ಬಳಕೆದಾರರನ್ನು ಆಕ್ರಮಿಸಬಹುದು. ಈ ಆಕ್ರಮಣವನ್ನು ತಡೆಗಟ್ಟುವ ಸಾಧನಗಳಲ್ಲಿ ಮುಖ್ಯವಾದದ್ದು ಔಷಧಗಳು. ಈ ಔಷಧಗಳಿಗೆ ರೋಗದಷ್ಟೇ ಹಳೆಯದಾದ ಚರಿತ್ರೆ ಇದೆ. ಆದರೆ ಕಾಲ ಕ್ರಮೇಣ ಔಷಧ ಮಾದರಿ, ರೂಪ, ಹೆಸರು ಇತ್ಯಾದಿ ಬದಲಾಗುತ್ತಾ ಬಂದಿದೆ. ಔಷಧ ನೀಡುವುದ ಒಂದು ಸೇವೆ ಎಂದು ಭಾವಿಸಿದ್ದ ಕಾಲ ಮುಗಿದು ಈಗ ಬೃಹತ್ ಉದ್ಯಮವಾಗಿದೆ. ಈಗ ಅದು ವ್ಯಾಪಾರ ಮಾತ್ರ. ಅದೇ ರೀತಿ, ಕೇವಲ ರೋಗಿಗಳು ಮಾತ್ರ ಔಷಧಿ ಸೇವಿಸುತ್ತಿದ್ದ ಕಾಲ ಹಿಂದೆ ಸರಿದು ಈಗ ಆರೋಗ್ಯವಂತರೂ ಔಷಧಗಳನ್ನೂ ಆಹಾರದಂತೆ ಸೇವಿಸಲು ಆರಂಭಿಸಿದ್ದಾರೆ.

ಈ ಹಿನ್ನೆಲ್ಲೆಯಲ್ಲಿ ಔಷಧಿವನ್ನು ಬಳಸುವ ಬಳಕೆದಾರರ ಹಕ್ಕುಗಳೇನು ಎಂಬುದನ್ನು ಆಲೋಚಿಸಬೇಕಾಗುತ್ತದೆ. ಕಾರಣ, ಔಷಧ ಹೆಚ್ಚಾದರೆ ಅಥವಾ ತಪ್ಪಾದರೆ ಅದು ವಿಷವಾಗುತ್ತದೆ. ಎಲ್ಲ ವಿಷಗಳೂ ಔಷಧವಾಗದಿರಬಹುದು. ಆದರೆ ಪ್ರತಿಯೊಂದು ಔಷಧವೂ ಸ್ವಲ್ಪಮಟ್ಟಿಗಾದರೂ ವಿಷವಾಗಿರುತ್ತದೆ.

ಮುವತ್ತು ವರ್ಷಗಳ ಹಿಂದೆ, ಅಂದಿನ ಅಮೇರಿಕದ ಅಧ್ಯಕ್ಷ ಜಾನ್. ಎಫ್. ಕೆನಡಿ ಅವರು ತಮ್ಮ ದೇಶದ ಪ್ರಜೆಗಳಿಗೆ ಕೆಲವು ಹಕ್ಕುಗಳನ್ನು ನೀಡಿದರು. ಅವುಗಳೆಂದರೆ ಸುರಕ್ಷತೆಯ ಹಕ್ಕು, ಮಾಹಿತಿಯ ಹಕ್ಕು, ಆಯ್ಕೆಯ ಹಕ್ಕು ಹಾಗೂ ಪರಿಹಾರ ಪಡೆಯುವ ಹಕ್ಕು. ಕೆಲವು ವರ್ಷಗಳ ನಂತರ ಆಂತರರಾಷ್ಟ್ರೀಯ ಗ್ರಾಹಕ ಸಂಸ್ಥೆಗಳ ಒಕ್ಕೂಟವು ಮತ್ತು ಷ್ಟು ಹಕ್ಕುಗಳನ್ನು ಸೇರಿಸಿತು. ಅವುಗಳೆಂದರೆ, ಮೂಲಭೂತ ಸೌಲಭ್ಯದ ಹಕ್ಕು, ಪ್ರತಿನಿಧಿಸುವ ಹಕ್ಕು. ಗ್ರಾಹಕ ಶಿಕ್ಷಣದ ಹಕ್ಕು ಮತ್ತು ಆರೋಗ್ಯ ಪೂರ್ಣ ಪರಿಸರದ ಹಕ್ಕು. ವಿಶ್ವ ಸಂಸ್ಥೆಯು ಈ ಎಲ್ಲ ಹಕ್ಕುಗಳನ್ನು ಅನುಮೋದಿಸಿದೆ.

ಬಳಕೆದಾರರ ಈ ಹಕ್ಕುಗಳು ಪದಾರ್ಥ, ವಸ್ತು ಹಾಗೂ ಸೇವೆಗಳಿಗೆ ಅನ್ವಯಿಸುವಂತೆ ಔಷಧಗಳಿಗೂ ಅನ್ವಯಿಸುತ್ತದೆ. ಉದಾಹರಣೆಗೆ ಸುರಕ್ಷತೆ. ಮಾರಾಟವಾಗುವ ಔಷಧಗಳು ಸುರಕ್ಷಿತವಾಗಿರಬೇಕು. ಮೊದಲೇ ಹೇಳಿದಂತೆ ಯಾವ ಔಷಧವೂ ಅಪಾಯದಿಂದ ಪೂರ್ಣಮುಕ್ತವಾಗಿರುವುದಿಲ್ಲ. ಅಪಾಯದ ಅಂಶವಿಲ್ಲದಿರುವ ಔಷಧ, ಔಷಧವೇ ಅಲ್ಲವೆಂದು ಹೇಳಲಾಗಿದೆ. ಆದರೆ, ಔಷಧಗಳು ಕನಿಷ್ಠ ಪಕ್ಷ ಸುರಕ್ಷಿತವಾಗಿರಬೇಕು ಹಾಗೂ ಉತ್ತಮ ಗುಣಮಟ್ಟ ಹೊಂದಿರಬೇಕು.

ಔಷಧಗಳ ಸುರಕ್ಷತೆ ಹಾಗೂ ಗುಣಮಟ್ಟದ ಬಗ್ಗೆ ವಿಶ್ವ ಆರೋಗ್ಯ ಸಂಸ್ಥೆಯು ಕೆಲವು ನಿಯಮಗಳನ್ನು ಪ್ರಕಟಿಸಿದೆ. ಸರ್ಕಾರಗಳು ಈ ನಿಯಮವನ್ನು ಜಾರಿಗೊಳಿಸಬೇಕು. ಜೊತೆಗೆ ಅವು ದೇಶದ ಔಷಧ ನೀತಿಯಲ್ಲಿ ಸೇರಿರಬೇಕು. ಆದರೆ ಬಹಳಷ್ಟು ತೃತೀಯ ರಾಷ್ಟ್ರಗಳಲ್ಲಿ ಈ ನಿಯಮ ಅನುಷ್ಠಾನಕ್ಕೆ ಬಂದಿಲ್ಲ. ಇದರ ಫಲವಾಗಿ ಕುಲಗೆಟ್ಟ, ಅಪಾಯಕಾರಿ ಔಷಧಗಳು ಮಾರಟವಾಗುತ್ತಿದೆ. ಉದಾಹರಣೆಗೆ, ಕೆಲವು ವರ್ಷಗಳ ಹಿಂದೆ ಮುಂಬಯಿನ ಆಸ್ಪತ್ರೆಯೊಂದರಲ್ಲಿ 14 ರೋಗಿಗಳು ಅಸುನೀಗಿದರು. ಅದಕ್ಕೆ ಕಾರಣ ಕುಲಗೆಟ್ಟ ಔಷಧ (ಗ್ಲಿಸರೀನ್) ಎಂದು ಜಸ್ಟೀಸ್ ಲೆಂಟನ್ ಆಯೋಗ ವರದಿ ಮಾಡಿತು. ಅದೆಷ್ಟೊ ಪ್ರಕರಣಗಳು ಬೆಳಕಿಗೆ ಬರುವುದಿಲ್ಲ.

ಬಳಕೆದಾರರ ಎರಡನೆಯ ಹಕ್ಕು ಮಾಹಿತಿ. ತಾವು ಖರೀದಿಸುವ ಯಾವುದೇ ವಸ್ತುವಾಗಿರಲಿ ಬಳಕೆದಾರರು ಅದರ ಬಗ್ಗೆ ಸಂಪೂರ್ಣವಾದ, ನಿಜವಾದ, ನಿಖರವಾದ ಮಾಹಿತಿಯನ್ನು ಪಡೆಯುವ ಸೌಲಭ್ಯವಿರಬೇಕು. ವಿಶೇಷವಾಗಿ ಔಷಧಿಯ ವಿಷಯದಲ್ಲಿ ಮಾಹಿತಿ ಮುಖ್ಯ ಪಾತ್ರವಹಿಸುತ್ತದೆ. ಸರ್ಕಾರ, ಆರೋಗ್ಯ ಅಧಿಕಾರಿಗಳು ಹಾಗೂ ಔಷಧ ತಯಾರಕರು ಈ ಮಾಹಿತಿಯನ್ನು ಒದಗಿಸಬೇಕು. ಸಮೂಹ ಮಾಧ್ಯಮ ಈ ವಿಷಯದಲ್ಲಿ ಹೆಚ್ಚಿನ ಸೇವೆ ಸಲ್ಲಿಸಬಹುದು.

ಆದರೆ ವಾಸ್ತವವಾಗಿ ನಡೆಯುತ್ತಿರುವುದೆ ಬೇರೆ. ಬಳಕೆದಾರರಿಗೆ ಔಷಧಿಯ ಬಗ್ಗೆ ನಿಖರವಾದ ಮಾಹಿತಿ ದೊರೆಯುತ್ತಿಲ್ಲ. ಜಾಹೀರಾತುಗಳು ಮಾಹಿತಿಯ ರೂಪ ಪಡೆದಿದೆ. ತಯಾರಕರು ಮತ್ತು ಮಾರಾಟಗಾರರು, ನೀಡುವ ವೈಭವೀಕರಿಸಿದ ಉತ್ಪ್ರೇಕ್ಷೆಯಿಂದ ಕೂಡಿದ ಜಾಹೀರಾತು ಮಾಹಿತಿ ಎಂದು ತಿಳಿಯಲಾಗಿದೆ. ಈ ಪರಿಸ್ಥಿತಿ ಬದಲಾಗಬೇಕು. ವಿಶ್ವ ಆರೋಗ್ಯ ಸಂಸ್ಥೆಯು ಔಷಧಗಳ ಬಗ್ಗೆ ಮಾಹಿತಿ ನೀಡುವ ಕೆಲವು ಕ್ರಮಗಳನ್ನು ಕೈಗೊಂಡಿದೆ. ನಮ್ಮ ದೇಶದಲ್ಲಿ ಕೆಲ ಸ್ವಯಂ ಸೇವಾ ಸಂಸ್ಥೆಗಳು ಔಷಧ ಮಾಹಿತಿ ಕೇಂದ್ರವನ್ನು ಸ್ಥಾಪಿಸಿದೆ. ಈ ಮೂಲಕ ಬಳಕೆದಾರರಿಗೆ ನಿಜವಾದ ಮಾಹಿತಿ ದೊರೆಯುವಂತಾಗಿದೆ.

ಬಳಕೆದಾರರ ಮೂರನೆಯ ಹಕ್ಕು ಆಯ್ಕೆಗೆ ಸಂಬಂಧಿಸಿದ್ದು. ಬಳಕೆದಾರರು ತಮಗೆ ಯಾವ ಔಷಧ ಬೇಕೊ ಅದನ್ನು ಖರೀದಿಸುವಂತಿರಬೇಕು. ಆ ಔಷಧಗಳು ದೊರೆಯುವಂತಿರಬೇಕು. ಮೇಲಾಗಿ ಆ ಔಷಧ ಕಡಿಮೆ ಬೆಲೆ ಇರಬೇಕು. ಆದರೆ ಮಾರುಕಟ್ಟೆಯಲ್ಲಿ 60 ಸಾವಿರಕ್ಕೂ ಹೆಚ್ಚು ಮಾದರಿ ಔಷಧಿಗಳಿದ್ದರೂ, ಅವುಗಳ ಬೆಲೆ, ಅಗತ್ಯ, ಇತ್ಯಾದಿ ಬಗ್ಗೆ ಶಂಕೆ ಮೂಡುತ್ತದೆ. ವಿಶ್ವ ಆರೋಗ್ಯ ಸಂಸ್ಥೆಯ ಪ್ರಕಾರ ಕೇವಲ 220 ಔಷಧಗಳು ಈಗಿರುವ ರೋಗಗಳನ್ನು ಗುಣಪಡಿಸಬಹುದು. ಆಯ್ಕೆಯ ಅವಕಾಶವಿದ್ದರೂ, ಅದು ಬಳಕೆದಾರರ ಕಲ್ಯಾಣಕ್ಕೆ ಪರಿವರ್ತನೆಗೊಂಡಿಲ್ಲ.

ಪ್ರತಿಯೊಂದು ಔಷಧಿಗೂ ಮೂರು ಹೆಸರುಗಳುಂಟು. ಮೊದಲನೆಯದು ರಸಾಯನಿಕ ಹೆಸರು. ನಂತರ ಜಾತಿವಾಚಕ ಹೆಸರು ಹಾಗೂ ಕಡೆಯದಾಗಿ ತಯಾರಕರು ನೀಡುವ ಬ್ರಾಂಡ್ ಹೆಸರು. ಜಾತಿವಾಚಕ (Generic) ಹೆಸರಿನಲ್ಲಿ ಔಷಧ ಮಾರಾಟ ಮಾಡಿದರೆ ಅದು ಅತ್ಯಂತ ಸುಲಭ ಬೆಲೆಯಲ್ಲಿ ದೊರೆಯುತ್ತದೆ. ಆಗ ಬಳಕೆದಾರರು ತಮ್ಮ ಆಯ್ಕೆಯ ಹಕ್ಕನ್ನು ಚಲಾಯಿಸಬಹುದು. ಈ ದಿಕ್ಕಿನಲ್ಲಿ ಪ್ರಯತ್ನಗಳು ಅವಶ್ಯ.

ಯಾವುದಾದರೂ ಔಷಧ ಸೇವನೆಯಿಂದ ಹಾನಿ ಉಂಟಾದರೆ ಬಳಕೆದಾರರು ಅದಕ್ಕೆ ತಕ್ಕ ಪರಿಹಾರ ಪಡೆಯುವ ಹಕ್ಕು ಹೊಂದಿದ್ದಾರೆ. ಆದರೆ ಅದು ಅಷ್ಟು ಸುಲಭದ ಕೆಲಸವಲ್ಲ. ಔಷಧದಿಂದಲೆ ಹಾನಿ ಸಂಭವಿಸಿತು ಎಂಬುದನ್ನು ನಿರೂಪಿಸುವುದು ಕಷ್ಟವಾದ ಕೆಲಸ. ಆದರೂ, ಈಗಾಗಲೇ ಗ್ರಾಹಕ ವೇದಿಕೆಗಳಲ್ಲಿ ಕೆಲವು ಪ್ರಕರಣಗಳು ಇತ್ಯರ್ಥಗೊಂಡಿದೆ. ಕುಲಗೆಟ್ಟ ಕಣ್ಣಿನ ಔಷಧದಿಂದ, ದೃಷ್ಟಿ ಕಳೆದುಕೊಂಡ ಬಳಕೆದಾರರು, ಪರಿಹಾರ ಪಡೆದಿದ್ದಾರೆ. ದೋಷಯುಕ್ತ ಗ್ಲುಕೋಸ್ (ಐವಿ ಫ್ಲೂಯಿಡ್) ನೀಡಿದ ಪರಿಣಾಮವಾಗಿ ಆರೋಗ್ಯ ಕೆಟ್ಟು. ಅದಕ್ಕೆ ಪರಿಹಾರ ಪಡೆದ ಪ್ರಕರಣಗಳೂ ಇದೆ.

ದಿನಬಳಕೆಯ ವಸ್ತುಗಳು ವಿಷಯಕ್ಕಿಂತ ಹೆಚ್ಚಾಗಿ, ಔಷಧಿಯ ವಿಷಯದಲ್ಲಿ ಬಳಕೆದಾರರ ಹಕ್ಕುಗಳು ಬಹಳ ಮುಖ್ಯವಾಗುತ್ತದೆ.

ನಮಗೆ ಬೇಕು ಅಗತ್ಯ ಔಷಧಿಗಳು

ಡಾಕ್ಟ್ರೇ ಒಳ್ಳೇ ಔಷಧಿ ಬರೆದು ಕೊಡಿ ಎಂದು ಅನೇಕಬಾರಿ ರೋಗಿಗಳು ವೈದ್ಯರನ್ನು ಕೇಳುವುದುಂಟು. ರೋಗಿಯ ಕಲ್ಪನೆಯಲ್ಲಿ ಒಳ್ಳೆಯ ಔಷಧಿ ಎಂದರೆ ಸಂಪೂರ್ಣ ಗುಣಮಾಡುವ, ಕಡಿಮೆ ಬೆಲೆಯ, ಅಡ್ಡ ಪರಿಣಾಮವಿಲ್ಲದ ಔಷಧಿ. ಈ ತರಹದ ಒಳ್ಳೆಯ ಔಷಧಿಗಳು ಇವೆಯೇ ?

ವಿಶ್ವ ಆರೋಗ್ಯ ಸಂಸ್ಥೆ (ವಿ.ಆ.ಸಂ.) ಮಾರುಕಟ್ಟೆಯಲ್ಲಿರುವ ಎಲ್ಲ ಔಷಧಿಗಳನ್ನು (70ರ ದಶಕದಲ್ಲಿ) ಪರಿಶೀಲಿಸಿದಾಗ ಹೆಚ್ಚಿನ ಔಷಧಿಗಳು ಅನಗತ್ಯ ಎಂದು ತಿಳಿದು ಬಂದಿತು. ವಿ.ಆ.ಸಂ. ಕೆಲವು ಅತ್ಯಗತ್ಯವಾದ ಔಷಧಿಗಳನ್ನು ಗುರುತಿಸಿ ಒಂದು ಅಗತ್ಯ ಔಷಧಿ ಪಟ್ಟಿ ತಯಾರಿಸಿ, 1977ರಲ್ಲಿ ಜಾರಿಗೊಳಿಸಿತು. ಜಗತ್ತಿನ ಎಲ್ಲ ರಾಷ್ಟ್ರಗಳಿಗೆ ಈ ಮಾದರಿ ಪಟ್ಟಿಯ ಆಧಾರದ ಮೇಲೆ ಒಂದು ಔಷಧಿ ಪಟ್ಟಿಯನ್ನು ತಯಾರಿಸಿ ಕೊಳ್ಳಲು ಕರೆಕೊಟ್ಟಿತು. ಈ ಪಟ್ಟಿಯಲ್ಲಿರುವ ಔಷಧಿಗಳನ್ನು ಎರಡು ವರ್ಷಕ್ಕೊಮ್ಮೆ ಪುನಃ ಪರಿಶೀಲಿಸಿ, ಆ ಔಷಧಿಗಳಿಗಿಂತ ಇನ್ನೂ ಹೆಚ್ಚು ಪ್ರಯೋಜನಕಾರಿ ಔಷಧಿ ಇದ್ದಲ್ಲಿ ಆ ಔಷಧಿಯನ್ನು ಪಟ್ಟಿಯಲ್ಲಿ ಸೇರಿಸಿಕೊಳ್ಳುವ ಸೌಲಭ್ಯವನ್ನು ಕಲ್ಪಿಸಿತು. ಭಾರತ ಸರ್ಕಾರ ಈ ಸಲಹೆಗೆ ಒಪ್ಪಿತಾದರೂ ಇತ್ತೀಚಿನವರೆಗೆ ಅಗತ್ಯ ಔಷಧಿ ಪಟ್ಟಿಯನ್ನು ಜಾರಿಗೆ ತರಲಿಲ್ಲ. ಭಾರತದಲ್ಲಿ ಹಾಫೀ ವರದಿ ಇಂತಹದೇ ಒಂದು ಅಗತ್ಯ ಔಷಧಿ ಪಟ್ಟಿಯನ್ನು ತಯಾರಿಸುವಾಗ ಇದನ್ನು ಆಧಾರವಾಗಿ ಬಳಸಿದೆ ಎಂಬುದು ಗಮನಾರ್ಹ.

ಅಗತ್ಯ ಔಷಧಿ ಎಂದರೆ ಯಾವ ಔಷಧಿ

ಚಿಕಿತ್ಸೆಗೆ ಅತ್ಯಗತ್ಯವಾಗಿರುತ್ತದೆಯೋ

ಚಿಕಿತ್ಸೆ ಪರಿಣಾಮಕಾರಿಯಾಗಬಲ್ಲದೋ

ಅಡ್ಡ ಪರಿಣಾಮಗಳಿದ್ದಾಗ್ಯೂ ಸುರಕ್ಷಿತವಾಗಿರುತ್ತದೆಯೋ

ಕಡಿಮೆ ಬೆಲೆಯಲ್ಲಿ ದೊರಕುತ್ತಿದ್ದು, ಜನಸಾಮಾನ್ಯರಿಗೆ ಕೊಂಡು ಕೊಳ್ಳಲು ಸಾಧ್ಯವಾಗುವುದೋ, ಸುಲಭವಾಗಿ ದೊರಕುವುದೋ

ಆ ಔಷಧಿಯನ್ನು ಅಗತ್ಯ ಔಷಧಿ ಎನ್ನಬಹುದಾಗಿದೆ.

ಭಾರತದಲ್ಲಿ ದೊರಕುವ ಔಷಧಿಗಳನ್ನು ಪರಿಶೀಲಿಸಿದಾಗ, ನಮ್ಮಲ್ಲಿ ಅಗತ್ಯ, ಅನಗತ್ಯ ಹಾಗೂ ಅಗತ್ಯ ವಿಲ್ಲದ ಔಷಧಿಗಳು ಇರುವುದು ಕಂಡುಬರುತ್ತದೆ. ಮಾರುಕಟ್ಟೆಯಲ್ಲಿ ದೊರಕುವ ಹೆಚ್ಚಿನ ಔಷಧಿಗಳು ಸರಕಾರೀ ಕೇಂದ್ರಗಳಲ್ಲಿ ಅಗತ್ಯ ಔಷಧಿಗಳು ದೊರಕುತ್ತಿದ್ದರೂ, ಕೆಲವುಬಾರಿ ಕೊರತೆಯುಂಟಾಗುತ್ತದೆ. ಔಷಧಿ ಶಾಸ್ತ್ರದ (Pharmacology) ಪಾಠ್ಯ ಪುಸ್ತಕಗಳಲ್ಲಿ ಇಲ್ಲಿಯವರೆಗೆ ಸಂಶೋಧಿಸಲಾದ ಎಲ್ಲ ಔಷಧಿಗಳನ್ನು ಚರ್ಚಿಸಲಾಗುತ್ತದೆ. ಅವುಗಳಲ್ಲಿ ಅಗತ್ಯವಲ್ಲದ ಅನೇಕ ಔಷಧಿಗಳೂ ಸೇರಿವೆ. ಈ ಅನಗತ್ಯವಲ್ಲದ ಔಷಧಿಗಳು ದಿನನಿತ್ಯದ ಎಲ್ಲ ಕಾಯಿಲೆಗಳಿಗೆ ಮೇಲಿಂದ ಮೇಲೆ ಉಪಯೋಗಿಸಲು ಯೋಗ್ಯವಾಗಿರದೇ , ಕೆಲವು ವಿಶೇಷ ಸಂಧರ್ಭಗಳಲ್ಲಿ ಮಾತ್ರ ಉಪಯೋಗಿಸಬಹುದಾಗಿದೆ, ಆದ್ದರಿಂದ ಈ ಔಷಧಿಗಳನ್ನು ಅಗತ್ಯ ಔಷಧಿಗಳೆಂದು ಪರಿಗಣಿಸ ಲಾಗುವುದಿಲ್ಲ.

ವಿ.ಆ. ಸಂಸ್ಥೆಯ ಪಟ್ಟಿಯಲ್ಲಿ ಸುಮಾರು 260 ಔಷಧಿಗಳನ್ನು ಅಂದರೆ 700 ಮಾರುಕಟ್ಟೆಯಲ್ಲಿ ದೊರಕುವ ಔಷಧಿಗಳನ್ನು (Formulations) ಸೇರಿಸಲಾಗಿದೆ. ಆದರೆ ಇಂದು ಭಾರತದ ಮಾರುಕಟ್ಟೆಯಲ್ಲಿ ಸುಮಾರು 70,000 ಔಷಧಿಗಳಿವೆಯೆಂದು ಹೇಳಬಹುದಾಗಿದೆ. ಮಾರುಕಟ್ಟೆಯಲ್ಲಿ ದೊರಯುವ 5 ಔಷಧಿಗಳಲ್ಲಿ ಒಂದು ಮಾತ್ರ ಅಗತ್ಯ ಔಷಧಿ ಎಂದು ಹೇಳಬಹುದು.

ಇಂದಿನ ನಮ್ಮ ದೇಶದ ಪರಿಸ್ಥಿತಿ ಜಗತ್ತಿನ ಅನೇಕ ದೇಶಗಳಲ್ಲಿ 70ರ ದಶಕಗಳಲ್ಲಿ ಕಂಡುಬಂದಿತ್ತು. ವಿ. ಆ. ಸಂಸ್ಥೆಯ ಅಗತ್ಯ ಔಷಧಿ ಪಟ್ಟಿಯ ಆಧಾರದ ಮೇಲೆ ಅನೇಕ ಅನೇಕ ರಾಷ್ಟ್ರಗಳು ತಮ್ಮ ಅಗತ್ಯ ಔಷಧಿ ಪಟ್ಟಿಯನ್ನು ರೂಪಿಸಿಕೊಂಡು ಜಾರಿಗೊಳಿಸಿದವು ಹಾಗೂ ತಮ್ಮ ಔಷಧಿಸ್ಥಿತಿಯನ್ನು ಸುಧಾರಿಸಿಕೊಂಡಿತು. ಉದಾ. ಬಾಂಗ್ಲಾದೇಶ್, ಶ್ರೀಲಂಕ ಇತ್ಯಾದಿ.

ಅಗತ್ಯ ಔಷಧಿಗಳು ಹೇಗೆ ಇತರೇ ಔಷಧಿಗಳಿಗಿಂತ ಹೆಚ್ಚು ಪ್ರಯೋಜಕ?

ಅಗತ್ಯ ಔಷಧಿಗಳು, ವೈಜ್ಞಾನಿಕವಾಗಿ ರುಜುವಾತಾಗಿರುವ ಔಷಧಿಗಳು ಈ ಔಷಧಿಗಳನ್ನು ರೋಗ ನಿವಾರಣೆ ಹಾಗೂ ರೋಗ ಚಿಕಿತ್ಸೆಗೆ ಪರಿಣಾಮಕಾರಿಯಾಗಿ ಉಪಯೋಗಿಸಬಹುದಾಗಿದೆ.

ಈ ಔಷಧಿಗಳು ಸಾಮಾನ್ಯವಾಗಿ ಒಂದೇ ಘಟಕದ್ದಾಗಿರುತ್ತದೆ. ವಿ. ಆ. ಸಂ. ಕೆಲವು ಎರಡು ಘಟಕಗಳಿರುವ ಸಂಯಕ್ತ ಔಷಧಿಗಳನ್ನು ಗುರುತಿಸಿದೆ. ಔಷಧಿ ಕಂಪನಿಗಳ ಸಂಯಕ್ತ ಔಷಧಿಗಳಿಗೆ ಯಾವ ವೈಜ್ಞಾನಿಕ ಆಧಾರವೂ ಇಲ್ಲ. ಈ ಸಂಯುಕ್ತ ಔಷಧಿ ಚಿಕಿತ್ಸೆ ದುಬಾರಿಯಾಗುತ್ತದೆ. ಹಾಗೂ ಹಾನಿಯೂ ಹೆಚ್ಚು. ಈ ಔಷಧಿಗಳ ಉಪಯೋಗದಿಂದ ಉಂಟಾದ ಅಡ್ಡ ಪರಿಣಾಮವು ಯಾವ ಘಟಕದಿಂದ ಎಂದು ನಿರ್ಧರಿಸುವುದು ಕಷ್ಟ. ಈ ಔಷಧಿ ತಯಾರಿಕೆಗೆ ಹಾಗೂ ಜಾಹಿರಾತಿಗೆ ಆಗುವ ವೆಚ್ಚವನ್ನು ಗ್ರಾಹಕ ತೆರಬೇಕಾಗುತ್ತದೆ. ಅಗತ್ಯ ಔಷಧಗಳ ಗುಣಮಟ್ಟ ಕಂಡು ಹಿಡಿಯುವುದು ಸುಲಭ.

ಔಷಧಿ ವ್ಯಾಪಾರಿಗೆ ಆಸ್ಪತ್ರೆ ಹಾಗೂ ಸರಕಾರಕ್ಕೆ ಔಷಧಿ ಶೇಖರಿಸಲು ಉಂಟಾಗುವ ಗೊಂದಲ ಕಡಿಮೆಯಾಗುತ್ತದೆ.

ವೈದ್ಯರಿಗೆ ಔಷಧಿಗಳನ್ನು ಬರೆದು ಕೊಡಲು ಸುಲಭವಾಗುತ್ತದೆ ಅನಗತ್ಯ ಔಷಧಿ ತಯಾರಿಸಲು ಉಪಯೋಗವಾಗುವ ಕಚ್ಚಾವಸ್ತುಗಳ ದುರ್ಬಳಕೆಯನ್ನು ಕಡೆಯಬಹುದಾಗಿದೆ.

ಅಗತ್ಯ ಔಷಧಿಗಳ ಒಟ್ಟು ಸಂಖ್ಯೆ ಸುಮಾರು 260, ಆದರೆ ಈ ಎಲ್ಲ ಔಷಧಿಗಳು ಎಲ್ಲ ಹಂತದಲ್ಲೂ ಬೇಕಾಗುವುದಿಲ್ಲ. ಅಗತ್ಯವಿರುವ ಔಷಧಿ ಸಂಖ್ಯೆ ಪ್ರತಿ ಹಂತದಲ್ಲೂ ಬದಲಾಗುತ್ತದೆ. ಪ್ರಾಥಮಿಕ ಆರೋಗ್ಯ ಕೇಂದ್ರದ ಮಟ್ಟದಲ್ಲಿ 30 ರಿಂದ 40 ಔಷಧಿಗಳು ಸಾಕಾಗುತ್ತದೆ. ಜಿಲ್ಲಾ ಆಸ್ಪತ್ರೆ ಮಟ್ಟದಲ್ಲಿ 100 ರಿಂದ 120 ಹಾಗೂ ವೈದ್ಯಕೀಯ ಕಾಲೇಜ್ ಆಸ್ಪತ್ರೆ ಮಟ್ಟದಲ್ಲಿ 260 ಔಷಧಿಗಳು ಬೇಕಾಗಬಹುದು.

ಆದರೂ ಇಂದು ನಮ್ಮ ದೇಶದಲ್ಲಿ ಏಕೆ ಇಷ್ಟೊಂದು ಔಷಧಿಗಳಿವೆ ? ಔಷಧಿ ಕಂಪನಿಗಳ ಮುಖ್ಯ ಉದ್ದೇಶ ಲಾಭಗಳಿಸುವುದು. ಬಹು ರಾಷ್ಟ್ರೀಯ ಕಂಪನಿಗಳು ಲಾಭಗಳಿಸಲು ಉಪಯೋಗಿಸಿದ ವಿವಿಧ ವಿಧಾನಗಳನ್ನು ಹಾಫೀ ಸಮಿತಿ ವರದಿ ನೀಡಿದೆ. ಭಾರತೀಯ ಕಂಪನಿಗಳು ಈ ಕಾರ್ಯದಲ್ಲಿ ಹಿಂದೆ ಬಿದ್ದಿಲ್ಲ. ಅಗತ್ಯ ಔಷಧಿ ತಯಾರಿಸುವುದು ಕೆಲವು ಬಾರಿ ಕಡ್ಡಾಯವಾದರೂ, ಔಷಧಿ ಕಂಪನಿಗಳು ಈ ನಿರ್ಧಂಧನೆಯನ್ನು ಜಡೆಗ ಣಿಸಿವೆ.

ಸರಕಾರ ಅಗತ್ಯ ಔಷಧಿ ದೊರಕುವಿಕೆ ಬಗ್ಗೆ ಸಂಪೂರ್ಣ ನಿರ್ಲಕ್ಷ ತೋರಿಸಿದೆ. ಔಷಧಿ ನಿಯಂತ್ರಣ ಔಷಧಿಗಳ ಅಗತ್ಯತೆಯ ಬಗ್ಗೆ ಯಾವ ನಿಲುವನ್ನೂ ಹೊಂದದೆ ಔಷಧಿ ಕಂಪನಿಗಳಿಗೆ ಸಹಾಯ ಮಾಡುತ್ತಿದೆ ಎಂದು ಸ್ಪಷ್ಟವಾಗುತ್ತದೆ. ಇದರ ಪರಿಣಾಮವಾಗಿ ಇಂದು ಮಾರುಕಟ್ಟೆಯಲ್ಲಿ ಅನಗತ್ಯ ಔಷಧಿಗಳು ಹೆಚ್ಚಿನ ಪ್ರಮಾಣದಲ್ಲಿ ದೊರಕುತ್ತಿವೆ. ಅನಗತ್ಯ ಔಷಧಿಗಳಲ್ಲಿ ಕೆಲವು ಅಪಾಯಕಾರಿ ಹಾಗೂ ಇನ್ನೂ ಕೆಲವು ಔಷಧಿ ಗುಣವುಳ್ಳದವು (ಅನುಮಾನಾಸ್ಪದ ಔಷಧಿ). ಅನೇಕ ಔಷಧಿಗಳು ಇತರೇ ದೇಶಗಳಲ್ಲಿ ನಿಷೇಧಿಸಲ್ಪಟ್ಟವು.

- ನಮ್ಮಲ್ಲಿ ದೊರಯುವ ನಿಕ್ಷೇಧಿಸಲು ಯೋಗ್ಯವಿರುವ ಅನಗತ್ಯ ಔಷಧಿಗಳು

(1) ಸಂಯಕ್ತ ಔಷಧಿಗಳು : ಭಾರತದ ಮಾರುಕಟ್ಟೆಯಲ್ಲಿ ದೊರೆಯುವ ಪ್ರತಿಶತ 80 ಔಷಧಿಗಳು ಸಂಯಕ್ತ ಔಷಧಿಗಳು. ಈ ಔಷಧಿಗಳು ಔಷಧಿ ಕಂಪನಿಗಳಿಗೆ ತಮ್ಮ ಭ್ರಾಂಡ್ ಜನಪ್ರಿಯಗೊಳಿಲು ಸಹಯಕವಾಗುತ್ತವೆ.

ಅನೇಕ ಬಾರಿ ವೈದ್ಯರಿಗೂ ಬ್ರಾಂಡ್ ಔಷಧಿ ಯಾವ ಯಾವ ಔಷಧಿ ಘಟಕಗಳಿಂದ ಮಾಡಲ್ಪಟ್ಟಿದೆ. ಎಂದು ತಿಳಿದರುವುದಿಲ್ಲ. ಈ ಔಷಧಿಗಳು ದುಬಾರಿ ಹಾಗೂ ಅವೈಜ್ಞಾನಿಕ.

ಉದಾ: ಕಾಂಬಿಪ್ಲಾಮ್, ಡೈಜಿನ್, ಸಿಫ್ರಿನ್ ಸಿ.ಟಿ.

(2) ಟಾನಕ್‌ಗಳು : ಬೇಯರ್ಸ್ ಟಾನಿಕ್, ಸ್ಯಾಂಟಿವಿನಿ, ಡೆಕ್ಸಾರೆಂಜ್

(3) ನೆಗಡಿ ಕೆಮ್ಮಿನ ಔಷಧಿಗಳು : ಆ್ಯಕ್ಷನ್ 500 ಕೋಲ್ಡರಿನ್, ಕೊಸಾವಿಲ್

(4) ಹೆಚ್ಚು ಪ್ರಾಮಾಣವುಳ್ಳ ವಿಟಮಿನ್‌ಗಳು ನ್ಯೂರೋಬಿಯಾನ್, ಬೆಕನೂಲನಿ ಕೊಬಾಡಕ್ತ

(5) ಆಹಾರ ಜೀರ್ಣಿಸಲು ಉಪಯೋಗಿಸುವ ಕಿಣ್ವಗಳು (ಅನುಮಾನಾಸ್ಪದ ಔಷಧಿ) ವಿಟರೆಕ್ಸಿವ್, ಡೈಜೇಪ್ಲೆಕ್ಸ್

(6) ಹಸಿವು ಹೆಚ್ಚಿಸಲು ಔಷಧಿಗಳು (ಔಷಧಿ ವಿಜ್ಞಾನದ ದುರುಪಯೋಗ)

(7) ಅನಾಲ್ಜೆನ್ (ಅಪಾಯಕಾರಿ ಔಷಧಿ) ನೋವಾಲ್‌ಜಿನ್, ಬರಾಲ್ಗನ್ ಎಮ್.

(8) ರಕ್ತಸ್ರಾವ ನಿಲ್ಲಿಸುವ ಔಷಧಿಗಳು (ಅಮಾನಾಸ್ಪದ ಔಷಧಿಗಳು) ಬಾಟ್ರೋಪಾನ್, ಗೈನ್ ಸಿ.ವಿ.ಸಿ.

(9) ಮೆದುಳಿನ ಟಾನಿಕ್‌ಗಳು (ಅನುಮಾನಾಸ್ಪದ ಔಷಧಿಗಳು) ಎನ್‌ಸೆಫ್‌ಬಾಲ್, ನೊಟ್ರೋಪಿಲ್

(10) ಕೆಮ್ಮಿನ ಟಾನಿಕ್‌ಗಳು (ಅನುಮಾನಾಸ್ಪದ ಔಷಧಿಗಳು) ಪ್ಲಾಂಥರ್, ಬೆನೆಡ್ರಿಲ್ ಫಾರ್ಮುಲಾ)

(11) ಬೇಧಿನಿವಾರಕಗಳು : ನಾರ್‌ಪ್ಲಾಕ್ಸ್, ಇತ್ಯಾದಿ

ಈ ಔಷಧಿಗಳು ಇಂದು ಮಾರುಕಟ್ಟೆಯಲ್ಲಿ ದೊರಕಲು ವೈದ್ಯರ ಪಾತ್ರವೂ ಇದೆ. ವೈದ್ಯರಿಗೆ ಅಗತ್ಯ ಔಷಧಿಗಳ ಬಗ್ಗೆ ತಿಳುವಳಿಗೆ ಕೊಡದೆ ಇದ್ದುದರಿಂದ ವೈದ್ಯರು ಅನಗತ್ಯ ಔಷಧಿಗಳನ್ನು ಬರೆದು ಕೊಡುತ್ತಾರೆ ಎಂಬ ವಾದ ಅರ್ಥವಿಲ್ಲದ್ದು, ಕಾರಣ ಇಂದು ದೊರಕುವ ಅನಗತ್ಯ ಔಷಧಿಗಳಬಗ್ಗೆ ಪಾಠ್ಯ ಪುಸ್ತಕಗಳಲ್ಲಿ ಯಾವ ಪ್ರಸ್ತಾಪವಿಲ್ಲ. ಆದರೂ ಬರೆದು ಕೊಡುತ್ತಿಲ್ಲವೇ? ವೈದ್ಯರು ಅನಗತ್ಯ ಔಷಧಿ ಬರೆದು ಕೊಡಲು ಔಷಧಿ ಕಂಪನಿಗಳ ಪ್ರಭಾವ ಹೆಚ್ಚಿದೆ. ಚಿಕಿತ್ಸೆಯಲ್ಲಿ ವೈದ್ಯರ ಪರಿಣತಿ, ರೋಗಿಯ ಸಹಕಾರ ಅತಿಮುಖ್ಯವಾದರೂ ಅಗತ್ಯ ಔಷಧಿಗಳು ಪಾತ್ರವನ್ನು ಕಡೆಗಣಿಸುವಂತಿಲ್ಲ. ಆದರೆ ವೈದ್ಯರೇ ಔಷಧಿಗಳ ಪಾತ್ರವನ್ನು ಕಡೆಗಣಿಸಿದಂತಿದೆ.

ಬಡತನ ಅನಕ್ಷರತೆ ಇರುವ ನಮ್ಮ ದೇಶದಲ್ಲಿ ಅನಗತ್ಯ ಔಷಧಿಗಳಿಂದ ಹಾಗೂ ಅಗತ್ಯ ಔಷಧಿಗಳ ಕೊರತೆಯಿಂದ ಜನರಿಗೆ ತೊಂದರೆ ಉಂಟಾಗುತ್ತಿದೆ. ಇಂದು ಔಷಧಿಗಳನ್ನು ಉಪಯೋಗಿಸಲು ಗ್ರಾಹಕ ತೀರ್ಮಾನ ಮಾಡದೇ ವೈದ್ಯರೇ ತೀರ್ಮಾನ ಮಾಡುವಾಗ ಅಗತ್ಯ ಔಷಧಿ ಪರಿಕಲ್ಪನೆ ಅವರಿಗೆ ಇಲ್ಲದಿರುವುದು, ದುರಂತವೆನಿಸುವುದಿಲ್ಲವೇ? ಒಳ್ಳೆಯ ಔಷಧಿ ಬರೆದುಕೊಡಿ ಎಂದು ಮುಗ್ಧವಾಗಿ ಕೇಳುವ ರೋಗಿಗೆ ವೈದ್ಯರು ಯಾವ ಉತ್ತರ ಕೊಡಬಲ್ಲವರಾಗಿದ್ದಾರೆ.

ನಮ್ಮ ಔಷಧಿ ಪರಿಸ್ಥಿತಿಯನ್ನು ಸುಧಾರಿಸಲು ಗ್ರಾಹಕ ಚಿಂತನೆ ಹೆಚ್ಚಿ ಅಗತ್ಯ. ಔಷಧಿ ಪಟ್ಟಿಯನ್ನು ಜಾರಿಗೊಳಿಸಲು ಚಳುವಳಿ ಆಗಬೇಕು. ಈ ಚಳುವಳಿಯಲ್ಲಿ ನೀವು ಭಾಗವಹಿಸಲು ಸಿದ್ದರೇ ?

ಡಾ॥ ಪ್ರಕಾಶ್ ಸಿ. ರಾವ್
ಕಾರ್ಯದರ್ಶಿ, ಔಷಧಿ ಕ್ರಿಯಾ ವೇದಿಕೆ
ಬೆಂಗಳೂರು

Facts you should know about Colour Adulteration

Colour adulteration is the most frequent form of adulteration.

No artificial food colouring is really safe

Colours are not foods and do not add to the nutritive value of foods

Colour serves to mask defects in food making inferior foods look superior

Colouring are high risk for children and the foetus in a pregnant mother

Colourings may react with the food and/of change to poisons in the body, causing mutations cancer or other toxic effects.

What is Food Adulteration

Use of any colour prohibited under the Prevention of Food Adulteration Act, in or upon and food or beverage

Use of marketed colours not stamped with the ISI mark of quality

Use of colour on foods such as rice, pulses, spices tea and coffee, where food laws do not permit artificial colouring

Use of permitted colours exceeding the maximum permissible limit of 0.2 gram of dye per Kg of the final food or beverage

Why Colour Adulteration

Consumers demand colour and variety in foods

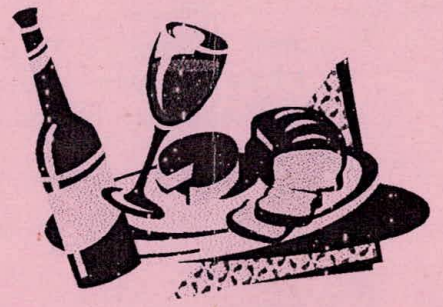
Availability of a wide range of colours that can produce the desired shade in foods

Food laws permit artificial colouring of certain foods

The consuming desire of traders to make their goods look superior and attractive and thereby increase sales and profit

Consumer ignorance, carelessness, indifference and lack of organised action to check the menace

Inadequate enforcement of food laws and absence of deterrent punishment for offenders



Simple Tests to Detect Colour Adulteration

Colour/ Simple Test

Metanil yellow (in rice pulav, ladoo, jelebi, halwa, gur, beverages, turmeric, mixed spices, saffron etc.)

Shake portion of the food with cold water, the water will turn yellow. Dilute the water till almost colourless and add few drops of concentrated hydrochloric acid. It will turn Red.

Rhodamine B or other red colour (on red chilli whole)

Rub the outside of the red chilli with cotton soaked in liquid paraffin. Cotton will become red.

Coal Tar Dye (in butter)

Dissolve 2 ml. of melted butter in ether, shake with 2 ml. of hydrochloric acid (1 part concentrated acid plus 1 part water) Allow to settle. Lower acid layer will turn pink or red in the presence of coal tar dye

Consumers role in checking colour Adulteration

Create consumer awareness of the evil and its consequences

Help monitor the adulteration and check the sale of adulterated stuff with the Government help, wherever necessary

Use natural coloured foods to brighten up means and teach others to do the same. If artificial colouring is a must, buy colours with ISI stamp

Reject artificially coloured rice, pulses, sweets, spices and beverages

Get organised and fight the menace

Health effects of common food colourings

1. Metanil Yellow:
   Degeneration of reproductive organs, sterility, stomach trouble, cancer

2. Lead Chromate:
   Anaemia, paralysis, brain damage, specially in children

3. Auramine Rhodamine B Blue
   VRS Orange II:
   Pathological lesions in vital organs like kidney, spleen and/or liver, cancer

4. Malachite green:
   Tumours in liver, lung, breast ovary and birth defects in offspring

5. Amarnath:
   Mutagenic

6. Ponceau 4R
   Lowering of red cell counts and haemoglobin in concentration

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Information Source:
Super Bazar, New Delhi

Suggested contribution : Rs.2/-

The Consumer Rights, Education and Awareness Trust (CREAT) is a non-profit, voluntary, non-political organisation working to promote consumer awareness. CREAT was established in Dec. 1993 and is registered as a public charitable Trust.

CREAT represents consumers in Petroleum consumer advisory committee, Chamber of Commerce (Consumer Affairs Committee). The activities of CREAT include publications, training, advocacy, redressal of grievances, consumer counselling, etc...

Associate membership fee Rs.100/- per year.

Consumer Awareness Series - 8

COLOUR ADULTERATION

CREAT
Consumer Rights, Education and Awareness Trust
239, 5th C Main, Remco Layout, Vijayanagar
BANGALORE: 560 040
Phone: 3403170