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a profile of the mission of the Children's Vaccine Initiative

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VACCINATE A CHILD
PROTECT A NATION

The Secretariat of the Children's Vaccine Initiative thanks the following for their generous contributions which supported its activities in the last year:

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PREFACE

The Children's Vaccine Initiative

The Children's Vaccine Initiative (CVI) is an international coalition of partners committed to ensuring that the benefits of vaccination reach all the world's children. CVI is cosponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the World Bank, the World Health Organization (WHO) and the Rockefeller Foundation. CVI brings together key players on the vaccine stage – those involved in research, development, licensing and production; in quality control, vaccine procurement and delivery; those that fund these activities; and those that assess the impact of vaccines and their usage – helping them work together more efficiently to achieve common goals.

An important part of CVI's role is to recommend how best the many different players in this vaccine 'continuum' can cooperate so that the health benefits of vaccines are widely and swiftly shared. Recognizing that the vaccine world is in a state of change, CVI established a Task Force to identify new directions, new approaches. In 1998, the Task Force published a Strategic Plan proposing what should be done to ensure that more children receive the life-saving vaccinations they need. The Plan highlights specific actions to be taken by national governments, by international organizations, the donor assistance community, the commercial vaccine industry, and by academia and research institutions. The background to the Plan and its main themes are reflected in this paper.

We have reached a significant watershed – a moment of enormous opportunity. The right action must be taken now if we are not to waste precious potential and needlessly lose millions of young lives.

PART I
The vaccination revolution

A health revolution has taken place during the second half of the twentieth century, a revolution that has been brought about by the use of a range of safe, effective vaccines. It is only two hundred years since the first vaccine, against smallpox, was discovered, yet today vaccines save three million children from death each year and millions more from suffering and disability.

In the early 1970s, fewer than 5% of the world's children were vaccinated at all. By 1990, a tremendous public health effort made it possible to reach almost 80% of children born each year and vaccinate them against six target diseases: diphtheria, tetanus, whooping cough (pertussis), polio, tuberculosis and measles. Vaccines have brought about the eradication of smallpox and controlled the transmission of poliomyelitis to the point that – hopefully – this disease will also soon be eradicated, while measles rates have also been drastically reduced. This massive global mobilization has been called the greatest public health achievement ever.

Since this first phase, the potential of vaccination has developed rapidly. Basic biomedical research has made many more vaccines and vaccine combinations available. These, and new vaccines at or near production, can protect against many of the major childhood killers.

Moreover, the pace of vaccine innovation is likely to increase. Investment in basic science over the last decade has yielded a better understanding of infectious diseases and a wide array of new approaches to combat them. New or improved vaccines against major and growing threats to humanity – diseases such as HIV/AIDS, malaria, tuberculosis and cancers arising from infectious diseases – are finally within our reach.

In view of these multiple opportunities, the challenge is to find ways to ensure that the vaccine success story continues – that the enormous impact that vaccines have had on the health and well-being of the world's peoples is strengthened as we approach the new millennium.

PART 2
Evolution and innovation

The two decades since the initial push to vaccinate the world's children began have been years of amazing success. An essential part of this success story has been the availability of traditional vaccines at low prices and the willingness of industrial countries to invest heavily, either bilaterally or through multilateral agencies, to provide the necessary vaccines and support the immunization delivery infrastructure in most of the developing countries. Thus, vaccine supply and quality control mechanisms, laboratory networks and cold chains to ensure the safe storage and delivery of vaccines have largely been defined and established.

There is, however, no room for complacency. Since 1990, the dramatic growth in vaccination coverage has levelled out and new vaccines are not being widely introduced. And although around three million lives are already being saved per year, many more could be protected by the greater use of vaccines which are available now. It is estimated that the wider use of vaccines against hepatitis B, measles, rubella (a cause of birth defects), and meningitis and pneumonia caused by *Haemophilus influenzae* type b (Hib disease), could prevent two to three million further deaths annually and enormous suffering in children and adults. In addition, vaccines just licensed or currently in the later stages of development – such as those against rotavirus diarrhoea, pneumococcal pneumonia, meningococcal meningitis in infants, and cholera in older children and adults – could prevent two million further deaths and widespread suffering each year.

These new products should be made widely available, more rapidly than were their predecessors, to all our children. One potential hurdle is that the new vaccines cost dollars, not cents, per dose. They are the product of years of research and development, involving higher costs and more complex production technology, making return on investment more difficult to predict. When Dr Jonas Salk discovered polio vaccine, he waived all intellectual property rights – his vaccine's 'patent'. But today, the public and private organizations investing in vaccine development and production need a fair return on their investment to stay in business, and this is largely secured by patents and intellectual property rights, including royalties. Partly as a result of this trend, and following a series of mergers and acquisitions,

there are now only five or six major vaccine-producing companies operating internationally, which largely determine which products reach the market first. The global vaccination 'system' must find ways to accommodate the reality that new vaccines will be more expensive.

Complex country needs

The past decade has also seen fundamental change in the economic climate and country capabilities. In the early days of vaccination, developing countries received external funding to establish vaccination programmes. Today, many of these countries have developed economically to the point that they are able to finance all or part of their programmes themselves. Such countries with strong national immunization programme infrastructures now wish to pursue, in addition to the original, six-vaccine formula, the use of other vaccines according to local disease prevalence. Humanitarian assistance partners, that are less able or willing to accept the burden of paying for immunization programmes in all developing countries, can thus focus their support on the continuing needs of the poorest countries.

Together to ensure vaccines for each child

This is a period of tremendous potential – both in terms of new vaccines becoming available and the ability of countries and partners to ensure that these vaccines reach the children. There is no simple, single solution to the question of how this potential can be turned into real benefit. A number of interlinked strategies, creating an innovative and coordinated approach, are required if we are to make the most of these many new opportunities and manage this period of change to maximum advantage. Some of these strategies, elaborated in the 1998 *CVI Strategic Plan*, are discussed briefly in the pages below.

PART 3
Taking responsibility for health

The *CVI Strategic Plan* defines and responds to needs in three key areas, i.e. how to ensure that:

- limited external financial resources support the disease control efforts of those in greatest need;
- existing vaccines of high quality are accessible to more people; and
- innovative research and development continue to take place on all vaccine fronts.

Actions expected of the major players in the vaccine continuum to achieve these aims, as well as those to be undertaken by the Secretariat to the Children's Vaccine Initiative, are outlined in Annexes 1 and 2 of this document respectively.

The best use of scarce resources

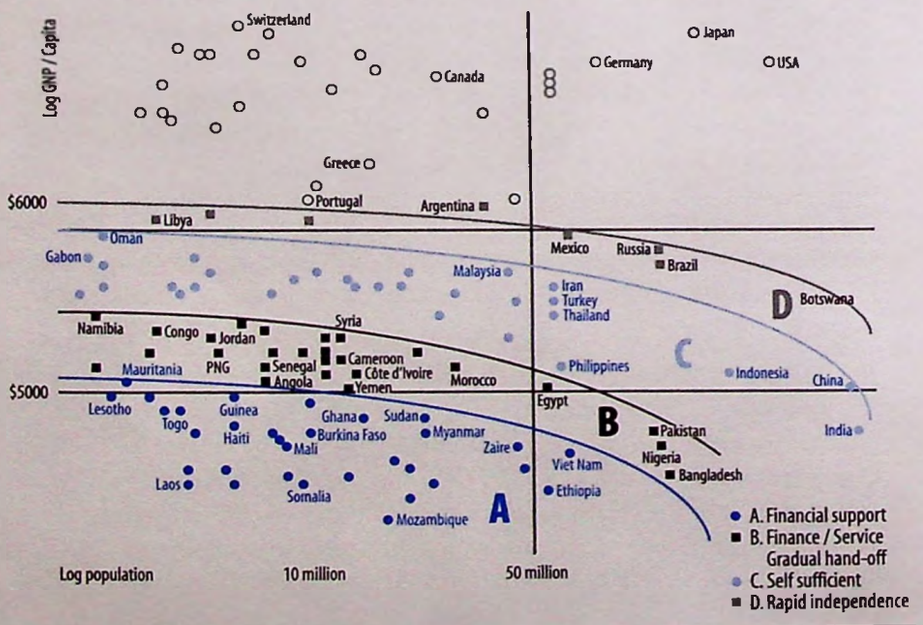
Faced with the reality that more developing countries wish to tailor their vaccination programmes to local priorities, and fewer industrialized countries are prepared to provide support indefinitely, what can be done to make better use of limited resources? Underlying the CVI Task Force's thinking has been the concept of responsibility and the need for greater self reliance to ensure sustainability. Countries must be encouraged to take responsibility for managing and financing their own vaccine programmes. This approach will allow the health benefits of vaccination to be shared more fairly by the world's poorest children.

In the past, traditional vaccines destined for developing countries have been bought in large quantities for all at a flat rate price. This has ensured supplies of vaccines, but it may not be the best approach for the future since it does not take into account the rapid economic and social progress which many developing countries have undergone. To target scarce resources in a systematic way to countries in greatest need and reward efficient suppliers, the CVI Task Force is promoting the UNICEF/WHO 'banding' strategy, which groups countries according to their economic development and size. The smallest and poorest countries (band A) have the smallest market and 'voice' and

are the least able to negotiate price, finance their vaccine needs, and hence should be the first target of external assistance. As a country's GNP increases, so does its ability to cover vaccine costs with correspondingly less external support. This system ensures that the neediest countries, mostly those in sub-Saharan Africa, continue to get the financial support they need, both for traditional vaccines as well as for the introduction of new ones. Countries in band B are better able to fund their own vaccines, at least for the six traditional, vaccine-preventable diseases, but may need additional external support to introduce new vaccines. Countries in band C and D can afford to pay all their vaccination costs either immediately or in the very near future.

In encouraging governments to take progressive responsibility for their own programmes, the UNICEF/WHO banding strategy also offers manufacturers the opportunity to recognize the vaccine and economic needs of the world's poorest countries and set their prices for these

WHO/UNICEF banding strategy: encouraging financial sustainability of immunization programmes and targeting assistance to those countries in greatest need



countries accordingly. Most important of all, it ensures that, at a time when resources are stretched, the world's most disadvantaged children will not be deprived of access to vaccines that their richer neighbours can take for granted.

In addition to promoting the targeting of external resources to countries in greatest need, the CVI Secretariat strives, through economic studies, to raise awareness in all countries of the 'value' of vaccination. New options for financing vaccination will be examined at a forthcoming international consultation.

Maximising what we have

The potential impact of vaccines can only be realized if they are actually available. What, then, can be done to ensure that adequate quantities of high-quality vaccines are accessible to all national immunization programmes and used in the most rational fashion, country by country?

A shortage of financial resources is not the only factor impeding the provision of vaccines. In addition to assisting countries to pay for the vaccines they need, the supply of good quality vaccines can be improved by focusing on a number of other areas. Communication between the national, regional, and international bodies concerned with vaccine quality and administration can be enhanced; financing infrastructures can be expanded and strengthened with the aim of encouraging countries to become more self-reliant; National Control Authorities need greater support to ensure the quality of all vaccines used. In addition, there must be forward planning to secure the supply of vaccines for both routine and special use, such as in emergency situations. Above all, countries themselves must develop the information and procedures that permit them to make rapid and rational decisions regarding their own vaccination efforts. This entails developing disease burden information and selecting national priorities. The CVI Secretariat facilitates these efforts through financial support and through the development of methods, such as those for cost-effectiveness analysis, to aid in decision-making.

CVI also aims to maximise efficiency overall by integrating and coordinating the specific efforts of the multiple players involved.

The potential of new vaccines

The current decade has seen the development of an unprecedented range of new vaccines while yet more wait in the wings. However, although there have been extensive and promising trials, new vaccines are not being widely and swiftly introduced. So what needs to be done to change this? And what will help ensure that research and development into new and improved vaccines continues to expand and bear fruit?

The problems of delayed introduction are often linked to logistical and financial obstacles rather than technical problems. Forward planning involves identifying the vaccines most likely to be needed and potential sources of supply. Furthermore, a variety of actions would speed the introduction process, including:

- the development of guidelines for the selection and introduction of new vaccines by immunization programmes;
- technical support for the design of new immunization programmes;
- improved collection of data, particularly on disease burdens; and
- the assessment and dissemination of lessons learned from countries that adopt new vaccines early.

The CVI 'agendas' to accelerate the introduction of Hib, pneumococcal conjugate and rotavirus vaccines, developed with international agencies and industry, identify for each vaccine what is required to bring their benefits to all children, earlier.

Since modern vaccines have proved to be more complex and expensive to produce than in the past, a vital motivation for the *continued* development of new and improved vaccines will be the expected financial return on investment. To safeguard the prospect of sufficient return, there must be systems to protect the intellectual property rights (IPRs) of vaccine developers, in line with the World Trade Organization agreements on Trade Related Aspects of Intellectual Property. Vaccine developers must also be assured assistance in the negotiation of such rights so that new or improved vaccines can be swiftly and widely introduced. The proper negotiation and management of IPRs, together with transfers of technological 'know-how' on vaccine manufacture and supply, where appropriate, will help ensure that vaccines reach those who need them, while generating enough revenue to fund new vaccine research and development.

Access to IPR and new technology can best be negotiated when all parties recognize the prerequisites for successful partnerships. Consultation between public and private sectors, such as that sponsored by CVI in Bellagio, Italy in February 1997, can increase understanding of these issues.[1]

While the anticipated return on investment will be a sufficient incentive to move most new vaccines into the mainstream, it is vital that the development of other vaccines, such as those to prevent shigella dysentery, tuberculosis and malaria, is also encouraged. Such vaccines have great public health potential, particularly in the world's poorest countries, but may seem to offer little promise of commercial return. They are therefore unlikely to survive in the competition for commercial development without additional resources and special attention.

The CVI Secretariat plans to address the status of these and other 'orphan' vaccines through a special consultation, as well as by considering the potential of public sector vaccine research, development and production institutions contributing to their ultimate availability.

The continued development of new and improved vaccines clearly depends on long-term support and commitment to institutions engaged in these activities. It also needs closer partnerships between

[1] Children's Vaccine Initiative/Rockefeller Foundation Conference on the Global Supply of New Vaccines, Bellagio, 3-7 February 1997 (document CVI/GEN/98.01)

the public and private sector, between those concerned with public health policies and those involved in the commercial development and production of vaccines. The CVI strives to promote such dialogue, *inter alia* through ensuring full participation of industry in all meetings (e.g. in those which have taken place on combination vaccines, rotavirus vaccines and acellular pertussis) and planning activities (such as the Task Force on Strategic Planning).

Vaccination and sustainability

Underlying the CVI Task Force *Strategic Plan* are the interrelated concepts of self-reliance and sustainability. Increasingly, assistance provided for immunization services is geared towards enabling countries to manage and finance their programmes themselves. There is less emphasis on providing standard services or products for all countries, more on helping countries to identify their needs, to devise infrastructures for procuring, financing and distributing the vaccines they choose, and providing the technical support needed to carry out defined aims. Encouraging countries to take on responsibility for financing and running their own vaccination programmes helps ensure sustainability and continuity. At the same time, it frees scarce resources, making them available to the world's poorest countries, which continue to rely on external assistance and, therefore, for making vaccines available to children in greatest need. CVI's support to increase national self-reliance includes the development of methods to assess disease burdens, disease treatment expenditures and vaccination policy cost-effectiveness, which can all be applied at country level.

PART 4
The will to succeed

The impact of vaccines on the health of the world's children has been enormous, perhaps greater than any other single health intervention. And according to the World Bank, improved vaccination is one of the best and most cost-effective health interventions that could be undertaken, saving millions of lives and promoting sustainable personal and economic development. Yet, as so often when things work well, with time and familiarity we take them for granted.

This is particularly true of vaccination. As vaccination rates rise and the threat of serious infectious disease fades, community perceptions of the value of vaccination change. This primary weapon against infectious disease becomes under-valued. Tragically, in some countries, vaccination rates have even fallen, leading to the re-emergence of infectious diseases which were previously controlled. A prime example is pertussis, which infected large numbers of children in Europe in the 1980s when public fears about the safety of vaccination outweighed understanding of the serious threat to health that whooping cough represents. Similarly, diphtheria reached epidemic proportions in the former Soviet states, when the breakdown in the health infrastructure left vaccination low on the priority list and many children unprotected. Experience also shows that while people may be prepared to pay high costs for drugs to treat an infection, they resist paying the much lower cost of a vaccination which would have prevented the disease in the first place.

In view of such tendencies, what can be done to promote vaccination as perhaps *the* most valuable and cost-effective tool in the fight against infectious diseases, and the attainment of health?

The need for national and international advocacy

Efforts need to be channelled into increasing awareness among decision-makers and society as a whole of the vital role that vaccination plays in the control of infectious diseases. To achieve this will mean supplying better information about the positive benefits of vaccination and making wider use of mass media such as television, radio and Internet. It should also include greater vigilance to counter misinformation and to remind people of the real risks and impact of infectious diseases on individuals and communities.

The CVI Secretariat cannot expect to undertake alone the daunting task of raising public and policy maker awareness of the value of vaccination in all countries where this is needed. Such a task needs to be shared among all players involved. To this end, a multi-organizational Working Group on Advocacy and Information Exchange has been created by the CVI Secretariat to catalyse and coordinate a range of efforts directed at a variety of target audiences, and policy makers in particular.

A culture of prevention

It is equally important to encourage and build support at grass-roots level among health workers, among community leaders and among the people who bring their children to be vaccinated – the parents. Support at this level creates greater demand for vaccination services which can in turn stimulate better and wider provision. Using resources to build such a 'culture of prevention' is a cost-effective investment that will pay dividends in terms of future health protection. And, in addition to saving lives, the saving in disease treatment expenditures that may be achieved by protecting more children through vaccination is not to be under-estimated.

Establishing solid commitment to vaccination through long-term advocacy efforts across many fronts is essential if the full benefits of vaccines are to reach individuals and communities in the years to come.

PART 5

Vaccination for a new millennium

The Children's Vaccine Initiative has reviewed its first seven years' work and experience, and refined a plan of areas for action and specific activities to be undertaken now and into the next millennium. The 1998 *CVI Strategic Plan* is the culmination of these deliberations. Progress achieved will provide a firm foundation on which to build, and the opportunities we recognize today must not be lost because of a lack of cohesive effort and support. Implementation of the Plan rests collectively with the many contributors to vaccine development and delivery. With these collaborators, the CVI Secretariat will continue to monitor for gaps in the overall effort and ensure that they are addressed.

Simple protection

An important aim of CVI has been to support research on simplifying vaccine delivery. This means finding ways of reducing the number of doses required to provide protection; making the process of administering the vaccine simpler and safer, preferably avoiding the need for injection with a hypodermic needle; and making vaccines themselves more durable, stable and of consistent good quality. Many steps have already been taken towards the ideal concept of a single-dose 'super vaccine'. Advances in biotechnology have led to improvements in specific areas, such as the development of mucosal delivery and combined vaccines, which simplify the vaccination process. Such work, taking place in

parallel with the development of new and improved vaccines, suggests that we are, indeed, standing on the threshold of a new 'golden age' in vaccination. We must maintain the vision of what might one day be possible if we are to overcome the challenges of this demanding intermediate stage. Finding the resources to support the research and development processes which are already bearing fruit must be a number one priority for all those involved in maximising the potential benefits of vaccination. Since these simpler methods are often most needed in countries where delivery infrastructure and capacity to pay is weakest, the CVI Secretariat articulates their importance, particularly to those funding research.

A right to health

The United Nations Convention on the Rights of the Child states that every child has the right to attain the highest possible standard of health. The Convention has been ratified by almost every country in the world and enshrines international acceptance of the fundamental human rights of children. But how can this theoretical support be translated into real improvements in children's lives? By putting the *CVI Strategic Plan* into practice, we shall be taking steps to prevent millions of children dying each year from infectious diseases, and saving many more from suffering and the tragic consequences of disability. We shall be turning human rights principles into practice. The health protection offered by a simple, safe vaccination is the basic right of the poorest child as well as his or her richer neighbour.

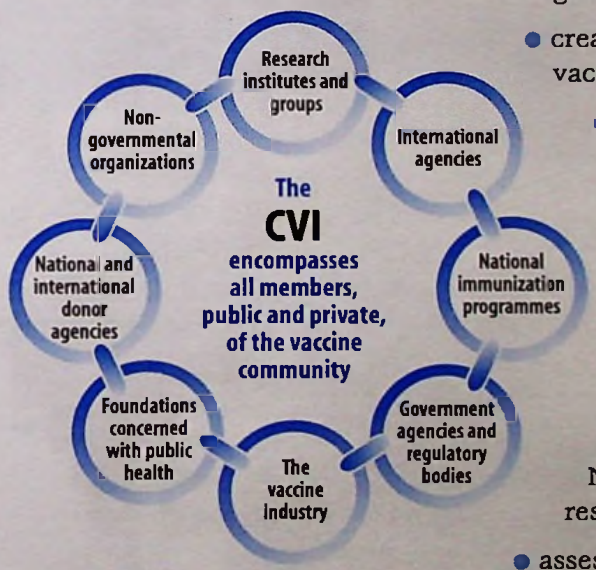
We have reached a significant crossroads. By taking the right action now, millions of children and their families can be saved suffering and death from preventable diseases.

Let us not forsake tomorrow's children by failing to act today.

ANNEX 1

The Children's Vaccine Initiative: A forum for exchange, a mechanism for commitment[2]

To make the potential benefits of expanding vaccination a reality, individuals and organizations from both the public and private sectors must collaborate by pursuing different actions based on their comparative strengths and capabilities. The CVI offers all those working in the vaccine "continuum" a forum in which they can exchange information and interact, and a mechanism for committing themselves to well-defined plans for reaching shared goals.



National governments ***should***:

- create a budget line for national vaccination efforts;
- meet UNICEF self-sufficiency targets;
- design five-year national plans for immunization;
- ensure that national immunization programmes use vaccines of known good quality only;
- create, or strengthen, National Control Authorities responsible for vaccines;
- assess the rationale for any local, government-supported vaccine production and assure viability of supply for existing and new vaccine needs; and
- recognize the value of disease prevention through vaccination and increase, accordingly, investment in both basic research and infectious disease surveillance.

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[2] Extract from the *CVI Strategic Plan*, (CVI/GEN/97.04)

International organizations ***should***:

- develop recommendations that encourage all countries to implement the widest practical range of vaccination activities to protect children against infectious diseases;
- implement existing strategies and develop new ones to target technical and financial support to the neediest countries, such as the UNICEF/WHO procurement strategy for new vaccines;
- offer technical assistance based on the organization's comparative strengths (such as UNIDO offering its assistance to selected local vaccine producers to help ensure the reliable manufacture of high quality vaccines);
- propose inventive policies such as World Bank low-interest rate lending to countries based on their vaccine purchases; and

- develop pro-active methods, in collaboration with industry, to guide the introduction of priority new vaccines into use in developing countries.

The donor assistance community ***should***:

- provide support within the context of national plans and in accordance with strategic global recommendations on specific issues, such as self-sufficiency targets and assessment of viability of local production, and
- teach selected countries how to procure quality vaccines at competitive prices on the international market.

The commercial vaccine industry ***should***:

- establish a 'partnership' with the public sector in the interest of children's health. (This envisaged 'partnership' entails the public sector emphasizing financial and procurement support to the neediest countries);

- review conclusions from public-private meetings, such as the Bellagio Conference of 3-7 February 1997, and implement suggestions therein;
- consider licensing intellectual property in a way that provides for the production of new vaccines for all markets;
- consider tiered prices and tiered royalties to reduce the price of vaccines to the poorest countries; and
- continue to invest actively in vaccine research and development.

Academia and research institutions ***should***:

- review and implement relevant suggestions from public-private sector coordination and collaboration meetings (such as the Bellagio Conference).

Nongovernmental organizations, including foundations, ***should***:

- support the administration, procurement and delivery of vaccines within their field operations;
- work in concert with international health agencies to strengthen health care delivery infrastructures in the neediest countries.

ANNEX 2
Activities of the CVI Secretariat[3]

In 1998 and beyond, proposed CVI Secretariat activities include the following:

Consensus development: strategic planning and priority setting

- Consultations on:
  - sustainable financing for vaccination programmes;
  - the increasing problem of 'orphan' vaccines; and
  - the future role of public sector institutions in vaccine research, development and production.
- Assessment of the health and economic value of new vaccinatio options.
- Continued public-private sector dialogue on i g co
- Creating a supportive environment for va harmonization of technical requirements production quality.
- Identification of ing a supply through ganiz Demand, Su ncin
- Conveni nsu

Strategy pric

- Ensur ialo vaccine
- Assessi g strategies n industry.

[3] Extrac 1998 (GEN/

- Promoting the introduction of Hib vaccine against meningitis and pneumonia.
- Promoting the final testing and rapid introduction of pneumococcal conjugate vaccines in developing countries.
- Supporting planning for introduction of other ARI vaccines e.g., for Respiratory Syntical Virus.
- Promoting early rotavirus vaccine introduction where most needed.
- Promoting wider appropriate rubella vaccine use.
- Assessing new vaccination technologies.

Advocacy, information exchange and resource mobilization

- Periodically convening the Working Group on Advocacy and Information Exchange to guide advocacy on vaccination by the CVI Secretariat and collaborators.
- Widely disseminating the *CVI Strategic Plan: Managing Opportunity and Change – A Vision of Vaccination for the 21st Century.*
- Completing and distributing widely a profile of the Children's Vaccine Initiative vision and mission, including a synopsis of its Strategic Plan.
- Completing and disseminating a series of position papers on important issues in vaccine development and supply to target audiences, e.g. the economic case for investment in vaccination.
- Producing and distributing three issues of the CVI Forum, emphasizing new vaccination options.
- Planning seminars for European, African and Asian policy makers on new vaccines.
- Selecting the recipients for the CVI Jenner and Pasteur Awards.
- Survey, with collaborators, opinion leaders from multiple disciplines and countries to establish a benchmark study of attitudes and awareness regarding vaccine.

The Children's Vaccine Initiative (CVI) is a global coalition of organizations from the public, nongovernmental and private sectors, including the vaccine industry, working together to maximize protection against infectious diseases through the development and utilization of safe, effective, easy-to-deliver and widely available vaccines.

Launched at the World Summit for Children in 1990, the CVI is co-sponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the World Health Organization (WHO), the World Bank and the Rockefeller Foundation.

VACCINATE A CHILD
PROTECT A NATION

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▸▸ Visit our new web site at www.vaccines.ch