

**Malaysia's Experience in
Increasing Access to Antiretroviral
Drugs: Exercising the
'Government Use' Option**

Chee Yoke Ling

TWN

Third World Network

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THE UNIVERSITY HEALTH CELL

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NOTE:

This paper is based on data and information from the Pharmaceutical Services Division, Ministry of Health, Malaysia.

1

Background

MALAYSIA has a population of 24 million. In the period 1986 to June 2005, the number of recorded HIV patients was 63,438 while AIDS patients numbered 10,044. Recorded AIDS deaths were 7,673. There are already 15,000 children orphaned by AIDS in the country.

The World Health Organization in June 2005 warned that an HIV epidemic is knocking on Malaysia's door¹. The figures, according to health authorities and NGOs, are a conservative estimate.

The budget in 2003 for pharmaceutical drugs of the Malaysian Ministry of Health (MOH) was USD 193.6 million, of which USD 3.6 million was for antiretroviral drugs (ARVs). Since prices of ARVs are high, and about 75% of the HIV positive persons are intravenous drug users who largely cannot afford treatment, the MOH was faced with the challenge of increasing access to affordable ARVs.

In facing the challenges of HIV/AIDS through the provision of antiretroviral drugs, the MOH underwent an experience that may be useful for other developing countries.

At the initiative of the MOH, in 2003, Malaysia became the first country to issue a compulsory licence following the adoption of the Doha Declaration on the TRIPS Agreement and Public Health by the 2001 Ministerial Conference of the World Trade Organisation (WTO).

¹ UNAIDS/WHO Report on the Global HIV/AIDS Epidemic 2004

The Declaration reaffirmed the rights, flexibilities and safeguards vested in WTO Members by the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). One of these is the use of compulsory licences on grounds to be determined by national law.

The 'Government Use' or 'public non-commercial use' option can be described as a special type of compulsory licence, whereby there is no need to have prior unsuccessful negotiations with the patent holder before authorising the import or manufacture of the subject matter of a patent.

Thus for the purposes of ensuring access to medicines, a government or a third party (contractor) authorised by the government can import or manufacture a generic version of a patented drug for 'public non-commercial use'. This means the use of those drugs in public hospitals and clinics.

2

Access to ARVs

THE ARVs² in the Malaysian MOH Drug List and their patent status are as follows:

1. **Nucleoside reverse transcriptase inhibitors (NRTI)**
Stavudine (not patented)
Didanosine (patented)
Zidovudine + Lamivudine combination (patented)
2. **Protease Inhibitors**
Ritonavir (not patented)
Indinavir (patented)
3. **Non-nucleoside reverse transcriptase inhibitors (NNRTI)**
Efavirenz (patented)
Nevirapine (not patented)

Malaysia's practice in providing access to ARVs at that time was as follows:

1. Monotherapy was free in MOH hospitals.

² d4T (NRTI) alternative name Stavudine
ZDV (NRTI) alternative names Zidovudine or AZT
EFZ (NNRTI) alternative name Efavirenz
NVP (NNRTI) alternative name Nevirapine
3TC (NRTI) alternative name Lamivudine

2. Triple combined drug treatment or Highly Active Antiretroviral Treatment (HAART) was given free to:
 - (a) infected mothers after delivery;
 - (b) infected children;
 - (c) healthcare workers infected in the line of duty;
 - (d) patients infected through contaminated products/blood transfusion.
3. Other patients on HAART were required to purchase two drugs, with one other drug provided free of charge.

According to the MOH, the payment requirement is to ensure commitment to treatment. The other reason is that with an annual drug budget of USD3.5 million for HIV/AIDS treatment, the MOH is unable to give free full treatment. However, the majority of patients are intravenous drug users (about 75%), many of whom cannot afford to buy the ARVs and who have serious problems in treatment compliance.

As a result of growing concerns over high prices of patented and non-patented drugs in Malaysia, the MOH (in particular, the Pharmaceutical Services Division) started in 2001 to seek price reductions from pharmaceutical companies.

In July 2001 the following reductions in percentage terms were obtained as a result of these negotiations:

1. Non-patented ARVs:

Ritonavir capsule and oral solution (10%)

Stavudine (25% – 34%)

Nevirapine (68.5%)

2. Patented ARVs:

Didanosine (36%)

Zidovudine (30%)

Zidovudine + Lamivudine combination (40%)

Indinavir (65%)

Efavirenz (65%)

However, negotiations with drug companies to effectively bring down prices were not satisfactory; the reductions were still inadequate, and prices remained too high.

It was at this juncture that Third World Network cooperated with the Ministry of Health (with full endorsement of the then Minister of Health), to organise an Expert Briefing on Parallel Importing and Compulsory Licensing on 16, August 2002.³

The briefing provided information to relevant government agencies regarding developments related to access to affordable medicines, intellectual property rights and the WTO TRIPS Agreement.

TWN facilitated the participation of local and foreign experts on issues relating to the Doha Declaration on the TRIPS Agreement and Public Health, patents and access to affordable drugs as well as the options available to developing countries such as compulsory licensing, parallel imports and 'Government Use'. The use of compulsory licences in developed countries was highlighted.

In order to increase access to ARV drugs, the government adopted a HAART policy in late 2002 with the following strategy:

1. Provide free HAART to patients with CD4 count < 400. Target: 10,000 patients (there are 4,000 patients⁴ on record and the government expects more unregistered patients to seek treatment with the availability of free drugs);

³ The Malaysian AIDS Council had earlier alerted the government to the compulsory licencing and parallel import provisions under the Malaysian Patents Act 1983.

⁴ Before the government use/compulsory licence, the MOH could provide treatment to only 1,500 patients. This number could be increased to 4,000 after the generic imports from Cipla, a generic manufacturer in India, under the Government Use authorisation.

2. Bring prices of HIV drugs down through negotiations with patent holders;
3. Encourage local production of HIV drugs that are not patented in Malaysia;
4. Consider the use of the 'Rights of Government' under the Patents Act 1983 (i.e., the 'Government Use' option).

3

From Negotiations to Government Use

THE Ministry of Domestic Trade and Consumer Affairs is responsible for intellectual property in Malaysia, and the administration of the Patents Act 1983. The examination and granting of applications for patents and other intellectual property claims lies with the Intellectual Property Corporation of Malaysia.

Sections 48 to 54 provides for **compulsory licences** (there is a prescribed form under the Act for applications for a compulsory licence, which is simple to use: see Appendix 1).

Sections 37(2) and 58A provide for **parallel import**, based on the international exhaustion of rights principle.

Section 84 provides for the '**Rights of Government**', the term for 'Government Use' in the Patents Act. There is no prescribed form required. A decision of the relevant government authority is sufficient.

In November 2002, given the limitations of negotiations with drug companies, and boosted by the Doha Declaration on TRIPS and Public Health, the MOH submitted a paper to the Malaysian Cabinet with a recommendation to import generic ARV drugs. The drugs concerned are patented in Malaysia.

The Cabinet approved on the basis of the government use provisions in section 84 of the Patents Act 1983.

Section 84(1) provides for the 'Rights of Government':

'Notwithstanding anything contained in [this] Act –

(a) where there is national emergency or where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the Government, so requires; or

(b) where a judicial or relevant authority has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive,

the Minister may decide that, even without the agreement of the owner of the patent, a Government agency or third person designated by the Minister may exploit a patented invention.'

The patent owner shall be notified of the Minister's decision 'as soon as is reasonably practicable'. Section 84(3) provides for 'the payment to the owner of the patent of an adequate remuneration'.

In January 2003, the MOH began price negotiations with the representative of the Indian company, Cipla, and applied for an authorisation from the Ministry of Domestic Trade and Consumer Affairs which is responsible for intellectual property. At this point, the opposition began.

GSK in February 2003 offered to drop the price of Combivir by 57% after the Cabinet decision to purchase drugs from India. In March, some other government agencies asked the MOH to reconsider their move, citing concerns that such an action would deter foreign investors. At the same time, GSK met with then Minister of Health.

In August 2003 the Ministry of Domestic Trade and Consumer Affairs suggested that the MOH does not use compulsory licensing.

In April GSK dropped the price of 3TC, AZT and Combivir by 31-57%. The MOH decided to proceed first with the import of non-patented drugs. Thus in May, the MOH issued contracts for Stavudine (USD5.54 per 60 tablets), Ritonavir (USD90.21 per 120 tablets) and Nevirapine (USD21.91 per 60 tablets) to be imported from India.

Meanwhile, the MOH stood firm on the imports under the 'Government Use' provisions and the Cabinet decision was reaffirmed. The authorisation for a period of two years beginning 1 November 2003 was finally obtained from the Ministry of Domestic Trade and Consumer Affairs for the import of AZT, ddI and Combivir.

The drugs were:

1. Didanosine 100 mg tablet (patent holder: Bristol-Myers Squibb)
2. Didanosine 25 mg tablet (patent holder: Bristol-Myers Squibb)
3. Zidovudine 100 mg capsule (patent holder: GlaxoSmithKline)
4. Lamivudine 150 mg + Zidovudine 300 mg tablet (patent holder: GlaxoSmithKline).

The conditions for the company assigned under the government use were as follows (see Appendix 2):

1. The imported drugs shall be supplied to government hospitals only.
2. Every box of medicines shall be labelled with the words 'MINISTRY OF HEALTH'.
3. The brand name, shape or color of tablet or capsule shall be different from the patented products in Malaysia.
4. The company shall keep records of sales in a Poisons Wholesale Book.
5. Compensation payment shall be paid to the patent holders within a period of two months after every time the products are imported.
6. The permit shall be valid for two years.

The quantity to be imported was specified by the MOH. The Minister of Health announced in November 2003 that the supply of HAART would be free once the import of generics started.

GSK and Bristol-Myers Squibb lodged complaints against the Malaysian government's move after the issuance of the 'Government Use' authorisation. Both companies used the threat of reduced foreign investment in the country, and one of them also expressed concerns that Malaysia's action would create a precedent internationally.⁵

At the same time, there was wide national media coverage on the availability of cheaper ARVs, a development that gained public support.

In February 2004, the MOH issued a contract to a local Malaysian company to import generic Zidovudine, Didanosine and a combination of Lamivudine and Zidovudine from generic manufacturer Cipla (India): see Annex 2.

The average cost of MOH treatment per month per patient dropped from USD315 to USD58, equivalent to about an 81% reduction, when generic drugs were used. The number of patients who could be treated in government hospitals and clinics increased from 1,500 to 4,000. The MOH target is 10,000 when there is more awareness of the ARVs availability and more outreach by the public health system to the needy patients.

As a result of the exercise of the right of government use, the patent holders dropped their own prices. There has thus been a considerable reduction in cost for the first and second line regimen ARVs, as seen in the tables on next page, for use in government hospitals and clinics.

⁵ A law suit has even been filed in the Malaysian courts by one of the patent holders, and it is still on record though not activated.

GlaxoSmithKline drops prices again from an earlier reduction in 2003

	2001 prices (USD)	2004 prices (USD)	% drop in price
Combivir(60 tablets)	286.28	57.99	80%
AZT(100 tablets)	77.58	36.08	53%
3TC(60 tablets)	141.75	46.39	67%

Source: Ministry of Health, Malaysia

Bristol-Myers Squibb drops prices of Didanosine

	2001 prices (USD)	2004 prices (USD)	% drop in price
Didanosine (100mg) (60 tablets)	63.55	32.68	49%
Didanosine (25 mg) (60 tablets)	44.49	8.17	82%

Source: Ministry of Health, Malaysia

Monthly Cost of Treatment Per Patient

Treatment	2001 price for patented drug (USD)	2004 price for patented drug (USD)	2004 price for generic drug (USD)
d4T + ddI + Nevirapine	261.44	197.10	45.32
Combivir + Efavirenz	362.63	136.34	115.14

Source: Ministry of Health, Malaysia

‘Adequate Remuneration’

Taking into account existing state practices and the UNDP Human Development Report 2001 recommendation, the MOH proposed to the patent holders a remuneration level of 4% of the value of stocks actually delivered.

However, according to MOH officials, the patent holders 'show no interest in claiming compensation'.

The possible reasons that they have identified are:

1. A precedent would be set for future government use/compulsory licence remuneration in Malaysia and other countries.
2. Bad publicity for the patent-holder, because they have accepted the practice of issuing compulsory licences and agreed to receive less than full royalties, thus setting an undesirable precedent from the industry's viewpoint.
3. Sign of acceptance of the rights of the MOH.

Thus there was no move on either side to proceed with negotiations on remuneration as of February 2006. However, a court case was filed when the government use authorisation was first issued, and this remains even though the patent holder has not activated the lawsuit. Meanwhile, the period of the government use authorisation has ended.

4

The Next Step: Encouraging Domestic Manufacture and Using TRIPS Flexibilities

CURRENTLY, the Malaysian government has a policy to encourage domestic manufacture of non-patented drugs. In 2003 Stavudine and Nevirapine which are not patented in Malaysia were registered for local production in order to increase access to those drugs.

In February 2004, the MOH received a proposal from a local manufacturer to manufacture a three-in-one ARV combination (Stavudine + Lamivudine + Nevirapine). In October the local manufacturer approached GSK, the patent holder, for a voluntary licence to use Lamivudine to manufacture the three-in-one combination drug, the other two components being non-patented. Negotiations have been completed on the royalty payment of USD0.042 (16 Malaysian sen) per tablet, i.e. 6.0 % of the price per tablet.

However, since only one of the three components is patented, assuming that there are equal proportions of each component the actual royalty is 18% per tablet. This is very high, especially when compared to the average remuneration rate of 4% for compulsory licensing that MOH had offered the same patent holder in relation to the imports of generic ARVs from India.

The other conditions are not publicly known, as in the case of most voluntary licencing arrangements.

Meanwhile, according to the MOH, patent holders are more cooperative now compared to the earlier period of failed negotiations and subsequent exercise of government use.

Since the government use authorisation ended in November 2005, the MOH has been considering two options: to negotiate prices of patented products to an acceptable level or to apply for a renewal of the authorisation.

It appears that the compulsory licensing option will not be used for the time being and the advantage gained from the government use order will be used instead for negotiating lower prices of the patented drugs. However, the limits to price negotiations and voluntary licensing as experienced in other developing countries (including Malaysia) point to the need for developing countries to use compulsory licences, including government use, to ensure access to affordable medicines.

As the issue of access to affordable ARVs gains momentum, the community of people living with HIV/AIDs in Malaysia has also begun to organise themselves to promote their rights. In late 2005, the Positive Malaysian Treatment Access and Advocacy Group (MTAAG+) was officially registered. This is a group of People Living with HIV/AIDS doing treatment literacy, treatment advocacy and networking.

Bilateral Free Trade Agreements

A recent development that is creating increasing concern is the negotiation of a bilateral free trade agreement (FTA) between Malaysia and the United States that was officially launched on 8 March 2006.

FTAs between the US and developing countries as well as Australia contain a chapter on intellectual property rights that expand the rights and protection for patent holders by extending patent protection periods, restricting the grounds for compulsory licensing and prevention of the use of clinical test data for generic drug registration. All these provisions have a negative impact on generic drug manufacture and access to affordable medicines. This has evoked serious concerns from many national health authorities and the WHO. For example, the African Union's ministers of trade in June 2005 and ministers of health in Oc-

tober 2005 have issued declarations that call for the rejection of intellectual property provisions in FTAs that compromise the rights and flexibilities of WTO Members to ensure access to medicines and public health.⁶ In January 2006, when intellectual property rights was the subject of negotiations between Thailand and the US, there were widespread protests in Thailand, with access to affordable medicines being a central issue of the protests.

On 3 March 2006 an open letter to the Malaysian Prime Minister was sent by MTAAG+ and Positive Living, PT Foundation (a program of a community-based organisation that provides a drop-in centre, outreach and peer counseling for People Living with HIV/AIDS). They have expressed their concerns over the possible inclusion of intellectual property rights provisions that will threaten access to affordable medicines and public health and sought assurance that the Malaysian Government will 'safeguard our human right to affordable medicines and treatment'. (See Appendix 3).

With reference to the government use authorisation, the signatories stated: 'We were very encouraged when the Government issued a special compulsory licence in 2003 to import some generic ARVs from India for use by MOH. The monthly treatment cost by government hospitals and clinics fell by 81% from USD315 to USD58. MOH has targeted 4,000 people to be on ARVs therapy. But this is still below the more than 10,000 AIDS cases that need urgent treatment. The import licence has also come to an end. So we hope and trust that the Government has plans to ensure continuing access to affordable ARVs. Without ARVs, more PLWHAs will die.'

Government Use in Indonesia

The second Asian country in the post-Doha Declaration period to issue a government use authorisation was Indonesia. This was on 5 October 2004 when a

⁶ The African Union in an inter-government organisation comprising all African countries except for Morocco.

Presidential Decree was issued in accordance with Article 5 of the Indonesian Government Regulation No. 27 of 2004 regarding the Mechanism of Patent Exploitation by the Government. This was in light of 'the urgent need of community in the effort to control HIV/AIDS epidemic'.

The Presidential Decree No 83 of 2004 Regarding Exploitation of Patent by the Government on Antiretroviral Drugs empowered the Minister of Health to appoint a 'pharmaceutical factory' as the patent exploiter on behalf of the Government, taking into account the recommendations from the Head of the National Drug and Food Authority. The two ARVs are Nevirapine (for seven years) and Lamivudine (for eight years).

The Decree also set the 'compensation fee' at 0.5% of the net selling value of the ARVs concerned to the patent holder: see Appendix 4. Production of the ARVs is underway.

Conclusion

The Malaysian experience illustrates that when health officials and ministers are informed of the rights and flexibilities under TRIPS, and national patent laws are designed appropriately, access to affordable drugs can become a reality. This is despite the pressures from the patent holders and even misgivings from other government agencies.

The challenge is to continue to exercise these rights and flexibilities to ensure access to treatment for HIV/AIDS, as well as to take these rights to treat other diseases of importance to developing countries.

Appendix 1

FORM 11, PATENTS ACT 1983 (MALAYSIA) APPLICATION FOR COMPULSORY LICENCE (PATENTS REGULATIONS 1996 – REGULATION 38)

Patents Form No 11
PATENTS ACT 1983

APPLICATION FOR
COMPULSORY LICENCE
(REGULATION 38)

To : The Registrar of Patents
Patent Registration Office
Kuala Lumpur
Malaysia

For Official Use

APPLICATION NO :

Filing Date :

Application received on :

Fee received on :

Amount :

* Cheque/Postal Order/Money Order/Draft/Cash

No :

Date of mailing :

Please submit one copy of this Form
together with the prescribed fee.

Applicant's or Agent's file reference

I. IN THE MATTER OF:

Patent Application No:Filing Date:

II. APPLICANT:

Name :

Address:

Address for service in Malaysia:

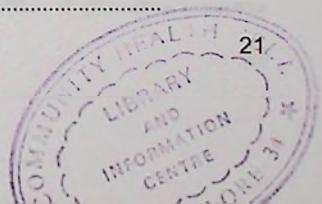
Nationality:

* Permanent residence or principal place of business:

Telephone Number
(if any)

Fax Number
(if any)

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III. REQUEST

The above applicant applies to the Registrar to transmit to the Board the request, in respect of the patent identified above, for the grant of a compulsory licence under section 49 and/or 49A of the Patents Act 1983, in accordance with the terms proposed in Part IV of this Form and upon the grounds set out in Part V of this Form.

IV. PROPOSED TERMS:

A Statement setting out the amount of royalty, the conditions of the exploitation of the patent and the restriction of the rights of the licensor or licensee, as the case may be, is attached.

V. ** STATEMENT OF GROUNDS attached.

VI. ADDITIONAL INFORMATION

The following items accompany this Form:

- (a) evidence that the patent owner has received a request from the applicant to obtain a licence contract but that he has been unable to obtain such a licence on reasonable terms and within a reasonable time
- (b) plan according to which the applicant intends to work the patented invention, including evidence that he has the ability to do so in Malaysia
- (c) other (specify)

VII. SIGNATURE

*** (Applicant/Agent)

(Date)

If Agent, indicate Agent's Registration No:

* Delete whichever does not apply

** The ground upon which the request is based shall be indicated by a reference to the statutory provision the applicant considers applicable (section 49(1)(a) and/or 49(1)(b) and/or 49A of the Patents Act 1983) and to the facts he considers as justifying the grant of a compulsory licence.

*** Type name under signature and delete whichever does not apply.

Note: This form is for use in the case of an application for a compulsory licence, after failure to obtain a voluntary licence through negotiations with the patent-holder concerned. However, for the purposes of a "Government Use" authorisation, there is no need for prior negotiations or a prescribed form, and a decision by the relevant government authority is sufficient.

Appendix 2

GOVERNMENT USE AUTHORISATION TRANSLATED FROM THE ORIGINAL COPY

29 October 2003

Director of Operations

Syarikat Megah Pharma & Vaccines (M) Sdn Bhd
Suite E 1103, Block E
Pusat Dagangan Phileo Damansara 1
46350 Petaling Jaya

Sir,

Authorisation for exploitation of patented invention in Malaysia

By virtue of Section 84(1)(a), Patents Act 1983, Syarikat Megah Pharma & Vaccines (M) Sdn Bhd (Company No : 552048-H) is hereby authorized to exploit patented inventions for the following drugs :

- i. Didanosine 100mg tablets produced by Bristol-Myers Squibb;
- ii. Didanosine 25mg tablets produced by Bristol-Myers Squibb;
- iii. Zidovudine 100mg capsules produced by GlaxoSmithKline; and
- iv. Lamivudine 150mg + Zidovudine 300mg tablet produced by GlaxoSmithKline.

2. The authorization is valid for two years, commencing November 1, 2003.

It is subject to the following conditions :

- i. the authorization shall be limited to the importation of the above listed drugs from Cipla, India;
- ii. the drugs to be imported shall only be supply to government (public) hospitals;
- iii. importation of the said drugs shall be subject to the terms and conditions as specific by the Ministry of Health, Malaysia;
- iv. the quantity to be imported shall be as specified by the Ministry of Health, Malaysia;
- v. all packaging of the drugs shall be labeled with the words "KEMENTERIAN KESIHATAN MALAYSIA" (Ministry of Health, Malaysia);
- vi. the name (brand), shape or colouring of the tablets or capsules shall be differentiated from that of the patented products in Malaysia;

- vii. the company shall be required to register the sale in the scheduled poisons register;
- viii. The ceiling price for the said drugs to be supplied to the Ministry of Health, Malaysia shall not exceed the following :
- | | |
|---|------------------------------------|
| (a) Didanosine 100mg tablet | - RM74.58 (per box of 60 tablets) |
| (b) Didanosine 25mg tablet | - RM22.80 (per box of 60 tablets) |
| (c) Zidovudine 100mg capsules | - RM5.89 (one set of 10 capsules) |
| (d) Lamivudine 150mg +
Zidovudine 300mg tablet | - RM153.50 (per box of 60 tablets) |
- ix. Payment of compensation shall be made to the patent holder(s) within 2 months of each import of the said drugs. The rate of compensation is to be determined at a later date.
3. The above terms and conditions may be amended or varied as deemed appropriate.
4. The authorization may be terminated at any time in the event of non-compliance with the terms and conditions as specific above.

(signature)

(TAN SRI DATO' MUHYIDDIN BIN HJ MOHD YASSIN)

(Minister of Domestic Trade and Consumer Affairs, Malaysia)

Appendix 3

OPEN LETTER TO PRIME MINISTER DATUK SERI ABDULLAH AHMAD BADAWI

3 March, 2006

[Note: Malaysia began formal negotiations on a bilateral free trade agreement with the United States on 8 March, 2006.]

Appeal for Malaysians to have access to affordable medicines

We understand that the Malaysian Government is about to begin negotiations with the USA for a free trade agreement (FTA). As a group representing people living with HIV/AIDS (PLWHAs) in our country, we are very concerned that the life-saving medicines we need may become even more unaffordable if a FTA is signed with the USA.

Excessive, high prices of antiretroviral drugs (ARVs) due to patents in the hands of some big global drug companies have led to world wide outcry in recent years. When there was competition from generic ARVs used to treat AIDS, the prices of patented drugs fell from US\$11,000 per patient per year to US\$150 per patient per year. Even then, this is too expensive for those who are poor and in need of treatment. That is why generic drugs are so very important.

No generic drugs means no access to affordable life-saving AIDS drugs. This will translate to more deaths to PLWHAs. In Malaysia, figures in June 2005 show that there are 63,438 reported cases of HIV infection, and 10,044 AIDS cases in Malaysia. Between 1986 and June 2005, we have already lost 7,673 lives.

At the same time, we understand that the Ministry of Health (MOH) is looking at reaching out to 1,200 intravenous drug users as a target for their Harm Reduction program. With this program, MOH is also establishing a strong referrals system to hospitals, rehabilitation centres, substitution therapy, etc. This program is an entry point towards encouraging more voluntary testing and counseling. Therefore, there are more likely cases of HIV/AIDs to be detected amongst this invisible population. This in turn will lead to a bigger number of detected HIV/AIDS cases in Malaysia. The impact of the FTA will also be on this invisible population. The World Health Organization in June 2005 has already warned that an HIV epidemic is knocking on Malaysia's door.

We were very encouraged when the Government issued a special compulsory licence in 2003 to import some generic ARVs from India for use by MOH. The monthly treatment cost by government hospitals and clinics fell by 81% from US\$315 to US\$58. MOH has targetted 4,000 people to be on ARVs therapy. But this is still below the more than 10,000 AIDS cases that need urgent treatment. The import licence has also come to an end. So we hope and trust that the Government has plans to ensure continuing access to affordable ARVs. Without ARVs, more PLWHAs will die.

That is why we are very worried about news reports on FTA negotiations with the USA. We do not know what is being proposed in the Malaysia-US FTA, but based on previous US FTAs and the US proposals in the controversial Thai-US FTA negotiations, there are a number of common provisions which are very alarming. We believe the US will demand that Malaysia also agree to similar provisions, and these will make all medicines more expensive.

For example, US FTAs usually force more medicines to be patented and the patents have to continue for more than 20 years, which is the length of time for patents to run. When a medicine is patented, it means there is a monopoly and so no other manufacturers can make that medicine. That means that the patent owner can charge as much as it likes because there is no competition.

We have learnt that US FTAs also impose monopolies for at least five years even when there is no patent, by blocking the use of test information by health authorities to register generic versions of the patented drugs.

We make a strong plea to Datuk Seri and the whole Malaysian Government to reassure us that public health will always be a top priority and that FTAs with Malaysia will not contain anything that goes against access to affordable medicines. We urge Datuk Seri to hold consultations so that we, the PLWHAs, and all Malaysians can learn more about FTAs that will be negotiated and how they will have an impact on public health and access to affordable medicines. We also urge Datuk Seri to continue with the Government's promise of transparency by making public suggestions and proposals in the FTAs.

For PLWHAs, the treatment that we need is a life long treatment. For us, it is a matter of life and death. So we strongly appeal to you, Datuk Seri, to safeguard our human right to affordable medicines and treatment. Please do not allow an FTA with the USA or any country that will harm the health of Malaysians.

Thank you.

1) Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)

[A group of People Living with HIV/AIDS doing treatment literacy, treatment advocacy and networking.]

2) Positive Living, PT Foundation.

[A program of Community-Based Organization to provide a drop-in center, outreach and peer counseling for People Living with HIV/AIDS.]

Appendix 4

DECREE OF THE PRESIDENT OF THE REPUBLIC OF INDONESIA

NUMBER 23 YEAR 2004

REGARDING

EXPLOITATION OF PATENT BY THE GOVERNMENT ON ANTI RETROVIRAL DRUGS

THE PRESIDENT OF THE REPUBLIC OF INDONESIA

Considering: a. that in line with the urgent need in the effort to control HIV/AIDS epidemic in Indonesia, it is necessary to provide access to Anti Retroviral Drugs that are still protected under Patent;
b. that as exploitation of Article 5 of Government Regulation No 27 of 2004 regarding the Mechanism of Patent Exploitation by the Government, it is necessary to stipulate a Presidential Decree regarding Patent Exploitation of Anti Retroviral Drugs by the Government;

In view of: 1. Article 4 paragraph (1) of the Constitution of 1945 as amended by the Fourth Amendment of the Constitution of 1945;
2. Law No 23 of 1992 regarding Health (State Gazette of 1992 No 100, Supplementary State Gazette No 3495);
3. Law No 14 of 2001 regarding Patent (State Gazette of 2001 No 109, Supplementary State Gazette No 4130);
4. Government Regulation No 27 of 2004 regarding Patent Exploitation Mechanism by the Government (State Gazette of 2004 No 106, Supplementary State Gazette No 4423);

DECIDES:

Stipulating: **DECREE OF THE PRESIDENT REGARDING PATENT EXPLOITATION OF ANTI RETROVIRAL DRUGS BY THE GOVERNMENT.**

First: The exploitation of patent of Antiretroviral Drugs by the Government is meant to comply the urgent need of community in the effort to control HIV/AIDS epidemic.

Secondly: The type, name of Patent Holder, Patent number and period of Patent exploitation of the Antiretroviral Drugs as referred to the First Dictum is attached in the Annex of this Decree.

- Thirdly: Minister of Health may appoint a Pharmaceutical Factory as the Patent exploiter for and on behalf of the Government to exploit the Patent by taking into account the recommendations from Head of National Drug and Food Control Authority
- Fourth: The Government shall give a 0.5% compensation fee of the net selling value of Anti Retroviral Drugs to the Patent Holder.
- Fifth: This Decree shall take effect on the date of its enactment.

Enacted in Jakarta
On 5 October 2004

THE PRESIDENT OF REPUBLIC OF INDONESIA

Signed
MEGAWATI SOEKARNOPUTRI

For true copy
Deputy Cabinet Secretary
Legal and Legislation Department,

Lambock V Nahattands

Annex

PRESIDENTIAL DECREE OF REPUBLIC OF INDONESIA

NUMBER : 83 YEAR 2004

DATED : 5 OCTOBER 2004

TYPE, NAME OF PATENT HOLDER, PATENT NUMBER, AND PERIOD OF PATENT EXPLOITATION OF ANTI RETROVIRAL DRUGS

NO	TYPE	NAME OF PATENT HOLDER	PATENT NUMBER	PERIOD OF PATENT EXPLOITATION
1	Nevirapine	Boehringer Ingelheim (BI)	ID 0001338	7 years
2	Lamivudine	Biochem Pharma INC	ID 0002473	8 years

THE PRESIDENT OF REPUBLIC OF INDONESIA

Signed
MEGAWATI SOEKARNOPUTRI

For true copy
Deputy Cabinet Secretary
Legal and Legislation Department,

Lambock V Nahattands

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by Chee Yoke Ling (32 pages \$6.00)



MALAYSIA'S EXPERIENCE IN INCREASING ACCESS TO ANTIRETROVIRAL DRUGS: EXERCISING THE 'GOVERNMENT USE' OPTION

- An HIV epidemic is knocking on Malaysia's door.
- The prices of some antiretroviral (ARV) drugs have become increasingly high.
- About 75% of HIV positive persons in Malaysia are intravenous drug users who largely cannot afford treatment.

In a direct and determined response to the above scenario, the Ministry of Health (MOH) in Malaysia initiated an experience that may be useful for other developing countries.

It resulted in Malaysia becoming the first country to issue a compulsory licence following the adoption of the Doha Declaration on TRIPS and Public Health by the 2001 Ministerial Conference of the World Trade Organisation (WTO).

TWN took an active part in this process by providing information to relevant government agencies regarding developments related to access to affordable medicines, intellectual property rights and the WTO TRIPS Agreement.

CHEE YOKE LING is a Legal Advisor to TWN. Of particular concern in her work is the ecological, social and economic impact of globalisation, especially in the developing countries of the South.

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