THE CHALLENGE
THIRTY YEARS
OF ESSENTIAL MEDICINES:

THE CHALLENGE
In 1977, the World Health Organization adopted the concept of essential medicines, one of the key elements of Primary Health Care, to ensure that all people could enjoy an economically and socially productive life. However, there are currently two billion people without regular access to medication, so it is appropriate to ask whether the concept of essential medicines has failed.

Consider for a moment, what a world without essential medicines to support Primary Health Care would be like.

First, in this world, pharmaceuticals are not selected: meaning that they are just another product and therefore, abide by market forces. The supply of drugs is directed at profitable wallets and diseases, and there are tens of thousands of pharmaceutical specialties, the majority of them mere copies of each other. In this imaginary world, the abundance of brands makes knowledge of them vital, or at least for a few in order to have some assurance of their quality and efficacy, and to understand which brand relates to which disease. In this world without essential medicines, the fundamental factor is that a drug is advertised and that it is better than a placebo. It is a world in which pharmaco-epidemiology yields to market research and this determines whether the priority health needs of the population are relevant. If the price justifies
it, the medicines will be available in acceptable quantity and quality. One knows, cost and efficiency are relative concepts and distinguishing oneself in the market comes with a price...

The description of this world might be never-ending, but it does not correspond to an imaginary world. Many of us have lived in it, and so, because we have known it as doctors and suffered it as patients, changing it was a crucial goal for us. Changing it to protect and promote public health. It was for this reason that we developed a concept capable of sprouting policies based on sober science, reason and peoples. This is why, nowadays, essential medicines are linked to public goods, human rights and a revolution in public health based on Primary Health Care. However, for hundreds of millions of people the enjoyment of this public good, the enjoyment of this human right and the participation in this health revolution are inaccessible. This publication is the story of a challenge, but it is also the record of an unfinished history. Hence, the problem persists and the battle continues.

Dr. Halfdan MAHLER
This book is the result of research conducted in 2007 thanks to the support of Dr. Germán Velásquez, Director of the World Health Organization (WHO) Secretariat on Public Health, Innovation and Intellectual Property and also one of the leading figures of the Essential Medicines Program over the last two decades. Dr. Velásquez’s collaboration has been all-embracing; from helping to locate and access WHO documents and files related to the Essential Medicines Program, to commenting and enhancing the authors' numerous drafts. In fact, it is thanks to his commentaries and suggestions that this publication was able to become a reality.

Any oversights belong exclusively to the authors. However, as far as the main conclusions and reflections are concerned, they belong to Dr. Velásquez as much as to the authors. It is only his generosity and humility that has kept his name off the cover.
CONTENTS

Foreword ...........................................................................................................................................VIII
Acknowledgements .......................................................................................................................... IX

Introduction .........................................................................................................................................3

I. Essential Medicines: The Great Health Reform ...........................................................................5
   2. Origins and Background at National Level .............................................................................8

II. From Alma Ata to the Thirtieth Anniversary of the Model List: A Hard and Not Always Understood Road .........................................................................................................................15
   1. Phase One. 1975-1981. Establishing the Programme ............................................................15

III. The Impact of the Essential Medicines Concept and the Road Ahead .................................33
   1. Reactions to the Essential Medicines Concept and DAP ......................................................33
   2. DAP's Principal Lines of Action and Activities .......................................................................38

IV. Conclusions and Challenges ......................................................................................................43
INTRODUCTION

The purpose of *Thirty Years of Essential Medicines* is to provide a contribution to discussions about the future of medicine as a whole and of essential medicines in particular. To that end, it offers a brief overview of the origins, development and vicissitudes of the World Health Organization's Action Programme on Essential Drugs. It documents the history of that successful programme, from its isolated and bold beginnings until the present. A present characterised by the existence of a complex and globalised world, marked by multiple inequalities and challenges, but also by the existence of unprecedented opportunities in each country's day to day existence.

This paper also describes the principal components of the Action Programme on Essential Drugs together with the substantive and organisational adjustments that have become necessary over the years. At the same time, and against the background of the link between the essential medicines concept and national medicines policy, this paper gives an account of the major events in the health sector in the last three decades, whose impact has been both national and global.

Besides serving a documentary and informative purpose, *Thirty Years of Essential Medicines* serves another, perhaps even
more important, function; that of a basis for thought and discussion. This anniversary is an opportune moment to plan the actions and policies to be pursued as the millennium progresses. The questions raised and different opinions expressed at the end of the paper are intended to encourage individual countries and the international community as a whole to examine the challenges they face now and those that they will face in the future with regard to medicines, as an essential component of any health system.
I. ESSENTIAL MEDICINES: THE GREAT HEALTH REFORM


According to the definition of the World Health Organization (WHO), essential medicines are those that satisfy the priority health care needs of the population. In other words, they are “of the utmost importance, and are basic, indispensable and necessary.” Currently, the criteria used to include a particular medicine in the WHO Model List of Essential Medicines are its relevance to meeting priority health needs, its cost-effectiveness and its safety and efficacy. National health systems must have access, at all times, to the selected medicines, in adequate amounts,
in the appropriate dosage forms, with assured quality and adequate information and at an affordable price.\textsuperscript{5}

The concept of essential medicines is linked to that of national medicines policy. For both of these, the principal point of reference is the primary health care model. The adoption of a national medicines policy based on the concept of essential medicines promotes the efficient management of pharmaceuticals, because decisions focus on a small number of medicines. The selection of essential medicines introduces a degree of rationality into the range of pharmaceutical products and strengthens the hand of the authorities in negotiations, enabling them to make better use of the available resources and guiding decisions on public funding.\textsuperscript{6} The list also makes it easier to monitor the availability of medicines, facilitates price control and adjustment of donations, optimises drug distribution and procurement by reducing the number of products that need to be stored and distributed and fosters economies of scale. The list thus makes it easier for prescribers and patients to familiarise themselves with the medicines, thereby improving the quality and efficacy of treatment and reducing the cost of health care.\textsuperscript{7}

The WHO Model List of Essential Medicines is a continually changing tool that is periodically updated. Its contents are not mandatory and it is rather, as its name suggests, an indicative list. Consequently, the medicines included in it are not equally "essential" to all countries; the list rather provides a basis to enable States to adopt their own national lists. To do so, the health


authorities must take into account their countries' specific epidemiological features, along with their human and financial resources and inter alia, environmental, genetic and demographic factors. In this light, the Model List of Essential Medicines may provide guidance for the four levels involved in selecting medicines: registration, development of national lists on the basis of epidemiological and therapeutic criteria, development of lists in the hospital and medical environment and lastly, medical prescription, to which the WHO Model Formulary also contributes. The latter publication, which was published for the first time in 2002 at the recommendation of the WHO Expert Committee on the Use of Essential Medicines, complements the Model List and serves, in turn, to help States in developing their own national formulary.\(^8\)

The Model List of Essential Medicines is prepared by the WHO Expert Committee on the Use of Essential Drugs, and then approved by the Director-General of WHO. The Committee is comprised of eight to twelve members drawn from WHO Advisory Panels for Drug Evaluation and for Drug Policies and Management,\(^9\) taking into account regional representation. In drawing up the list, an effort is made to maintain a balance between the Committee's necessary independence and the broad participation of interested parties (industry, patients' groups and the authorities). To achieve this, the Committee's meetings are usually private, though there is also a channel for submitting comments on proposals for the inclusion or deletion by the Committee of medicines in the List.\(^10\)

---


10. *Ibid.* proposals are made by Headquarters as well as by the WHO Regional Offices and departments concerned, which also channel proposals from outside WHO.
2. Origins and Background at National Level

In the 1960s and 70s, in response to skyrocketing expenditure on medicines, various developing countries initiated policies to rationalise medicine expenditure in order to ensure wider and better access. The situation in these countries was paradoxical; on the one hand, tens of thousands of pharmaceutical specialties were flooding their markets as the result of the proliferation of commercial variations of the same active ingredients and the insistence on using proprietary names rather than the international nonproprietary name. Nevertheless, in spite of this surfeit, most of the population was unable to afford the medicines needed to address the most basic needs, as their prices and marketing were decided with an affluent population in mind. The background to this was marked by failure to select medicines, unfettered advertising, a chaotic drug distribution system, a lack of objective information on medicines and weak or non-existent regulatory agencies.


15. M. Mamdani, op. cit., p. 3
Countries such as Peru, Sri Lanka, Egypt, Cuba and Costa Rica identified the development of national lists of priority medicines, bulk procurement and local manufacture\textsuperscript{16} as the channels for responding to the imbalance that existed.\textsuperscript{17} The identification by WHO of a range of cost-efficient and high quality drugs was the institutional response to assure progress in public health in certain countries. In this respect, formulation of national drug lists dates back to the 1950s in countries such as Sri Lanka and Papua New Guinea, to the 1960s in Cuba and Peru and to the 1970s in countries such as Mozambique. The Scandinavian countries and\textsuperscript{18} Tanzania had both adopted lists of essential medicines,\textsuperscript{19} and a number of industrialised countries such as Canada and Australia practised selection of medicines.\textsuperscript{20} In addition, in the hospital sphere, many health centres in industrialised countries have been adopting lists of basic drugs for several decades.\textsuperscript{21}

Particularly significant were the initiatives taken by Sri Lanka and Peru. Sri Lanka, which began selecting drugs to satisfy priority health needs in hospitals in 1959,\textsuperscript{22} deserves credit for having

\begin{itemize}
\item \textsuperscript{17} M. Mamdani, op. cit., p. 8.
\item \textsuperscript{18} In Norway, drugs were only awarded health registration if they demonstrated a therapeutic improvement. B. Jodal, “Selecting drugs on the basis of need”, \textit{World Health Forum}, Vol. 6, 1985, pp. 67-69.
\item \textsuperscript{20} T. Smith, “Limited lists of drugs: lessons from abroad”, \textit{British Medical Journal}, vol. 290, 1985, p. 532
\item \textsuperscript{21} In the 1930s the New York Hospital adopted restricted drug formularies, a practice that had become generalised by the 1970s in the United States, the United Kingdom, Italy, Denmark, Sweden and Norway. O. M. Bakke, “How many drugs do we need?” \textit{World Health Forum}, Vol. 7, 1986, p. 252.
\item \textsuperscript{22} It was in this year that the Ceylon Hospitals Formulary was adopted and the national formulary committee was set up. See W. A. S. de Silva, “Essential
one of the oldest and most successful systems for selecting pharmaceuticals; selection was subsequently supplemented by promotion of generic drugs and centralised drug procurement by a single agency.\textsuperscript{23} Elsewhere, in June 1960 Peru drew up a list of basic drugs and in 1971 instituted a basic drugs programme.\textsuperscript{24} The Peruvian programme was particularly significant on at least two counts. First, it prompted the adoption of the first international list of essential medicines, for which credit is due to the Andean countries.\textsuperscript{25} Though, this achievement was short lived because it was premature, because of pressure received by the Andean countries after the adoption of the list, and because of the weakness of the Andean Group at that time. Second, it caught the attention of WHO, whose then Director of the Pharmaceuticals unit, Dr. Fattorusso, sent Dr. Nakajima, later to become the Director-General of WHO, to Peru. In Peru, Dr. Nakajima met Dr. Antezana, who was many years later to become Assistant Director-General of WHO; in both cases after previously having directed the essential drugs programme and unit.


\textsuperscript{25} Executive Secretariat of the “Hipólito Unanue” Convention, \textit{Informe sobre petitorio básico de medicamentos indispensables, sistema de registro sanitario, sistema de control de calidad y farmacopea común para la subregión andina}, Second meeting of the health council, Lima, 25/5/1976, CS/II/di 1, pp. 19-78.
International cooperation in the field of pharmaceuticals has a long history, dating back to the nineteenth century in the field of biological standardisation and the adoption of pharmacopoeias. However, it was not until the end of the 1960s, after many countries had gained independence, accompanied by promises of improvements in the field of health, that rationalisation of expenditure on drugs and inequitable access to them became matters of priority in the international sphere, both for intergovernmental and international institutions. Countries in the Non-aligned Movement faced with major challenges in the fields of health and economics put the issue of drugs at the top of their agenda for their meeting in Colombo in 1976. At the same meeting, they urged developing countries to cooperate in the production, supply and distribution of drugs and requested the assistance of the international organisations.

Meanwhile, a debate was underway within international organisations over the appropriate development strategy to pursue. Besides creating infrastructures, a start was made on promoting another approach, focusing on the social aspects of development, with the inclusion of issues such as equity, redistribution of wealth and human rights. In the sphere of health, this approach was reflected in the concept of "primary health care" and the "Health for All by the Year 2000" strategy, which introduced and shaped a new health model as well as redirecting the work of WHO, which henceforth became more concerned with the problems in the developing countries. WHO added to this model

a comprehensive vision for its activities and paid greater attention to health determinants as well as to social and economic factors. In the area of pharmaceuticals, the needs of developing countries and the determined commitment of the Director-General, Dr. Halfdan Mahler, led to assistance with developing and implementing national policies alongside traditional technical and normative matters. This assistance reflected the conviction that a “more effective health policy, based on the development of primary health care, calls for a resolute essential drugs policy, based on peoples' actual needs.”

The concerns of the recently independent countries also included drug manufacturing capacity, and in 1978 the World Health Assembly declared local manufacture of essential drugs to be a “legitimate aspiration”. Two years previously, the Working Group on Drugs had been jointly set up by WHO, UNCTAD and UNIDO, with the assistance of the United Nations Department of Technical Cooperation for Development. As well as facilitating the creation of the Action Programme on Essential

27. V. Fattorusso, op. cit., p. 177.
29. Initially, UNCTAD focused on technology transfer and promoting the local and regional pharmaceutical industry. Later on, it broadened its interest to cover issues such as the protection of intellectual property and the impact of trade agreements and investment treaties on drug policy.
30. In 1969, UNIDO brought together a group of experts to establish pharmaceutical industries in the developing countries; the group considered questions of quality control and personnel training and recommended that production be adapted to local requirements. At subsequent meetings, it continued to stress the need to seek responses suited to local circumstances and to adopt national basic drug lists. See R. Blum et al. (Eds.), Pharmaceuticals and health policy, London: HAI, 1981, pp. 224-225.
31. The Working Group undertook the first major analysis of the problems faced by the developing countries in obtaining safe, effective and affordable medicines; this was to be one of the bases of numerous national and international policies in this respect. UNDP, Pharmaceuticals in the Developing World: Policies on Drugs, Trade and Production, New York: UNDP, INT/009/A/01/99, 1979.
Drugs (DAP), this type of collaboration, in combination with the contribution in the early 1980s, of United Nations funds or programmes such as UNICEF, marked the emergence of a United Nations policy on drugs. Within the United Nations, where pharmaceuticals were concerned, UNCTAD was assumed to be taking responsibility for trade and technology issues and UNIDO for industry, with WHO being ultimately responsible for developments affecting health.

32. M. Mamdani, op. cit., p. 16
1. Phase One. 1975-1981. Establishing the Programme

The essential medicines concept arose at a time of great changes in the field of international health cooperation. In 1977, the World Health Assembly endorsed the “Health for All by the Year 2000” strategy whose purpose, via the new "primary health care" model, was the attainment of a level of health by all citizens of the world to permit them “to lead a socially and economically productive life”\(^\text{33}\) by the year 2000. The Health for All Strategy was underpinned by equity, the community dimension and a comprehensive approach to health.\(^\text{34}\) Essential medicines are not only crucial to the success of the strategy,\(^\text{35}\) and included among the eight basic elements of primary health care, they are also part and parcel of its very philosophy. Accordingly, “Health for


\(^{34}\) The Declaration of Alma-Ata included a number of principles that were later taken up by the Strategy: uniform distribution of health resources and access to essential care, the right to participate in the planning and implementation of health care, provision of promotive, preventive, curative and rehabilitative services, sustainable and acceptable health technology and the need for the action of many other sectors in addition to the health sector.

\(^{35}\) V. Fattorusso, op. cit., p. 179.
All” involves “selecting technology that is appropriate for the country concerned in that it is scientifically sound, adaptable to various local circumstances, acceptable for those for whom it is used and to those who use it and maintainable with resources the country can afford”. Likewise, the essential drugs concept is based on the selection of drugs on the basis of local health needs, financial resources and the existing health system.

In May 1975, before representatives of WHO Member States at the World Health Assembly, Dr. Halfdan Mahler insisted on the need to develop national pharmaceutical policies based on the affordability, quality and availability of drugs. The States responded to the report by the Director-General by adopting a resolution in support of national pharmaceutical policies that meet actual health needs and urged the Secretariat of WHO to help States to formulate them. Rapidly, the concepts of “essential drugs” and of “national drug policy” entered the vocabulary of global public health. After the compilation, in 1976, of national practices based on lists of basic drugs, the first meeting of the Expert Committee on Selection of Essential Drugs was held and, in 1977, WHO adopted the first Model List of Essential Drugs.

38. WHA, Prophylactic and therapeutic substances, 1975, WHA28.66. In the same resolution, the Assembly requests the Director-General to advise Member States on “the selection and procurement, at reasonable cost, of essential drugs of established quality corresponding to their national health needs”.
Within WHO itself, the essential drugs concept was initially implemented by the Drugs Policies and Management Unit, which was set up in 1977 within the Division of Diagnostic, Prophylactic and Therapeutic Substances. This Division already managed the Pharmaceuticals unit, which was responsible for normative and technical matters and which would provide the first staff of the Drugs Policies and Management Unit. During its four years of existence, the new unit carried out valuable work whose result, of far greater significance, was the expert meeting that produced the first Model List, the convening of the Working Group on Drugs, and the preparation of a report submitted to the 1978 World Health Assembly proposing the basic lines of action in respect of essential drugs.

The World Health Assembly responded to the report by adopting a resolution in which it urged its Member States to establish lists of essential drugs, to optimise their systems of drug procurement, to enact legislation and to collaborate with WHO and other agencies to attain these objectives. For its part, the Executive Board requested the Director-General to "appeal to governments and the pharmaceutical industry to participate in WHO's action programme of technical cooperation aimed at making available ... essential drugs." In 1979, the creation of DAP was approved, although it did not start operating until 1981, when the Drugs Policies and Management Unit disappeared.

---

43. G. Walt, J. W. Harnmeijer, "Formulating an essential drugs policy: WHO’s role", in N. Kanji et al., op. cit., p. 27.
47. K. Lee, op. cit., p. 84.
case, the programme carried on with the activities and staff of the disbanded unit. The objective of the Action Programme on Essential Drugs and Vaccines (EDV), which was conceived as an operational global programme, i.e. one jointly developed by WHO Headquarters and regional offices, was to help Member States to develop national drugs policies and to ensure regular supply of a selected number of safe and effective drugs of acceptable quality and at the lowest possible cost.


Initially, DAP encountered significant problems with funds and direction. Doubts as to its orientation and capacity prompted criticism by the industry and certain countries, which soon afterwards shifted from bitter criticism to attempting to influence the orientation and activities of DAP. For its part, in 1982 the programme itself informed the Executive Board of WHO that the lack of funds was preventing it from carrying out its activities. At the time, there was also some confusion about the nature of the programme, as it was uncertain whether it was a new unit, a conventional WHO programme, or a strategy.


Three crucial developments at the operational, political and institutional levels put an end to the programme's faltering start. First of all, the Danish International Development Agency reached an agreement with WHO, UNICEF and the Tanzanian authorities to implement an essential drugs programme in Tanzania that would serve as an example of what could be achieved. The project's Director, Dr. Lauridsen, later joined DAP as a manager. Secondly, in 1982 the Member States of WHO approved the main lines of action of DAP, and the World Health Assembly adopted an action programme incorporating the main elements of a national drugs policy. The final qualitative leap was taken in 1983, when DAP was transferred from the Division of Diagnostic, Prophylactic and Therapeutic Substances to the Office of the Director-General, thus acquiring greater visibility, support and protection.

In 1983, the work plan of DAP was outlined; its main task was identified as helping countries to obtain access to drugs. At the operational level, and with a view to disseminating the essential drugs concept, DAP became directly involved in one or two national drugs strategies in each region. This led to the development of a mutually enriching relationship: on the one hand, the programme provided technical assistance to countries and on the other, the experience garnered served to promote the essential

---

56. This led to no small number of internal disputes: the transfer to the Office of the Director-General meant that the salary of the Manager of DAP was equal to that of a Director, higher than the salary of the Manager of the Pharmaceuticals unit. Moreover, in contrast with the Pharmaceuticals unit, DAP was mainly funded by directly collected extrabudgetary funds, which enabled it to raise its profile and to double the size of its staff between 1982 and 1989. G. Walt, J. W. Harnmeijer, “Formulating an essential drugs policy: WHO’s role”, op. cit., p.44.
drugs concept and the need to develop national drugs policies. In 1984, the World Health Assembly requested that the Director-General develop activities designed to promote the rational use of drugs and drew attention to the importance of improved knowledge and flow of information and control of marketing practices.

The Conference of Experts on the Rational use of Drugs, held in Nairobi in 1985, gave an impetus to the revised drug strategy adopted by the World Health Assembly in 1986. The Nairobi conference, which had been painstakingly planned to avoid the argument over drug marketing from monopolising the debate, reached a consensus over the need to develop national policies based on the essential drugs concept and marked the starting point for international efforts to promote rational use of drugs. The revised strategy adopted a broader vision of essential drugs, stressed their validity for industrialised countries and called for an effort to develop DAP’s information and training activities, and to focus normative activities within the

61. In response to the polemic surrounding the adoption of the International Code of Marketing of Breast-milk Substitutes, the pharmaceutical industry took the initiative and adopted its own code in 1981. HAI severely criticised the code and urged WHO to adopt its own, and the debated appeared to be on track for Nairobi. See HAI, *Not to be taken, at least not to be taken seriously*, Geneva: HAI, 1982.
63. K. Lee, op. cit., pp. 209-210
Redefinition and New Centres of Attention

Dr. Mahler’s successful period of office came to an end in 1988 and the former head of the defunct Drugs Policies and Management Unit, Dr. Nakajima, was elected as the new Director-General of WHO. As DAP was by then well established and had already proved successful in promoting the essential drugs concept, the new Director-General decided to transfer both DAP and the Pharmaceuticals unit to the recently established Division of Drug Policy and Management. Generally speaking, the new Director-General’s approach to management was more rigid and bureaucratic, in contrast to the dynamic approach of his predecessor. As far as DAP was concerned, Dr. Nakajima endeavoured to avert the polemic confrontation that had arisen in the past, and indicated that the activities of DAP should be limited to providing specific advice at the request of a State, thus giving rise to

---

64. G. Walt, J. W. Harnmeijer, “Formulating an essential drugs policy: WHO’s role”, op. cit., p. 38

65. The result was similar to that of the adoption of the Code on breast-milk substitutes, as the Assembly adopted a resolution on Ethical criteria for medicinal drug promotion, 1988, WHA41.17.

66. Headed -ad interim- by Dr. Fattorusso. Dr. Lauridsen left the Programme and, shortly afterwards, Dr. Antezana took over. J. W. Harnmeijer, G. Walt, (Coords.), An evaluation of WHO’s Action Programme on Essential Drugs, op. cit., p. 55.


uncertainty as to the desired orientation of the programme.69

Whatever the case, DAP continued to promote the adoption of national drug policies, either by directly providing States with assistance or via promotional documents and activities. For example, in 1988 it adopted one of its most widely disseminated documents, *Guidelines for developing national drug policies*.70 In addition, in the wake of the 1986 Revised Strategy, DAP was particularly concerned with promoting rational use of drugs, and its work took on a broader focus that included sociocultural factors affecting drug consumption and the importance of agents within the health system in determining those patterns of consumption. It was at this time that DAP began to foster the inclusion of an educational component into national drug programmes, to encourage the development of international awareness, to mobilise resources and to promote international initiatives to provide education on rational drug use.71

In 1990, in his report to the World Health Assembly, the Director-General affirmed that DAP had “had a positive impact on the understanding, acceptance and implementation of the concept of essential drugs”, although he urged that methods of implementation be improved.72 After a number of changes had been adopted,73 it was affirmed in 1993 that management had

---

69. The change of Director-General meant a switch from resolute support for a programme that was committed to change in drug policies to different and weaker support restricted to ad hoc technical cooperation. See A. Hardon, “Consumers versus producers: power play behind the scenes”, N. Kanji et al., op cit., p.62.


73. *Ibid*. The Programme accelerated activities, reinforced cooperation with countries and intensified operational research.
considerably improved. Nevertheless, between 1993 and 1994, DAP was beset by budgetary problems. It was then determined that in its capacity as a specialised technical entity, DAP was vested with special authority to advise on sensitive political and financial matters, and that it was precisely this activity that should be preserved in spite of the vagaries of the budget. In 1995, the Assembly considered DAP to be a priority programme for WHO, and this brought with it greater funding from the regular budget. In the years that followed, the programme published *Guidelines for drug donations,* and addressed issues surrounding the provision of potentially hazardous medicines during crises, and of the safe disposal of unwanted pharmaceuticals in and after emergencies.

In the organisational sphere, the early years of this third phase, especially between 1988 and 1991, were marked by some degree of confusion within DAP as a result of differences of opinion concerning the vision and management of its programme. As a result, at the beginning of 1992 the Director-General decided to split DAP from the Division of Drug Policy and Management, and the programme became directly answerable to the Assistant Director-General. One year later, the Traditional Medicine Unit

---

76. WHA48.26
was transferred from the Division of Drug Policy and Management to DAP. In 1997, the position of coordinator of the programme's main areas was established and work was divided into two main areas: policy and technical development and national programme development.\(^81\)


DAP was always concerned with the economic aspect of drugs and this concern was further developed in the early 1990s in the areas of promotion and advisory services.\(^82\) In 1992, and in response to a long-standing mandate from the revised strategy, which had been adopted in Nairobi, DAP started its activity to provide comparative information on drug prices, which was to prove particularly valuable and successful.\(^83\) Shortly after, in the mid 1990s, economic globalisation and its impact on health resulted in DAP expanding its sphere of action and adding to its traditional activity issues such as, the privatisation of health services and the impact on health of trade liberalisation and the international harmonisation of intellectual property rights.\(^84\)

\(^81\) In April 1996 Dr. Margaretha Helling-Borda gave up the position of Director of DAP, and was replaced by Dr. Jonathan Quick.

\(^82\) Thanks to publications such as Access to Drugs and Finance, 1991, Guide d'analyse économique du circuit du médicament, 1995, and, after 1995 the Health Economics and Drugs collection.

In 1996, the Secretariat presented a report on the global drugs situation to the World Health Assembly, marked by unequal access, lack of adjustment of drug norms to local circumstances, the existence of promotional practices resulting in harmful effects on health, and the need for better information and training for the public and for health professionals. These issues were compounded by concern about the potential impact of new international trade agreements, and in particular about the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), on access to drugs. The Assembly responded by urging Member States to reassert their commitment to the adoption of national drug policies and to tackle each of the problems mentioned, and requested the Director-General to report on the impact of the work of the World Trade Organization (WTO) with respect to national drug policies and essential drugs and to make recommendations for collaboration between WTO and WHO, as appropriate.

Between 1996 and 1997, the work of DAP on the links between the economy, medicines and globalisation was intensified. In 1997, DAP published a report that became a reference in this area, *Globalization and access to drugs: implications of the WTO/TRIPS Agreement*, which, though contentious, foresaw what the Doha Declaration was later to recognise. Though it gave rise to a bitter


86. WHA, *Revised drug strategy*, 1996, WHA49.14, pf. 2.10


debate, including indignant letters from PhRMA and the Government of the United States of America, it did not lead to a substantial revision of the document.\textsuperscript{89} Thus, the 1997 \textit{Globalization and access to drugs: implications of the WTO/TRIPS Agreement} report recognised for the first time the right of WTO Members to make maximum use of the flexibilities provided for in the Agreement in order to protect public health.\textsuperscript{90} During the same period, DAP took part in other important studies relating to the impact of the new international trade agreements on access to medicines,\textsuperscript{91} and on health reform.\textsuperscript{92} A new strategy, that was adopted in 1997, confirmed DAP's mission and set objectives and priorities for action,\textsuperscript{93} at the same time introducing an important reform of DAP's administration and staff.

In 1998, Dr. Brundtland was appointed Director-General. She instituted reforms affecting the internal organisation of WHO and its image outside. As regards drugs, the Health Technology and Pharmaceuticals cluster was established. The cluster absorbed DAP, the Division of Drug Management and Policies, the Global Programme for Vaccines and Immunization and the Programme on Health Technologies, which were reorganised into three departments: Essential and other drugs, the Department of Vaccines

\begin{itemize}
\item \textsuperscript{89} G. Velásquez, P. Boulet, \textit{Globalisation and access to drugs. Perspectives on the WTO/TRIPS Agreement}. Geneva: WHO, 1999, WHO/DAP/98.9 (Revised)

\item \textsuperscript{90} The explanation provided in the document with regard to compulsory licenses and exhaustion of property rights is essentially identical to that used in the Doha Declaration. See Ministerial Conference, \textit{Declaration on the TRIPS Agreement and Public Health}, 14.11.2001, WT/MIN(01)/DEC/2; See also C. Correa, \textit{Implications of the Doha Declaration on the TRIPS Agreement and Public Health}, Geneva: WHO, 2002, WHO/EDM/PAR/2002.3.

\item \textsuperscript{91} F. Lobo, G. Velasquez (Eds.), \textit{Medicines and the new economic environment}, Madrid: Civitas, Universidad Carlos III, WHO, 1998.


\item \textsuperscript{93} WHO, \textit{WHO essential drugs strategy: Objectives, priorities for action, approaches}, Geneva: WHO, 1997, DAP/MAC(9)/97.4
\end{itemize}
and other Biologicals and the Department of Blood Safety and Clinical Technology.\textsuperscript{94} In the new organisation chart, the Department of Essential Drugs incorporated all the components of DAP together with those of the Division of Drug Policy and Management, apart from biologicals.\textsuperscript{95}

During 1998 and 1999, progress was made in the field of drug financing and DAP published various reports and advised approximately a dozen governments on the development of more equitable and sustainable systems of financing as well as organising centralised drug procurement for several countries and continuing to provide information on the prices of medicines.\textsuperscript{96} In addition, the arrival, in 1993 of the World Bank in the field of health and the intensification of the work done by UNICEF in the same field, resulted in DAP attempting to coordinate a joint approach by all three organisations to support national drug policies by setting up the Inter-Agency Group on Coordination in Medicines, in which the European Union also participated.\textsuperscript{97} However, whether for operational reasons or because of occasionally incompatible foci, the hoped-for coordination proved weak.

Between 1997 and 1998, pursuant to various resolutions of the World Health Assembly, DAP was deeply involved in work on the relationship between pharmaceuticals and trade. Its activities included analysis and information on the impact of trade agreements on health, helping States to guarantee access to drugs within the framework of those agreements and participating in international conferences on the relationship between trade and

\begin{itemize}
\end{itemize}
health. In fact, WHO had been criticised for its absence from the negotiations over trade agreements with a potential impact on health, and in particular those of WTO. In response, Dr. Brundtland asserted that “when trade agreements affect health, WHO must be involved from the very beginning”, in view of which, WHO and DAP in particular began to analyse the impact of existing trade agreements, and of those under negotiation, on access to drugs. In 1999, the World Health Assembly, after having considered the report of the Director-General on the revised drug strategy, requested her to expand the work already carried out, particularly as regards the impact of trade agreements on access to proprietary medicines.

The work of DAP and of WHO is not restricted to analysing the trade agreements; it also resolves problems arising from certain interpretations of those agreements. For example, at the end of the 1990s, WHO supported South Africa in the claim submitted by 39 pharmaceutical companies when the Government of South Africa attempted to avail itself of the flexibilities contained in TRIPS. In actual fact, DAP had collaborated with the South African national drug programme, which was considered to be a programme of special importance on account of its potential impact on other African countries, and which involved activities such as advising on drug legislation, development of a list of essential drugs, and the establishment of a network of regional essential drug coordinators.

99. “WHO gets mandate to tackle trade impacts on health”, *Essential drugs monitor*, nº 27, 1999, p. 18
During the second half of the 1990s, DAP further developed its expertise on the impact of international trade regulation on health, as well as exploring the tools available under international human rights law. While for DAP the ideal of health as a human right had always been fundamental, it was after 1998 that it incorporated human rights into its discourse.\textsuperscript{104} Incorporation of human rights into the work of WHO, and of DAP in particular, benefitted from the intense campaign by various NGOs on behalf of access to medicines within the United Nations human rights organs. In 2000, the Committee on Economic, Social and Cultural Rights affirmed that the core obligation of the right to health included access to essential drugs,\textsuperscript{105} and this was endorsed by a number of resolutions of the Sub-Commission on the Promotion and Protection of Human Rights\textsuperscript{106} and of the United Nations Commission on Human Rights.\textsuperscript{107} In 2001, both the United Nations General Assembly\textsuperscript{108} and the World Health Assembly\textsuperscript{109} endorsed this assertion.

The incorporation of human rights into the work of DAP

\textsuperscript{104} At the time, it was asserted that “Consideration of equity and health as a human right has been strongest in WHO’s work on drug financing, globalisation and drug supply systems in the context of health reform”. WHO, \textit{Interim Report of the Biennium 1998-1999}, Geneva: WHO, WHO/HTP/EDM/MAC(11)/99.4, p. 7

\textsuperscript{105} Committee on Economic, Social and Cultural Rights, \textit{General Comment n° 14, The right to the highest attainable standard of health}, 2000, E/C.12/2000/4, pf. 43.


correlates with the increased attention they receive from the World Health Assembly. As a reflection of this, the Director-General declared before the Fourth Ministerial Conference of WTO, which adopted the decisive Doha Declaration on the TRIPS Agreement and Public Health, that “access to health care is a human right (...). This involves access to health facilities, prevention, care, treatment and support, and - of course access to life-saving medicines.” Substantive work on access as a human right began in 2002, and the 2003 Report of the Essential Drugs Department included an explicit reference to access to drugs as a human right. As a result of this trend, the Strategy 2004-2007 of the Department of Essential Medicines included the promotion of access to medicines as a human right amongst its new areas of work.

WHO began the new millennium with determined action in the area of access. In 2000, and in connection with HIV/AIDS, the Member States requested that the Director-General support the establishment of drug price monitoring systems, promote rational use of drugs and monitor the pharmaceutical and public health implications of trade agreements. Numerous delegates also stressed the need for WHO to advise countries on those implications. The reference to monitoring the public health implications of international trade agreements was repeated in a resolution of the World Health Assembly the following year, in which the Director-General was requested to support Member

States in achieving the priorities set out in the WHO medicines strategy.\textsuperscript{115} In 2002, when DAP celebrated its twenty-fifth anniversary, the procedure and criteria for updating the Model List were revised,\textsuperscript{116} and the network for monitoring the impact of globalisation and TRIPS on access to essential drugs was created.\textsuperscript{117}

In 2003, in addition to addressing the relationship between intellectual property and access to medicines, and encouraging use of the flexibilities provided for by the trade agreements, the World Health Assembly alluded to the relationship between intellectual property rights and innovation. Stimulated by the need to develop medicines for neglected diseases, the establishment of a time-limited body to examine the relationship between public health, innovation and intellectual property rights was approved; a body that was also mandated to put forward concrete proposals.\textsuperscript{118} In February 2004, the Director-General established the Commission on Intellectual Property Rights, Innovation and Public Health. In the same year, the Department of Essential Medicines presented a number of recommendations on research priorities to meet public health needs,\textsuperscript{119} and pursued its work of information and advice on all aspects of intellectual property and access.\textsuperscript{120} Again, in the same year, the Department of Essential Medicines was reorganised into two departments: the Department

\textsuperscript{115} WHA, \textit{WHO medicines strategy}, 2001, WHA54.11


\textsuperscript{117} With the participation of four WHO collaborating centres: Centre for Health Economics, Institut Català de Farmacologia, LSE Health and Social Care and the Nucleus for Pharmaceutical Policies.

\textsuperscript{118} WHA, \textit{Intellectual property rights, innovation and public health}, 2003, WHA56.27.


of Technical Cooperation for Essential Drugs and Traditional Medicine, and the Department of Medicines Policy and Standards.\textsuperscript{121} For their part, the Member States of WHO were urged “to take into account in bilateral trade agreements the flexibilities contained in the Agreement on Trade-related Aspects of Intellectual Property and recognised by the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference (Doha 2001).”\textsuperscript{122}

In 2006, in response to the report of the Commission on Intellectual Property Rights, Innovation and Public Health, the World Health Assembly\textsuperscript{123} agreed to the establishment of an intergovernmental working group to draw up a global strategy and plan of action which, on the basis of the recommendations made by the Commission, should be capable of promoting innovation in accordance with public health priorities.\textsuperscript{124} In the same year, the Assembly urged the Director-General to continue to provide support to Member States in relation to the implications of trade agreements for health.\textsuperscript{125} In 2007, Member States were urged to support the work of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property\textsuperscript{126} and together with the Secretariat, to continue their activity to promote rational use of medicines.\textsuperscript{127}

\begin{thebibliography}{9}
\bibitem{}126. WHA, \textit{Public health, innovation and intellectual property}, 2007, WHA60.30.
\bibitem{}127. WHA, \textit{Progress in rational use of medicines}, 2007, WHA60.16.
\end{thebibliography}
1. Reactions to the Essential Medicines Concept and DAP

From the moment of its inception, the essential medicines concept left no one in the medicines field indifferent. Indeed, at the outset of DAP, Dr. Halfdan Mahler referred to essential drugs as a "minefield", and throughout his period of office as Director-General he requested political support for DAP on several occasions.\textsuperscript{128} States, international organisations, physicians, patients, pharmacists and consumer organisations rapidly took position on the question of essential drugs and although no one any longer disputes the validity of the concept of essential drugs, whether for developing or rich countries, this was certainly not the case initially.

The position of the pharmaceutical industry has gone through several phases, from complete rejection, through a less categorical attitude, and finally to full acceptance of the essential medicines concept. In 1977, the International Federation of Associations

\textsuperscript{128} R. Blum \textit{et al.} (Eds.), op. cit., p. 223
of Pharmaceutical Manufacturers declared that the concept of essential drugs was considered “completely unacceptable by the pharmaceutical industry” and was "in fact strongly advocated by left-wing radicals in developed countries because it strengthens their requests for a reduction in the number of products in their home countries".\textsuperscript{129} This reaction was followed by a series of declarations stating that the essential drugs list resulted in lower quality care and introduced an arbitrary filter between the drugs on the market and the consumer.\textsuperscript{130} Nevertheless, as the essential drugs concept gathered strength in the public health sphere, the industry changed its position to one which, although maintaining that lists of essential drugs had an adverse effect on health, skills and innovation, accepts that the specific situation of the developing countries may occasionally justify lists of essential drugs.\textsuperscript{131} Whatever the case, the industry's opposition to the spread of the essential drugs concept to the developed countries and to the private sector,\textsuperscript{132} was overcome by economic rationale, public health needs and the industry's own interests, and it began to cooperate with WHO on specific aspects of DAP.\textsuperscript{133}

The hostility aroused both by the selection of essential drugs and DAP was rekindled years later by the position adopted by


DAP towards the harmonisation of standards of protection for intellectual property. The adoption of TRIPS, which is almost unanimously agreed as having been introduced “as a form of compensation to the developed countries for the alleged concessions made by them to the developing countries” within the framework of GATT,\textsuperscript{134} led DAP to draw attention to the positive and negative effects of protection of intellectual property on pharmaceuticals. Although the passage of time and the adoption of legal instruments such as the Doha Declaration have confirmed the analysis made by DAP in the mid 1990s, and most particularly the proper identification in the Agreement of flexibilities that make it possible to protect public health, the advice provided first by DAP and then by the Department of Essential Medicines led to considerable criticism of WHO and of its officials.

Whatever the case, the pharmaceutical industry has not been alone in its objections to the essential drugs concept and to policies to rationalise expenditure on pharmaceuticals. Numerous forms of pressure have been brought to bear on countries that have endeavoured to rationalise their drug policies, and it has to be recognised that the issue of essential medicines goes beyond the health sector and involves political and economic ideology.\textsuperscript{135}


\textsuperscript{135} N. Kanji \textit{et al.}, op. cit., p. ix.
The position adopted by certain countries with regard to the adoption of rational drug policies can be explained in terms of political and ideological outlook and the need to defend national industry. First and foremost, those countries that uphold the free market in order to attain their social objectives have criticised or attempted to avoid adopting policies to control expenditure on medicines. Secondly, it has been observed that certain protests about WHO’s essential medicines policy were in fact attempts to protect the private market from the restrictions entailed by public drug formularies. In this latter connection, an evaluation has been made of the willingness or refusal of certain countries to provide donations to DAP in relation to the development of their national pharmaceutical industry.

However, while health professionals as a rule welcomed the essential drugs concept, they were not unanimous. Some physicians were initially opposed to lists of essential medicines on the grounds that they infringed their right to prescribe. These criticisms were voiced despite WHO itself emphasising that the Model List was indicative and despite the fact that there was never any attempt to call for the adoption of restrictive and mandatory lists. Moreover, some physicians pointed out the need for lists of essential medicines to distinguish between primary health care and hospital care, and believed them to be appropriate only


for the former, an argument that contradicts not only contemporary hospital practice, but also the first steps towards lists of basic drugs.

In any case, with the passage of time the concept of essential medicines has become accepted and has received the support of countries, academia, institutions, professional bodies, and the law. Consumer associations were early supporters of the essential drugs concept and of DAP as were scientific publications. Within civil society, Health Action International (HAI) was founded in 1981 by the association of several groups of consumers and non-profit organisations united by the goal


141. See point I. 2. of this paper, particularly p.19.

142. Twenty years after having chaired the Expert Committee on the Selection of Essential Drugs, Dr. Joan-Ramon Laporte offered a response to the criticism levelled at the Model List, observing that the almost identical nature of the various national lists of essential drugs bolstered the validity of the concept and that “when the purpose of work relating to the use of drugs is to select the proper drug for the right patient on the basis of reliable therapeutic criteria, a common method is evolved, leading to the same results”. J-R. Laporte, “Essential Drugs”, Annals of Internal Medicine, vol. 94, 1981, p. 281.

143. UNICEF made an essential contribution by supplying essential drugs through its supply agency, UNIPAC. However, the launch of the Bamako Initiative led to it distancing itself from WHO. In addition, the General Assembly of the International Federation of Red Cross and Red Crescent Societies gave explicit support to the essential drugs concept.

144. For example, the International (drug) Dispensers Association was awarded recognition by WHO for its support for the concept of essential drugs. See, H. V. Hogerzeil, “IDA and the concept of essential drugs”, International Journal of Risk & Safety in Medicine, nº 12, 1999, pp. 75-77.

145. In addition to the support already mentioned of the United Nations human rights bodies we should add that given to the Model List by national courts and drug legislation.


of promoting safer, more rational and economic use of drugs,\textsuperscript{148} which is why the concept of essential drugs and DAP were its main focus of attention.

2. DAP’s Principal Lines of Action and Activities

The creation of DAP confirmed the reorientation of WHO's activity in the pharmaceuticals sector. It is true that in 1981, after DAP had begun working, WHO continued its traditional technical and normative activity in the field of medicines. However, DAP supplemented this activity with the provision of advice to States on drug policy and direct guidance and assistance in solving specific problems.\textsuperscript{149} It is precisely this that has been the principal activity of DAP throughout some 30 years of existence. Depending on the context; the mandate given by the Member States in the World Health Assembly and the resulting instructions given to the Director-General, this activity has varied from responding to an express request from States to fostering a genuine change in drug policies. At the operational level, and with a view to promoting drug policies that first and foremost respond to public health needs, DAP has implemented four different approaches: i) Analysis of the drug situation in a country; ii) Development of a plan for the implementation of a national drug policy linked to a national health policy; iii) Enhanced support for all aspects of drug policy, and iv) Support in specific technical areas. Generally speaking, over the years DAP has devoted between 65\% and 70\% of its resources to providing countries with assistance.


\textsuperscript{149} R. Blum \textit{et al.} (Eds.), op. cit., p. 223.
DAP came into being as an operational programme to help countries to ensure regular supply at the lowest possible cost and rational use of safe and effective drugs of acceptable quality.\(^{150}\) To do this, in addition to providing countries with direct assistance, DAP has also implemented other activities in a wide variety of areas. These involve training programmes for ministry of health staff, courses and workshops for health professionals,\(^{151}\) collaboration with non-governmental organisations, international initiatives relating to public health and drugs,\(^{152}\) and collaboration with regional integration bodies for the development of regional medicines policies.\(^{153}\) It is possible to identify three general trends from an analysis of DAP's action. While in the 1980s the adoption of national medicines policies was encouraged, from the second half of the 1990s, and more so after the beginning of the new millennium, the focus shifted to implementing and modernising those policies,\(^{154}\) and to analysing the impact of external factors on them.


\(^{153}\) Regional level cooperation has been one of the strong points of DAP’s activity, both via cooperation through the regional offices of WHO and through direct cooperation with other regional organisations, such as the Andean Group, ASEAN and the CFA and ACP countries.

\(^{154}\) See in this connection, the annual report for 2003, op. cit., in particular pp. 1-4
Direct Assistance during the 1990s

Between 1990 and 1991, DAP undertook 75 analyses of national situations and programmes, carried out 55 training programmes in 30 countries and provided direct assistance on 33 occasions to implement national medicines policies or essential medicines programmes. Between 1992 and 1993, 80 countries received technical assistance from DAP, 39 on specific issues and 25 on broader matters. Between 1994 and 1995, 66 countries received technical assistance from DAP, between 1996 and 1997, 58 countries received direct technical assistance and a comparative analysis of the national medicines policy of 12 countries was carried out. Between 1998 and 1999, 29 countries received direct support in implementing and monitoring their national medicines policy, 14 countries received assistance in the economics and financing of medicines and 18 on medicines management and supplies. During the same period, assistance was provided to a further 18 countries on regulatory activities and quality control and direct assistance on rational use to 23 countries. Also worthy of note is the existence, in all these activities, of intense and productive linkage between WHO Headquarters and the various regional offices.

Has the global medicines situation improved thanks to the action of DAP? Since the 1970s, the number of countries with lists of essential medicines has increased from less than 12 to more than 160. As has been noted by the Executive Board, DAP was an example of “an outstanding WHO programme through which a great deal of progress had been effected in the countries in which it worked”. Its influence is not limited to the adoption of lists, but includes their updating, the adoption of national medicines policies and their updating and fostering measures such as the adoption of generic medicines policies. In addition to the above, two particularly important consequences of DAP’s action should be mentioned. First, because “governments attempting to rationalise their drug systems face enormous political and economic pressure”, the role of WHO and of DAP, “in providing political, moral and financial support to these countries is critical”. Second, these thirty years of effort have achieved something far more significant than the adoption of numerous national lists of essential medicines: nowadays it is perfectly normal, if not obvious, to talk of rational use of medicines, of rationalisation of expenditure on medicines, of national medicines plans and promotion of national medicines policies. That this should be the case is also largely thanks to the fundamental contribution of DAP.

156. Executive Board, Working Paper nº 6, 95th session of the Executive Board, 221/1/1995 (annex 6)

157. Thus, for example, in less than a decade following the publication of the Guidelines for developing national drugs policies, 51 countries had introduced national medicines policies. Moreover, between 1999 and 2003 the number that had updated their national medicines policy increased by eight; in the last five years the number that had updated their essential drugs list increased by twelve, the number having adopted a plan to implement the national medicines policy increased by eight and those authorising generic substitution by sixteen. See. See WHO, DAP Report of the Biennium 1996-1997, op. cit., p. 5; WHO, Annual Report 2003. Essential Drugs and Medicines, op. cit., pp. 1-4.

IV. CONCLUSIONS AND CHALLENGES

If by reform we mean a change for the better, a major health reform occurred in 1977 with the adoption of the WHO Model List of Essential Drugs. The essential medicines policy recommended by WHO embodies many qualities; it is a technically valid, economically feasible and socially acceptable option and thus helps to encompass the four dimensions of health reform - scientific and technical, economic, social, and political. Thanks to these qualities, the essential medicines concept, and with it DAP, are still alive today, having survived numerous onslaughts.

“The essential drugs concept is today a key issue on the international health agenda. Together with the concept of primary health care, it is one of the major achievements of WHO over the last two decades, and its most durable pharmaceutical


initiative”.\textsuperscript{162} Essential medicines are perhaps the most cost-effective element of public health after immunisations and key health promotion habits.\textsuperscript{163} By mobilising resources and opinion, DAP has transformed the essential drugs concept into a key issue on the international health agenda and has changed the way the pharmaceutical policies of developing countries are discussed.\textsuperscript{164}

DAP operates within a highly complex technical, social, political and economic environment; it conducts a vast range of activities in order to respond to an imbalanced economic and technological situation that denies large segments of the world's population access to the most essential drugs and vaccines.\textsuperscript{165} No doubt the sphere of medicines is the scene of convergence and of a power struggle between highly diverse interests, which is why legal confrontation and political pressure “are endemic and have to be taken into account”,\textsuperscript{166} and this has been done by DAP since its very beginning. Whatever the case, the essential medicines concept has proved to be far more than a passing trend, and it has imposed its rationale on health management models born out of excessive confidence in the ability of the market alone to solve problems in the health sector. The challenges facing the essential medicines concept and the work of WHO in the field can be formulated in a number of questions.

\begin{itemize}
\item \textsuperscript{162} K. Weersuriya, P. Brudon, “Essential drugs concept needs better implementation”, \textit{Essential Drugs Monitor}, n° 25 & 26, 1998, p. 32
\item \textsuperscript{164} M. Reich, “Essential drugs: Economics and politics in international health”, \textit{Health Policy}, vol. 8, n° 1, 1987, pp. 43 y 48.
\item \textsuperscript{165} WHO, Global medium-term programme. \textit{Programme 12.2}, op. cit., p.4.
\end{itemize}
The first question that needs to be addressed, particularly on account of the consequences of different concepts on access to medicines, concerns the nature of medicines. For some, medicines are industrial and commercial commodities rather than health products. This concept is rooted in a rationale which maintains that the market alone is capable of providing the necessities for social justice, including access. However, considering medicines as mere commodities gives rise to problems such as failure to supply unprofitable markets, the lack of research into diseases specific to developing countries and the determination of prices on the basis of financial calculations that do not always match public health needs. For these reasons, WHO maintains that medicines are not mere commercial commodities, but an essential element within health care, conferring on them the quality of a public good and an essential element in ensuring the right to health.

Another fundamental question concerns the future of the essential list concept. There are two facets to this question; firstly, what will be the consequences for essential medicines lists of the profound changes affecting the majority of health financing systems, whose effects it is hard to predict? On the one hand there is a temptation to apply too strict a definition in determining what constitutes a list of essential medicines, thereby justifying the withdrawal of certain medicines from the list, which as a rule means that they are sold on the open market at unsubsidised prices. On the other hand however, there is undeniable and legitimate pressure, both

from public health systems and from the complex network of private providers, for drugs to be selected on the basis of cost-effectiveness criteria. To solve this dilemma, there is a need for clear selection criteria and a transparent selection process that are also subject to revision by those concerned; this is the case of the WHO Model List. It is also important for selection committees to consist not only of clinical pharmacology specialists, but also to include other professionals concerned with medicines such as economists, anthropologists, and specialists in politics and law.

This latter requirement leads us directly to a major problem, namely, that the current state of affairs indicate a regression. The essential medicines concept came into being partly as a response to the surfeit of pharmaceutical specialties, which were simply brand names containing relatively few molecules. The selection of medicines was an attempt to put an end to this state of affairs by introducing criteria of rationality and cost-effectiveness into medicines policy. Nowadays, although for a different reason, a surfeit of medicines persists in many countries. Belief in the unfettered progress of science has led to the conviction that there is a multitude of medicines available to treat each condition and that they are moreover constantly being updated, the most recent (and most expensive) being the best. The surfeit of unnecessary drugs is a serious problem in developed countries and “the need for drug selection is not restricted to developing countries. Health care costs in general and drug costs in particular are rising everywhere. (...) The concept of essential drugs is just as valid in developed countries, in teaching hospitals, and in health insurance schemes”\textsuperscript{170}

The essential medicines concept was developed for drugs intended to prevent, treat or cure any illness. Nevertheless, and partly as a result of attempts to limit the essential medicines concept to the developing countries, there seems to be a trend to restrict DAP’s action to diseases which “disproportionately affect poor countries”, a term which generally refers to malaria, tuberculosis and HIV/AIDS. This trend runs counter to the very spirit of the essential medicines concept, which is designed for widespread application. The Annual Report 2005 warns of the undesirability of disease-oriented programmes operating in isolation, not only on account of unnecessary managerial redundancy, but also because of the risk of developing a partial view of health and of the issues raised by medicines.

A distinct, albeit related set of issues concerns the possibility of the essential medicines concept being the victim of its own success within WHO. It is worth pointing out that the different programmes and areas of work are showing considerable interest in the essential medicines concept, and this is reflected in the adoption of lists of essential medicines in specific areas. While one can take satisfaction in the usefulness of the concept, there is no denying that there is occasionally a lack of coordination. For this reason, consideration should be given to the possibility of restoring a single list along with that of intensifying cooperation among the different selection committees, thus preserving the original objectives: to avert proliferation and a piecemeal approach to the selection of medicines.

We should also draw attention to the difficult road ahead as regards regulation of intellectual property rights, protection

of public health and promotion of innovation based on actual health needs. There are two distinct issues, the issue of innovation and that of access. WHO and DAP have on repeated occasions expressed their support for intellectual property rights as a spur to innovation. This support has gone hand in hand with examination and analysis of the scope and potential of intellectual property; while on many occasions it has proved to be a valuable tool in promoting innovation, on others it has shown itself to be dysfunctional. At present, in the wake of reports such as the United Kingdom Commission on Intellectual Property Rights and the WHO Commission on Intellectual Property Rights, Innovation and Public Health there is a tendency to assume that intellectual property is a tool for encouraging innovation, and not necessarily the only one or the best. Consequently, there are various channels through which investment in innovative medicines intended for priority diseases may be encouraged and revived. For this reason, the recommendations due in 2008 from the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property are awaited with special attention.

As far as regulation of protection for intellectual property and its impact on access to medicines is concerned, following the clarification and acceptance of the flexibilities provided for by the TRIPS Agreement that protect public health, there is currently a proliferation of bilateral trade agreements which restrict the tools available to facilitate access to medicines. The World Health Assembly has referred to those agreements and indicated that States must ensure that they do not undermine their ability to protect public health. It should also be remembered, as the Indian courts have recently affirmed, and as specialised case law has been insisting for some time, that States enjoy considerable margin for manoeuvre in defining, in accordance with their level of industrial
development, the requirements for patentability, which permits the patenting of genuine innovations rather than cosmetic changes. In this respect, both the emergence of the debate over the consequences of intellectual property rights on access to medicines and the examination of the channels whereby innovation may be encouraged have resulted in numerous industrialised and developing countries querying the nature of the patents awarded by them, and on numerous occasions they have corrected the laxness with which patents have been awarded in recent years.
Behind the simple description of essential medicines as those that meet the real health needs of the population, is one of the biggest revolutions of the last decades. The essential medicines’ concept encompasses those medicines that meet people’s real health needs as well as the cost-containment of pharmaceutical products. As a result, it has been a contentious issue throughout the three decades of its existence. The World Health Organization’s Essential Medicines Programme, a firm promoter of access to medicines as a human right, has been the subject of numerous debates, the most recent surrounding the impact of intellectual property on access to medicines. This book is the first historical summary of the last thirty years of essential medicines. The book calls for the essential medicines’ concept to be put into action and identifies the current and future obstacles to making access to essential medicines an effective human right.

Fernando Antezana, PhD in Biochemistry and Pharmaceutical Sciences, was Deputy Director-General of the World Health Organization, President of the Executive Council of the World Health Organization and Minister of Health of the Republic of Bolivia. He was also Head of the Essential Medicines Programme.

Xavier Seuba, PhD in Law, is a Lecturer in Public International Law at the Pompeu Fabra University, Barcelona. He has worked for the World Health Organization on medicines-related issues, particularly in the areas of intellectual property rights and human rights. He has also served in the United Nations Office of the High Commissioner for Human Rights.