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Conference report

International Conference on National Medicinal Drug Policies

Sydney, Australia: 8–11 October 1995

Editorial note. In recent years there have been few occasions on which a large group of countries have met to define proper policies with respect to drugs, their approval and marketing. The International Conference on Harmonization has established many standards, but its approaches have been determined largely by the interests of a number of large industrialized countries and groupings – notably the European Union, the USA and Japan. The Sydney Conference of October 1995 was different. The countries represented were largely those at a less advanced stage of development, seeking to determine their own needs and joint interests. Although participation in the Conference was largely from South East Asia and the Western Pacific area, the meeting attained a global standard and much of its work is applicable to any country in the world. The attached account of the meeting's work is a slightly abridged and edited version of that issued officially after the Conference.

Introduction

The theme of the Conference was: "*Can a comprehensive approach to national medicinal drug policy meet both health and economic needs?*" The conference explored these questions from an international perspective, but particularly concentrating on the Asia-Pacific region. This region contains over half of the world's population and is one of the fastest growing pharmaceutical markets. Increasing population, widening income gaps. Changing epidemiological patterns, constrained public budgets, rising pharmaceutical expenditure, lack of trained personnel and counterfeit drugs are some of the forces that governments in the region are obliged to manage in order to provide safe and affordable essential drugs to their people. Many countries in the region are also developing their own pharmaceutical industries in order to increase self-sufficiency and to contribute to their economic development.

In 1988, building on its experience with essential drugs programs, the World Health Organization (WHO) published "Guidelines for Developing National Drug Policies". The WHO has strongly encouraged countries to implement national drug policies to help in meeting the basic health care needs of their populations, especially at the primary health care level. National drug policies enable countries to tailor their allocation of resources to their particular needs, reflecting major health issues and the way in which their health services are delivered.

An increasing number of countries are giving considerable political commitment to the development and implementation of national drug policies. However, due to a variety of economic and other

pressures, successfully implementing and sustaining a policy can be difficult. This is particularly so if the objective is to address comprehensively what are usually regarded as the four major parts of a national drug policy, i.e.:

- to ensure or improve the quality of medicines;
- to ensure equitable access to them;
- to ensure their rational use;
- to establish or main, where appropriate, a viable local pharmaceutical industry.

The challenges of national drug policies apply to both developing and industrialised countries. There are many tensions between economic and health objectives. These tensions are increased by many of the international changes currently taking place, especially in relation to trade, changes in the multinational pharmaceutical industry and constraints on public sector financing.

The Conference was designed to encourage participants to think broadly about national drug policy, rather than examining any one technical issue in great depth. In some areas (for example, the quality, safety and efficacy of medicines) international for a already exist to consider the issues. In other areas, for example, rational use of drugs, specific meetings and studies are needed to examine in detail successful approaches and unanswered questions. This conference aimed to bring governments, the pharmaceutical industry, academics, health professionals and consumers together at a regional and an international level, to discuss experiences and challenges and to establish networks for further development of national drug policies.

The conference sought in particular to:

- discuss the needs and experiences of countries in the region in developing national drug policies;
- explore the complexities and tensions involved in national drug policies;
- strengthen networks and collaboration between countries;
- recommending action to strengthen national drug policies in the Asia-Pacific region.

The 300 participants came from almost 50 countries, with representatives of governments, international organizations, academia. Consumer organizations, the health professions and the pharmaceutical industry. Various countries outside the region were represented, including some from Europe, Northern America, Latin America, and Africa; also represented was the World Health Organization (headquarters and regional offices), the World Bank, UNICEF, UNIDO, industry associations and individual companies, consumer organizations (such as Health Action International/Consumers International) other voluntary organizations, professional associations, universities, and non-profit organizations such as the Dag Hammarskjöld foundation, the Medical Lobby for Appropriate Marketing and Management Sciences for Health.

The programme

The four days of the conference were designed to create an environment in which greater understanding would result from a constructive dialogue between nations in the region, between the international agencies and between the different sectors and experts involved in drug policies. The openness with which countries, organizations and individual experts presented and analyzed their experiences contributed greatly to the successful discussions which took place at the conference.

In addition to formal presentations at the conference, there was a poster display of interesting initiatives, programs and research relevant to national drug policy; topics included were drug information, academic detailing, drug promotion and training for the rational use of drugs.

Exploring the issues

In a keynote address on the second day. Dr. Alfredo Bengzon, of Ateneo de Manila University in the Philippines. Encouraged participants to step out of conventional ways of thinking about drug policy and consider how it illustrates fundamental relationships between health and society: "Drugs are essential to health and health is essential to development". Reform in a national drug policy is inevitably characterised by issues and conflicts that are complex and multifaceted requiring comprehensive and inclusive responses. Dr. Bengzon observed that national medicinal drug policies are part of a reform process which "cannot be unilaterally imposed through legislation, regulation or litigation, but instead must emanate from true intersectoral collaboration and commitment". Solutions cannot be based solely on technical proficiency, political experience or economic necessity. Instead, "... responses should be crafted through open, honest, thoughtful and productive development dialogue directed at achieving a 'win-win' situation, one in which all positions are advanced, not necessarily equally so, but certainly equitably so".

Margaretha Helling-Borda, the Director of the WHO Action Programme on Essential Drugs, traced the history of national drug policies since the essential drugs concept was formulated by the WHO in 1975. At present, 130 countries have national essential drugs lists, while nearly 40 countries have adopted national drug policies, and another 25 countries are developing such policies. A revised version of the 1988 WHO "Guidelines for Developing National Drug Policies" will soon be available. Major challenges identified by the WHO are the need to understand how both private and public sectors can work in an integrated way to assure equitable and affordable access to necessary drugs, and the need to assess and better understand the policy process.

This second day provided an opportunity to share the experiences of several countries in the region in establishing national medicinal drug policies.

Some successful elements, in developing a national drug policy appeared to be:

1. Political commitment and government leadership. As a consequence, legislation, an administrative structure and resources, both human and technical, are all needed.
2. Clear definition and promulgation of the policy to all the sectors affected by the policy.
3. Involvement of all sectors in an honest open dialogue. This results in recognition and respect for, the differing skills, needs, aspirations and interests which each sector can bring to the development and implementation of a national drug policy. With this broad involvement, recognition must be given to the complexity of the process. Adequate time must be allowed for all sectors to develop a sense of 'ownership' of the policy.
4. Development of an essential drugs list and/or drug formulary supported by the provision of information on the optimal use of medicines. With this approach generic labelling and generic prescribing should be encouraged.
5. Recognition of the potential value of some traditional medicines and inclusion of appropriate traditional medicines in the national drug policy.
6. Knowledge and sharing of the experiences of other countries with collaboration and support from such countries as well as from regional and international organizations.

Experience shows that weaknesses and threats to a national drug policy include:

1. Failure to integrate a national drug policy into a national health policy. The WHO takes the view that a national drug policy should be considered as an integral part of total health care. Failure to do this may result in a less effective delivery of a national drug policy and all its potential

benefits may not be achieved. Government commitment to a national drug policy is also easier to sustain if it is developed in the context of a broad health policy.

2. Lack of continued political commitment. Experience to date has shown that the development and implementation of a national drug policy is more complex and takes longer than may be expected at first. There is therefore a need for the long-term commitment of governments to the goals of a national drug policy. Within government this commitment may be threatened by the continuing competition for government resources. In an effort to resolve these issues a decentralised approach to a national drug policy may be useful in some countries. Such an approach will need to be evaluated carefully because an apparent benefit in central costs may be lost by duplication of resources in the periphery and a breakdown in a cohesive approach to policy implementation. Decentralisation should be implemented in stages rather than by drastic changes.
3. Inappropriate drug use. There are many issues which can contribute to this problem, such as inappropriate dispensing, lack of information, or inappropriate promotion. These examples include the way in which dispensing doctors, in some countries, are found to to prescribe in a less objective manner than non-dispensing doctors. Similarly, the widespread supply of inappropriate medicines through retail outlets may be a threat to the implementation of a national drug policy. Possible approaches to resolve this could be the establishment of peer-review processes and the development of a national code of pharmacy practice.
4. International trade agreements and free trade associations. Such arrangements may conflict with the goals of a national drug policy in some countries. Governments should be aware of this when they are developing a national drug policy.

Presentations on the development and testing of indicators to measure the progress of national drug policies and comparative analyses of countries' experiences illustrated some new initiatives in documenting and assessing the development and implementation of policies. The need for clear policy objectives and indicators was confirmed.

Workshops

Workshops (concurrent sessions to explore some key issues and problems in more detail) were held on the third day. The four workshops were on access to medicines, rational use of drugs, the quality, safety and efficacy of medicines, and the contribution of the pharmaceutical industry to national drug policy and public health goals. The participants to each workshop were asked to consider a number of pre-formulated questions designed to stimulate thinking of participants and ensure that the principal aspects were dealt with. Each workshop produced draft recommendations which contributed to the final recommendations of the conference.

Access to medicines

The workshop on this issue sought:

- to identify realistic strategies for ensuring equitable access to medicines;
- to identify mechanisms by which the private sector can deliver essential drugs at affordable prices to the whole population;

- to suggest how to make the public sector effective in providing access to essential drugs;
- to discuss the outlook over the next 5 years for the relative importance of both sectors in delivering affordable essential drugs.

The experiences of countries at varying levels of development illustrate several approaches to providing access. They include liberalisation of a market to reduce shortages of drugs, attempts to introduce generic drug strategies and provide a restricted but adequate selection of drugs for public sector supply together with price control. One country illustrated the attempt to reform a state-subsidised system to one in which the government provides the funds, but where the purchasing of health care is managed by autonomies authorities which buy products and services including pharmaceuticals from a range of agencies.

The following principles were agreed:

1. Health should be seen as a driving force for development and national drug policies should be part of a health policy.
2. Political will is essential for implementation of successful policies to improve access.
3. The focus should be on finding ways to ensure equitable access particularly for the poor.
4. Market forces alone cannot guarantee access to needed drugs for the entire population; the market therefore needs to be regulated.

Some 'Key lessons' emerging from experience to date were also defined. To summarize them:

Geographical access has been achieved variously through using:

- community run pharmacies (vital elements here are community participation, existence of an essential drug list and good procurement);
- various types of "drugstores" with different levels of staff training;
- informal drug sellers;
- "health packs", including drugs and distributed through community health workers.

Financial access has been achieved variously through:

- price controls (as in Sri Lanka, Pakistan);
- health insurance (as in the Philippines, Thailand);
- co-operatives/drug funds (as in Thailand, the Philippines);
- dissemination of comparative pricing information (as in Pakistan, the Philippines);
- active price competition through supply of generic drugs (as in Indonesia, the Philippines).

Various other lessons emerge from experience in the region, e.g.:

- when setting prices, convincing evidence of the superiority of one drug compared with others is needed;
- there is a need for pluralistic approaches to the design of strategies for improving access to medicines;
- economic and other incentives are needed to foster availability of drugs at low cost.

Rational use of drugs

This workshop set out:

- to examine a variety of experiences to identify issues and problems;

- to identify promising methods, barriers to progress, gaps to be addressed;
- to develop strategies for improving the rational use of drugs.

Experiences on this issue were available not only from individual countries but also from a number of bodies working internationally, notably the International Network for the Rational Use of Drugs (INRUD) and the Action for Rational Drugs in Asia (ARDA). Relevant presentations were also provided by the Medical Lobby for Appropriate Marketing (MaLaM) and the WHO Multi-Country Ethical Criteria Study. Sub-groups considered a variety of specific topics ranging from the setting of goals to all the aspects of practical execution and the (very necessary) monitoring of progress towards rational use.

Creative approaches which were reviewed included the use of clinical guidelines, district-level self monitoring, drug audits, doctor's self-audit, interactive patient-provider groups to reduce the excessive use of injections, and mothers' drug information groups to improve the standard of self-medication in the family.

Several *key issues* come to the fore on this topic:

- the undisputed right of health providers and consumers to objective, understandable drug information;
- the fact that many activities to encourage rational use, although of good intentions and quality, take place in isolation, not known by or supported by government;
- the fact that in many countries, the political will to implement programs to encourage rational use still appears to be lacking, and specific funds for this purpose are seldom made available;
- the fact that the extent of and reasons for irrational drug use often remain unexplored;
- the evidence that interventions are sometimes mounted without adequate exploration of underlying causes, a thorough analysis of possible alternative strategies, or provision of means to monitor progress;
- the observation that activities to encourage rational use are often started without full involvement of all interested parties;
- the fact that successful interventions often remain unpublished and are therefore rarely replicated; strategies for the dissemination of results are poorly developed;
- the evidence that drug use behaviour is often irrational yet that social and cultural barriers may impede rational use;
- the finding that, where some drugs are underutilised, progress towards rational use is likely to involve a rise in costs, which may be problematical;
- the problems arising from the fact that in many countries drugs are inevitably prescribed by health workers who are not officially licensed to do so (for example, nurses and drug sellers); training these workers can be difficult as it would imply training in illegal practices;
- the existence of widespread illiteracy, which impedes the flow of drug information;
- common failure in involve the media adequately in promoting the rational use of drugs;
- the fact that in several countries advertisements for prescription-only drugs can be directed to the public;
- unawaresness among many prescribers of the costs of the drugs which they prescribe;
- the fact that some important activities have been initiated or supported by consumer movements;
- the frequent failure to monitor the quality and acceptability of drug promotion.

Quality safety and efficacy of medicines

Every country subscribes in principle to the notion that people should have drugs which are of reasonable quality, safety and efficacy. WHO guidelines have identified certain components as necessary in achieving these standards, but the problem remains as to the minimum standards which must be attained in a given situation.

The Association of South East Asian Nations (ASEAN) Pharmaceuticals Project which reported the experience of the ASEAN nations in general and the particular experiences of Indonesia and Malaysia in developing regulatory agencies. Key issues and perspectives in harmonisation or regulatory requirements, good manufacturing practice, drug information and product label regulation were set out in a series of presentations. The progress and problems involved in information exchange in the region were presented by the ARDA group. The plans and needs in technical co-operation between countries developed at the 1994 WHO meeting in Kuala Lumpur were also presented.

The participants identified issues in:

- drug legislation and regulation (including inspection and enforcement);
- standards for quality, safety and efficacy (including the WHO export certification scheme, good manufacturing practice and attempts at harmonisation);
- export control (including export-only products);
- information gathering, processing and exchange;
- training;
- the impact of labeling on the quality use of products;
- consumer education and empowerment.

There is much heterogeneity among countries in all of these issues ranging from 'good' to 'much room for improvement' and hence tremendous potential for interregional and intra-regional communication, collaboration and exchange of technology and information. This may be achieved with help from agencies such as the WHO, the World Bank and the Asian Development Bank.

Generally, there is a lack of knowledge and experience with successful models of quality, safety and efficacy in the region. There are limited initiatives for harmonisation of regulatory requirements between countries:

- pharmaceutical product registration is a priority issue and should be based on published requirements;
- there is a lack of consistency of definitions and their application in drug regulation and quality, safety and efficacy criteria;
- some countries have not yet formulated a national drug policy and even where a policy exists quality, safety and efficacy may not be included;
- funding shortfalls impede the activities of regulatory authorities;
- basic training facilities are available within the region, but there is a need for countries with special expertise to provide education for personnel from countries that require additional training;
- the WHO certification scheme has been of limited value in providing product quality assurance to importing countries;
- controls over exported products are inadequate in many exporting countries;
- communication and collaboration between countries and the transfer of information need improvement;

- there is no universal program for harmonisation of standards and requirements for the quality, safety and efficacy of medicines. The International Conference on Harmonisation (ICH) is an initiative of the major industrialised countries, such as the USA, the European Union and Japan, and its quality, safety and efficacy procedures are difficult for newly industrialising countries to adopt. There are concerns that the ICH lacks transparency and accountability, and that adopting ICH standards may result in countries losing their regulatory sovereignty.

This workshop discussed the contribution of the pharmaceutical industry to national drug policy and public health goals. The objectives were:

- to define the issues and assess the success of local and multinational industry initiatives in meeting the objectives of a national drug policy;
- to explore ways in which the strengths of the pharmaceutical industry can benefit a country development;
- to assess the impact of the General Agreement on Tariffs and Trade (GATT) and regional trade blocks on national drug policies.

A number of problems and issues were identified for discussion concerning strategies for developing a mix of local and multinational industry. One primary issue was: should all countries inespective of size seek to have a local industry or a multinational presence or some mix of the two?

Case studies from Bangladesh, China and Indonesia were presented. A presentation from UNIDO illustrated some of the training processes and practical results of UNIDO assistance to the development of a domestic industry in Thailand. Presentations were given on the key issues of the GATT. Intellectual property rights and regional trade blocks.

Two participants raised issues in relation to the GATT: a local Indian company which is likely to be affected by changes in Indian patent law and an expert from Latin America who has begun to analyse the practical outcomes of the first activities following the implementation of the GATT and North American Free Trade Agreement (NAFTA). A member of the ASEAN Secretariat presented the policy and timetable for the ASEAN Free Trade Area agreements on pharmaceuticals and analysed the likely impact of tariff reducson and intellectual property protection. An overview of Japan's pharmaceutical development policy showed the importance of pharmaceutical research and development for the changing disease patterns in Japan and Japan's strategy for becoming a global pharmaceutical manufacturing force and net exporter of drugs.

There were many complex issues revealed in the presentations and in the various perspectives of participants. This workshop was unique in combining sectors to discuss the problems. Although it was impossible to go into many of the issues in great depth, the future contribution of industry to national drug policy and public health goals emerged as the key issue that participants discussed. This discussion was facilitated by considered statements and suggestions for future areas of collaboration.

While the pharmaceutical industry ranges from small local manufacturers to international corporations there are many common issues. Some of the important issues identified by the workshop included:

- the critical importance of good manufacturing practices to ensure medicines are of a good and constant quality;
- there is often a lack of partnership between some of the players involved in national drug policies;
- there are large variations in the prices of the same drugs in different countries, these may be due to the original prices being set in developed countries, transfer prices of raw materials, competition in the local market or industry policies.

An issue that was talked about at great length was the need for a new way of thinking about the social responsibilities of the pharmaceutical industry. This would include considering not only the product, but also the information, education and communication processes surrounding its use. This requires redefining the role of industry to include a greater awareness of consumer needs.

Other issues were the development of a domestic industry and the need for subsidies. The problems of lack of trained personnel and technological knowledge were also identified. These would be important in encouraging appropriate local research and development. Other issues raised related to the effect of the GATT on local industry and possible differential treatment of local versus multinational companies.

Some lessons learned were that the establishment of a national drug policy helps rationalize the availability and provision of safe and effective drugs in a country. However, a policy can only be successful if all sectors are involved in its development and implementation. The affordability of drugs should be a part of an overall national health policy.

It was noted that when price is the sole factor in the purchase of drugs, quality may sometimes be sacrificed. Good quality and cost-effectiveness are also essential factors to be considered in the procurement of drugs.

Conclusion

On the final day of the meeting the discussions from the workshops were reviewed. All the needs, challenges, opportunities and barriers affecting the implementation of national drug policies were drawn together and a series of general recommendations and specific recommendations for each of the four parts of a national drug policy were prepared. These were discussed and amended in a plenary session to obtain a consensus. The conference then endorsed a set of recommendations on national drug policies and policy process, access to medicines, rational use of drugs, the pharmaceutical industry and quality safety and efficacy.

The conference, in relation to its theme 'Can a comprehensive approach to National Medicinal Drug Policy meet both health and economic objectives?', endorsed an open, participatory, intersectoral process to develop, implement, and monitor national drug policies, involving all relevant levels of government, health professionals, consumers, academia, industry and other interested parties.

The final recommendations reflect the view of the conference that the tensions between health and economic objectives should be more constructively managed within a policy framework which validates and consciously deals with both. Above all, the conference clearly stated the importance of health and health policy as not only a right, but also a fundamental contribution to development. drug policy should be clearly linked to health policy and the health issues should be considered in the development of trade and economic policies. The development of a socially responsible industry serving health objectives is a good economic objective in itself.

Professor Prawase Wasi, of Mahidol University in Thailand, in the final address discerned that the conference was unique in establishing a sense of community between so many people from different sectors and countries.

The strength of the conference was that through a widely representative and participatory process, so many people, from different countries, and different backgrounds could exchange views, agree on principles to guide the way forward and arrange follow-up for national and regional action. This has resulted in many formal and informal contacts which are leading to new activities to advance some of the ideas discussed at the conference.

Recommendations

Objectives of a national medicinal drug

The objective of a national medicinal drug policy is – within the scope of a national health policy – to ensure equitable access to and rational use of safe and effective drugs of good quality and affordable price in order to improve health outcomes. The policy must also consider areas such as local production, technology transfer and traditional medicine.

General conference recommendations

1. Political will is essential for implementation of successful national medicinal drug policies and should be publicly supported at the highest level of government.
2. The conference emphasized the need for continued regional consultation and mutual assistance in developing, implementing and sustaining national medicinal drug policies with the support of relevant international organizations, including the WHO.
3. Policies must be tailored to individual country's needs, but the conference also stressed that countries should draw from the experiences of other countries and take advantage of the documented impact of existing policies.
4. National medicinal drug policies should be developed within the context of a national health policy.
5. Health is a fundamental human right and a good investment. Where present resources are inadequate and public spending on health is low, additional public spending should be sought, as well as international support and solidarity.
6. Government should develop, implement and monitor the national medicinal drug policy through an open, participatory intersectoral process involving health professionals, consumers, academia, industry and other concerned parties. Efforts should be made to ensure more equitable empowerment of all parties involved.
7. National medicinal drug policies should:

- guide resource allocation to improve equity and efficiency in the provision of health care;
- be evidence-based and performance-based;
- be tailored to individual country's needs;
- promote the essential drug concept in both the public and private sectors;
- promote legislation and regulation which is realistic and which can be implemented in the national context;
- encourage and empower consumers to play an active role in policy – planning and implementation;
- encourage social responsibility among public and private health providers, industry and other key implementors;
- involve the media and include a media strategy.

8. Countries should establish an adequate mechanism for developing, implementing and sustaining a national medicinal drug policy. This includes adequate financial and human resources, and may involve formation of a national drug policy unit.
9. In developing, implementing, sustaining and monitoring national medicinal drug policies governments are encouraged to:

- establish partnerships with other countries in training, technical assistance, informationsharing and other areas of need; and provide appropriate mechanisms and funding to assist this process;
- ensure that adequate resources are allocated for development of facilities and human resources for all aspects of national medicinal drug policy implementation including education, training and research;
- develop education and training programs in all disciplines;
- assess systematically the capacity and performance of public and private pharmaceutical systems;
- design and implement self-monitoring systems using reliable indicators;
- develop adequate legislation and programs to achieve quality, safety and efficacy objectives;
- investigate different methods of gathering and evaluating objective, up-to-date information for policy-making and planning;
- encourage key players to co-operate in providing, releasing and disseminating necessary information;
- establish multisectoral co-ordination groups in selected areas such as quality, safety and efficacy programs, rational use of drugs and local production.

10. A national medicinal drug policy should identify economic mechanisms which foster the achievement of health objectives through improved access, rational use of drugs, quality, safety and efficacy, and other aspects of the national medicinal drug policy.

11. Global (for example, WHO), regional and country efforts should be made to analyse and, address the consequences of international harmonisation, macroeconomic changes, structural adjustment and international trade developments (General Agreement on Tariffs and Traded World Trade Organisation, Agreement on Trade Related Aspects of intellectual Property Rights) on access, rational use of drugs, quality, safety and efficacy, local industrial development and other aspects of the national medicinal drug policy. Health issues should be considered as the policies are being formulated.

Conference recommendations

Access to medicines:

1. Approaches and mechanisms should be developed, to remove financial barriers to essential drug access which include promotion of generic policies, encouragement of social and community insurance schemes and creation of incentives for improving access in underserved areas.

Methods should be developed and implemented to gather and exchange information on prices, pricing mechanisms, pricing policies, patterns of drug use and economic analysis by governments, non-government organizations, universities etc., and encourage industry to share information not currently accessible.

2. The WHO should set up a committee of experts which would consider ways to monitor and report on the prices and pricing mechanisms of essential drugs and raw materials, and the performance of manufacturers and suppliers of drugs and raw materials.

3. Governments should develop the capacity to perform routine economic analysis of health care interventions. On occasions it will be valuable to carry out economic analysis of individual pharmaceutical products.

4. Governments should preserve and/or improve procurement systems in the public sector and support efforts of non-government organizations to make affordable essential drugs available to low income and other target populations.

Rational use of drugs:

1. Governments should publicly endorse the rational use of drugs components of the national medicinal drug policy and should establish a national rational use of drugs co-ordination unit to initiate, monitor and evaluate activities to promote the rational use of medicines. This unit should be supported by multisectoral advisory committees, appropriately qualified staff and an operating budget.

2. Governments should establish national rational use of drugs programs within the scope of the national medicinal drug policy. In the planning and implementation of these programs all sectors should be involved, for example, relevant departments in the ministry of health and other ministries, health professionals, academia, industry, and consumers. Rational use of drugs activities by, in particular non-government organizations, university and consumer groups should be supported.

3. Governments should ensure and facilitate training to appropriate levels of competence for all drug providers including doctors, pharmacists, other health professionals and drug retailers. This may imply a change in legal requirements.

4. Governments should foster cost-effective targeted interventions with measurable outcomes aimed to promote the rational use of drugs at all levels of health care, for example, through simple self-monitoring systems and other interventions of proven effect.

5. Health providers and consumers have a right to objective and usable drug information. Governments should ensure that this is generally available, for example, through health education programs, the news media and ethical drug promotion. National ethical criteria for drug promotion, based on the WHO Ethical Criteria for Medicinal Drug Promotion, should he developed and enforced.

Quality, safety and efficacy of medicines:

1. Registration of pharmaceutical products should he strengthened by development and implementation of guidelines and processes for good regulatory practice.

These guidelines should include information on the principles and requirements. Or the uniformity of terminology and of definitions for drug regulation, inspection, quality requirements and quality product information.

2. Adequate resources (human and financial) should be allocated for quality, safety and efficacy programs. Opportunities should be taken to optimise resources for development of infrastructure and personnel for quality, safety and efficacy programs by sharing, harmonising and training. Training activities should include academia, government and industry facilities.

3. Harmonisation activities within the region should include:

- drug standards (including good manufacturing practice);
- drug evaluation;
- bioavialability;
- bioequivalence;
- drug stability;
- establishing strong linkages to maximise effective communication and collaboration between countries for quality safety and efficacy requirements;
- standards of drug information.

Countries with specific expertise and systems within government and industry should be utilised for the training and upgrading of personnel from countries that may require such training.

4. The WHO Certification Scheme should be reviewed at suitable intervals and, when appropriate, modified. The review process should include:

- a procedure to ensure that the standard format is adopted;
- development of valid indicators to monitor its effectiveness;
- development of usable guidelines prepared by specialists in communication;
- a system for peer review among countries;
- a system for evaluation and for reporting complaints from importing countries.

5. There should be adequate drug regulatory controls over exported products by exporting or donating countries.

6. The International Conference on Harmonisation should be expanded to allow active involvement by all countries and access by consumer organizations, so as to evaluate its implications for the region and also to emphasise consumer interests and health policy perspectives.

Industry contribution to national medicinal drug policy and public health goals:

1. A new paradigm for a socially responsible industry is required. Both industry and national medicinal drug policies should redefine the product, not just as a drug, but as a medication process incorporating information services which must be related to health outcomes based on developed indicators. Honest and full information is an essential part of it. All parties should recognise that a socially responsible industry and profitability are compatible.

2. Involvement of industry with all partners is essential in the development, implementation and monitoring/evaluation of national medicinal drug policies. In order to achieve effective and ongoing participation, the best model and process should be identified. Some of the factors to be considered in developing the model could be:

- the need to meet on neutral grounds;
- the need for frank and open discussions;
- the desirability to start with a specific problem, such as information or good manufacturing practice;
- the need to establish key representative bodies within and outside the industry to set standards and facilitate consultation.

3. The industry should work together with governments, funders, recipients and providers to help improve affordability, availability, and access to essential drugs and drug information.

Industry should be encouraged to participate in human resource and technical development both within the industry and with the other partners.

Research and development in the region is desirable and development of local industry should be encouraged.