

THE PATIENT IN FOCUS

A STRATEGY FOR PHARMACEUTICAL SECTOR REFORM IN NEWLY INDEPENDENT STATES



WORLD HEALTH ORGANIZATION
Programme for Pharmaceuticals
Action Programme on Essential Drugs



a 59254

EUR/ICP/QCPH 06 22 02
WHO/DAP/98.8
ORIGINAL: ENGLISH
UNEDITED

THE PATIENT IN FOCUS

**A Strategy for Pharmaceutical Sector Reform
in Newly Independent States**



Scherfigsvej 8
DK-2100 Copenhagen Ø
Denmark
Tel.: +45 39 17 17 17
Telefax: +45 39 17 18 18
Telex: 12000
E-mail: postmaster@who.dk
Web site: <http://www.who.dk>



Action Programme on Essential Drugs
World Health Organization
CH-1211 Geneva 27
Switzerland
Telefax: +41 22 791 4167
E-mail: dapmail@who.ch
Web site: <http://www.who.ch/programmes/dap>

February 1998

TARGET 31

QUALITY OF CARE AND APPROPRIATE TECHNOLOGY

By the year 2000, there should be structures and processes in all Member States to ensure continuous improvement in the quality of health care and appropriate development and use of health technologies.

ABSTRACT

The paper describes pharmaceutical sector reform in the newly independent states (NIS) and sets out strategies for its further development. This global strategy will function as a guideline for further reform at country level.

Recent years show many regulatory improvements, but drug treatment also has become more complex, with improved availability and decreased affordability. For the patient the situation is largely dependent on the disposable income. Given the economic hardship of increasingly large groups of the population it is clear that access to quality drugs is no longer within reach of many of them.

The transitional period brings about a serious deterioration of the health status of the population. To reverse this negative trends and to be effective within a changed economic and political environment, pharmaceutical sector reform has to enter a new stage of development. The objective of such continued reform should be to: *ensure affordable access to good quality drugs and their appropriate prescribing and use.* Priorities are: access (affordability of drugs), sector management (policy development, enforcement, information), quality (quality assurance, professional levels), rational drug use (sustainable programmes for drug prescribing and use, the role of the pharmacist), education (basic education, continuous programmes). Access has the highest priority as it affects the patient immediately and has a big political and social impact.

Objectives of pharmaceutical sector reform, i.e. how to improve the situation for the patient, are presented with targets for each priority area. Indications of country needs, possible interventions and involved organizations are given for country implementation. Further support of key persons and organizations is needed to stimulate new approaches for the benefit of all patients.

Keywords

HEALTH CARE REFORM
EDUCATION
ECONOMICS, PHARMACEUTICAL
DRUG UTILIZATION
PHARMACEUTICAL PREPARATIONS – supply and distribution
QUALITY CONTROL
LEGISLATION, DRUG
HEALTH SERVICES ACCESSIBILITY
COMMONWEALTH OF INDEPENDENT STATES

© World Health Organization

All rights in this document are reserved by the WHO Regional Office for Europe. The document may nevertheless be freely reviewed, abstracted, reproduced or translated into any other language (but not for sale or for use in conjunction with commercial purposes) provided that full acknowledgement is given to the source. For the use of the WHO emblem, permission must be sought from the WHO Regional Office. Any translation should include the words: *The translator of this document is responsible for the accuracy of the translation.* The Regional Office would appreciate receiving three copies of any translation. Any views expressed by named authors are solely the responsibility of those authors.

TABLE OF CONTENTS

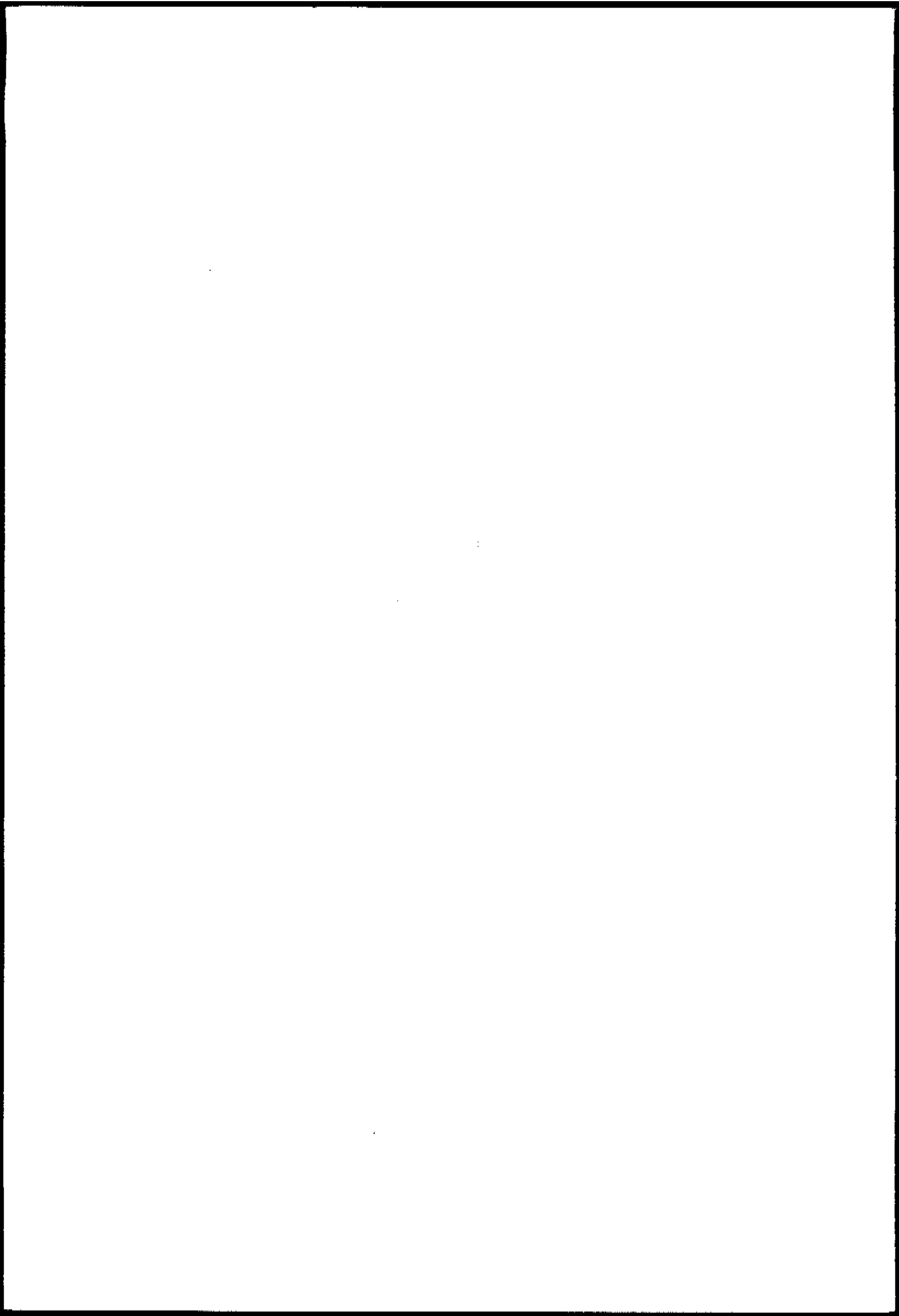
AUTHORS

EXECUTIVE SUMMARY

1. INTRODUCTION.....	3
2. GLOBAL DIRECTIONS IN HEALTH CARE AND THE ROLE OF PHARMACEUTICALS	3
AN IMPORTANT ROLE FOR PHARMACEUTICALS.....	4
WHAT DOES THIS MEAN FOR NIS?	4
3. SITUATION ANALYSIS AND ACHIEVEMENTS IN NIS.....	5
3.1 CHANGING HEALTH STATUS AND HEALTH CARE	5
3.2 PHARMACEUTICAL SECTOR REFORM – CURRENT STATUS	5
GLOBAL DEVELOPMENT OF THE PHARMACEUTICAL SECTOR	5
LEGISLATION AND REGULATION	6
QUALITY ASSURANCE	7
PROCUREMENT AND DISTRIBUTION.....	7
DRUG FINANCING	8
RATIONAL DRUG SELECTION AND USE.....	9
HUMAN RESOURCE DEVELOPMENT	9
NATIONAL DRUG POLICIES.....	10
3.3 A NEW TRANSITION PHASE: CHANGED CONDITIONS FOR REFORM.....	11
3.4 SUMMARY OF DEVELOPMENTS AND CONCLUSIONS	11
CHALLENGES FOR THE SECTOR	13
4. STRATEGIC VISION AND PRIORITY-SETTING.....	13
4.1 OUR MISSION.....	13
FIVE PRIORITIES.....	13
4.2 WHY THESE PRIORITIES?	14
IMPROVE ACCESS: FOCUS ON THE PATIENT	14
STRENGTHEN SECTOR MANAGEMENT (DRUG POLICIES, REGULATION, ENFORCEMENT, INFORMATION)	14
QUALITY DRIVE (QUALITY ASSURANCE, GMP, GPP).....	15
ENCOURAGE APPROPRIATE DRUG USE (SELECTION, PRESCRIBING, CONSUMPTION)	15
EDUCATION AND TRAINING: MOTIVATING VIEWS.....	15
5. FROM VISION TO ACTION!.....	16
5.1 THE PATIENT IN FOCUS – OBJECTIVES.....	16
5.2 ACTION PLAN	17

ANNEXES

- A. HEALTH CARE DEVELOPMENTS IN THE EUROPEAN REGION
- B. ECONOMIC INDICATORS, HEALTH CARE & DRUG EXPENDITURE AND PHARMACEUTICAL SECTOR STRUCTURE NIS (1996–1997)
- C. ABBREVIATIONS
- D. TARGETS PER PRIORITY AREA
- E. IMPLEMENTATION PLAN: COUNTRY NEEDS, APPROACHES AND ORGANIZATIONS INVOLVED



Authors

WHO Regional Office for Europe (WHO/EURO)

Programme for Pharmaceuticals – Special Project for Newly Independent States (NIS)

Nata Menabde, Project Manager for NIS

Frans Stobbelaar, Economic Adviser

Acknowledgements

EURO and DAP collaboration

This paper is part of an intensive collaboration on pharmaceutical sector reform in the newly independent states between the WHO/EURO Programme for Pharmaceuticals (Copenhagen) and the WHO Action Programme on Essential drugs (DAP, Geneva).

Financial contributions

The work of WHO within the Special Project for NIS on pharmaceutical sector reform is made possible by contributions from the United Kingdom Know How Fund (UK KHF), the United States International Development Agency (USAID) and the Apotekerfonden af 1991 of the Danish Pharmaceutical Association.

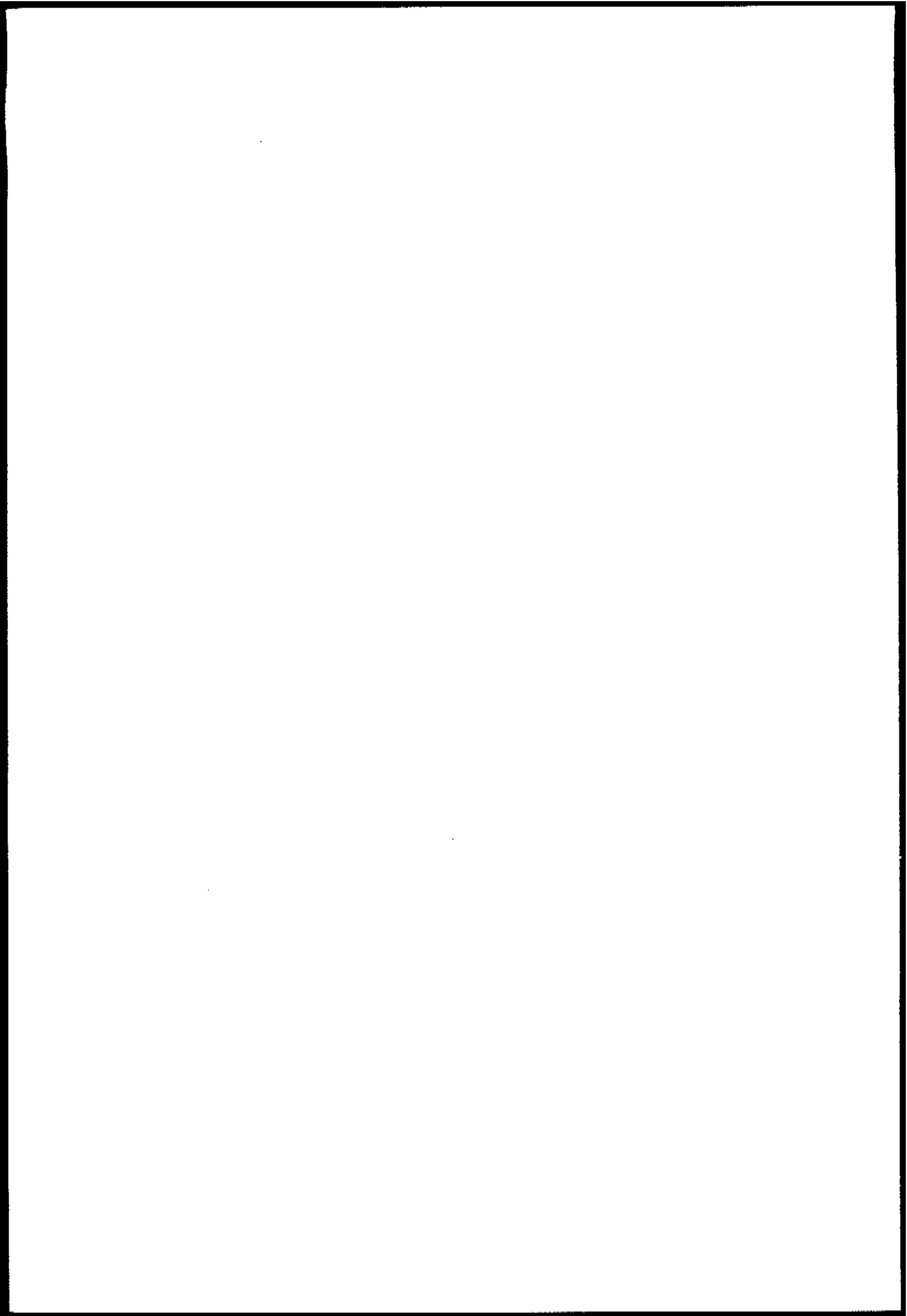
Thanks to contributors

The following persons contributed comments, suggestions and visions to this paper:

P. Brudon, Action Programme on Essential Drugs (WHO/DAP); K. Bremer, Action Programme on Essential Drugs (WHO/DAP); K. Fonnesbæk Rasmussen, Director WHO Collaborating Centre for Drug Policy & Pharmacy Practice Development, Denmark; J. Idänpään-Heikkilä, Director Division of Drug Management and Policies (WHO/DMP); K. de Joncheere, Regional Adviser for Pharmaceuticals (WHO/EURO); J. Quick, Director Action Programme on Essential Drugs (WHO/DAP); Ph. Saunders, Project Manager Essential Drugs Project, United Kingdom; P. Spivey, Action Programme on Essential Drugs (WHO/DAP); J. Svihovec, Charles University, Czech Republic; A. Tibouti, Regional Adviser Health Systems, United Nations Children's Fund (UNICEF), Switzerland.

Armenia:	A. Mkrtchian, Deputy Minister; G. Shmavonian, Deputy Minister; E. Gabrielian, Head of Armenian Drugs and Medical Technology Regulatory Administration
Azerbaijan:	A. Maharramov, Chief Pharmaceutical Department; A. Jabrailov, Senior Drug Policy Expert Ministry of Health; N. Ibrahimov, Head of Department Ministry of Health
Belarus:	A. Kurchenkov, Deputy Minister; G. Godovalnikov, Head Pharmaceutical Department; V. Shipitsa, Department of Education, Science, Culture, Health Care and Social Protection, Cabinet of Ministers of Belarus
Georgia:	V. Giorgadze, First Deputy Minister; R. Makharadze, Director, Pharmaceuticals Department; G. Gvasalia, Head Republican Hospital
Kazakhstan:	A. Dujskeev, Head Department of Pharmaceuticals and Medical Equipment; K. Abdullin, Deputy Director Department of Pharmaceuticals and Medical Equipment; L. Kuznetsova, Head Department of Drug Supply
Kyrgyzstan:	B. Kalieva, First Deputy Minister; M. Mambetov, Senior Officer Administration of the President; K. Cholponbaev, Head Drug Department; S. Kourmanaliev, Head Department of Drug Quality Control and Medical Equipment
Republic of Moldova:	M. Magdei, Minister; V. Prokopishin, Deputy Minister; V. Gasnash, Head Drug Board; B. Parii, Director National Pharmacological Centre
Russian Federation:	A. Vilken, Deputy Minister; R. Khabriev, Head State Inspection of Quality Control of Pharmaceuticals and Medical Equipment; E. Nekrasov, Deputy Head Department of Pharmaceutical Supplies and Medical Equipment
Tajikistan:	N. Saidov, Head Drug Agency
Turkmenistan:	E. Sahatov, Director Centre for Drug Registration and Quality Control
Ukraine:	A. Kartysh, Deputy Minister; P. Sereda, Chief Pharmaceuticals Department; A. Stefanov, Director Scientific Institute for Pharmacology and Toxicology
Uzbekistan:	B. Yuldashev, Deputy Minister; J. Djalilov, Director, State Centre on Drug Testing and Standardisation; B. Shaislamov, Deputy Head, Department for Drug and Medical Technology Quality Control; I. Hujakulov, Pharmaceutical Committee

Yelena Egorenkova, Else Jartved and Rosemary Bohr from WHO/EURO provided assistance in the layout and editing of this document.



Executive summary

The strategy paper "The Patient in Focus" describes the pharmaceutical sector reform in the newly independent states (NIS) and sets out strategies for further development. The paper is developed by the World Health Organization, Regional Office for Europe, Programme for Pharmaceuticals in collaboration with the WHO Action Programme on Essential Drugs (DAP) in Geneva and with representatives of all the NIS and the Russian Federation. The paper should be seen as a global strategy to function as a guideline for further sector reform at country level. Interpretation of this paper may differ per country, depending on their particular state of development and national implementation capacity.

HEALTH, HEALTH CARE AND PHARMACEUTICALS

The transitional period has brought about a serious deterioration of the health status of the population. Major health indicators show a worsening trend and life expectancy is now almost 15 years less than in western Europe. At the same time countries are in the midst of an unprecedented health care reform. These changes come when less money is available: *do more with less.*

Today, many citizens in NIS are deprived of elementary health care services and access to essential drugs. As pharmaceuticals play an important role in the effectiveness of health care, access to drugs is elementary. Clear strategies to further develop the pharmaceutical sector are necessary to reverse the negative health trends in these countries with a total population of 285 million people.

CURRENT SITUATION AND ACHIEVEMENTS IN NIS

The biggest changes in almost all NIS were drug distribution system and the diminishing budget allocations for health care. The shortage of funds in the health care system affects appropriate drug treatment directly, as pharmaceuticals are often the first victim to fall out of the budget. For the patient, in addition, limiting access to drugs means limited access to health care.

During this period of change many positive developments in the pharmaceutical sector have taken place, although they were sometimes overshadowed by temporary setbacks and slow economic growth.

Many improvements have been achieved as seen from the regulators point of view. For health professionals drug treatment has become more complex, with improved availability (due to privatization) and decreased affordability. For the patient the situation is largely dependent on his or her disposable income. Given the economic

Health trends in NIS

- Decrease of life expectancy (many will not reach pension)
 - Increased morbidity of circulatory system, infectious and communicable diseases.
 - Emerging epidemics of "poverty" diseases
 - Increased resistance due to irrational drug treatment
 - Low health care budgets
-

the introduction of a market oriented

Major developments in the pharmaceutical sector

- + Legislation is drafted or adopted and regulatory agencies are established.
 - + The quality of drugs in the countries is slowly improving, while privatization has improved availability of drugs.
 - + Training of key persons is delivering first results and there is growing knowledge of financing and cost-containment instruments.
 - + Drug policies are a useful tool in pharmaceutical sector reform, while networking and assistance are contributing to new solutions.
 - Lack of access to drugs due to the low affordability and insufficient budgets in hospitals (large patient payments, deteriorating hospital pharmacy) and for outpatient care.
 - Many people are deprived of essential health care.
 - Problems with the enforcement of new laws and regulations.
 - Universities and continuous education need new methods while there is a lack of reliable independent drug information.
-

hardship of increasingly large groups of the population it is clear that access to quality drugs is not any longer within reach of many of them.

A NEW TRANSITION PHASE

After the first reform steps have been taken and because of a changed economic and political environment, the pharmaceutical sector is now entering a new stage of development. Economic growth and decentralization give room for new development; health care reform may gradually deliver results; knowledge and local capabilities improve. However, despite the positive economic development in several NIS, it is clear that these countries will remain in a transitional stage for several years, and that the environment for change and innovation will not always be positive and stable.

STRATEGIC VISION AND SETTING PRIORITIES

The objective of continued reform of the pharmaceutical sector should be to:

- *Ensure affordable access to good quality drugs and their appropriate prescribing and use.*

Access has the highest priority: it affects the patient immediately, has a big political and social impact, while improving prescribing practices of doctors. Governments and insurance (funding), health care providers (drug selection and prescribing) and suppliers (offer alternatives) can contribute. Continued improvements in sector management will strengthen recently established structures and create sustainability. National drug policies have a stimulating strategic role.

Quality, not only of the drugs on the market, but of the profession as well, needs further development. Special attention should be paid to enforcement of regulations. Rational selection and prescribing of drugs is critical in NIS because of inherited prescribing practices (free health care and drugs) and the current lack of money. A comprehensive approach, including initiatives at regional and hospital level, is needed to achieve tangible results. Fundamental changes in the educational system should make health professionals more patient focused and health outcome oriented, with special emphasis on drug selection and prescribing.

Priorities for pharmaceutical sector reform in NIS

1. **Access.**
Improve the affordability of drugs, especially for hospital patients
 2. **Sector management.**
Policy development, implementation and enforcement; improve information and communication
 3. **Quality.**
From quality control to quality assurance (including GMP), enhance professional levels
 4. **Rational drug use.**
Sustainable programs for rational prescribing and use of drugs; involve the pharmacist
 5. **Education.**
Reform basic education, targeted continuous post-graduate programs.
-

OBJECTIVES AND IMPLEMENTATION

The Patient in Focus. Objectives of pharmaceutical sector reform are to improve the situation for the patient. These patient oriented objectives are presented lead to targets for each priority area. In addition: indications are given of country needs, possible interventions and involved organizations. These can be used for country implementation plans.

Collaboration, networking and support of key persons and organizations is needed to share knowledge and stimulate new approaches for the benefit of all patients.

1. Introduction

Since the beginning of the 1990s, widespread economic and social changes have substantially affected health care in general and the pharmaceutical sector in particular in the newly independent states (NIS).¹ While the health care systems are suffering from severe underbudgeting and overcapacity, the pharmaceutical sectors in most NIS are being transformed through privatization into market-oriented supply systems for which new regulations, control systems, public capacity and new compensation mechanisms for patients are needed.

This paper describes the current status of pharmaceutical sector reform in the NIS and sets out strategies for its further development. The main issues are:

- global directions in health care and pharmaceutical sector reform
- analysis of the current situation and achievements to date
- identification of the main challenges and priorities
- strategies for future development, including a policy framework.

The paper has been developed by the Programme for Pharmaceuticals at the WHO Regional Office for Europe, in collaboration with the WHO Action Programme on Essential Drugs (DAP) in Geneva and representatives of all the NIS. It is intended as a global strategy for this part of the WHO European Region and as a guideline for further reform of the pharmaceutical sector in the various countries. Interpretation may vary between countries, depending on their particular stages of development and national capacities to implement the proposed reforms.

2. Global directions in health care and the role of pharmaceuticals

The challenges facing the pharmaceutical sector in the NIS in the next few years are different from those of the past three to five years, when basic structures and procedures had to be created in a difficult, chaotic environment which was often hostile towards such developments. The fundamental issues have been discussed and some basic structures are now in place, although these are not as yet very developed. The major changes that have taken place in health care are shown in the box.

The pharmaceutical sector is now entering on a new stage of development, against the background of further changes in the economic and political environments. This development should not only be seen in the context of the economic transition. It should also take account of global changes in health care and be based on general principles.

Major health care developments

- Focus on prevention instead of cure
 - More efficient (cost containment), effective (health gain) and better quality health care services
 - Diversification of funding
 - Shift from hospital care to primary health care
 - Shorter hospital stays
 - From narrow specialization to broader approaches
 - Decentralization of decision-making and budgets
 - Cost sharing
 - Patient orientation instead of product orientation
 - Self care
-

¹ Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Republic of Moldova, Russian Federation, Tajikistan, Turkmenistan, Ukraine, Uzbekistan.

In addition, and very important for countries in transition, reform of overall health care has become a major factor. In 1996, the Health Care Reform Conference in Ljubljana, with the participation of all Member States, adopted a Charter² confirming that the principles of equity, solidarity and professional ethics were fundamental, and that reform should have clear targets for health gain. Citizens were asked to share responsibility for their health, while governments should guarantee the financing of sustainable care, universal coverage and access for all citizens.

AN IMPORTANT ROLE FOR PHARMACEUTICALS

The global directions in health care reform are affecting the pharmaceutical sector in several ways. The importance of the ambulatory (pharmacy) sector will grow, co-payments will become common and patients will be more knowledgeable and demanding. But there is more ...

In a recent publication³ WHO connected health care reform with the pharmaceutical sector and emphasized the role of drugs in health care:

- Access to drugs is a major factor in access to and effectiveness of health care systems (hospital and primary care) and by that a necessary condition for health care reform.

At the beginning of 1996, the WHO Executive Board passed a resolution urging Member States to reaffirm their commitment to: develop and implement national drug policies, ensure equitable access to essential drugs, increase efforts to improve rational use, enhance regulatory systems, control unethical marketing of drugs, eliminate inappropriate donations, and involve society (including health workers, consumers and industry) in improving access to and appropriate use of drugs.⁴ In 1996 the Regional Committee recognized the important role of pharmaceuticals in health care and expressed concern about their persistent irrational use and the financial constraints that limit access to drugs.⁵

WHAT DOES THIS MEAN FOR NIS?

These principles and guidelines are especially valid in the transitional economies of the NIS, where many citizens do not have access to even elementary health care services and essential drugs. Clear strategies to develop the pharmaceutical sector further are necessary because of:

- the important role of drugs in the effectiveness of health care and in the success of health care reform;
- the need to build sustainable care with universal coverage, including access to essential drugs;
- the need to reduce the large patient (co-)payments for drugs so as to make them affordable for the growing numbers of vulnerable and poor people;
- the need to improve prescribing by health workers and encourage rational use of drugs by patients (compliance);
- the need to target health gain and quality of care.

² *The Ljubljana Charter on Reforming Health Care*. Copenhagen, WHO Regional Office for Europe, June 1996.

³ WHO Task force on Health Economics, Drugs and Health Sector Reform, Geneva, December 1996.

⁴ WHO Executive Board, Revised Drug Strategy, Geneva, January 1996.

⁵ WHO Regional Committee for Europe, Resolution on Pharmaceuticals, Copenhagen, September 1996.

3. Situation analysis and achievements in NIS

3.1 Changing health status and health care

The economic, social and cultural transition in the NIS has led to a serious deterioration in the health status of the population. All health indicators⁶ show worsening trends, and life expectancy is now almost 15 years less than in western Europe.⁷

At the same time, health care is being fundamentally reformed in those countries. The reforms aim at the introduction of payroll tax-financed health insurance systems, new provider payment systems and systems of user charges, decentralization, privatization, a reduction in capacity and recognition of patient choice. Until financial incentives are in place, major changes, restructuring and operational reforms will not get off the ground. These changes come at a time when less money is available: more has to be done with less.⁸ This calls for effective preventive health strategies to reverse the alarming trends and ensure that health care is not pushed into higher cost categories.

The focus and investment needed for these reforms are taking the full attention of health policy-makers. In several countries this is leading to a situation where the pharmaceutical sector is not being properly taken into account. For patients, however, drugs are an important element of health care and limiting access to them limits access to different health care services.

Major health and health-related trends in NIS

- Decrease in life expectancy (especially of men)
 - Increased morbidity of circulatory system diseases, bronchitis, asthma, infectious diseases, communicable diseases, injuries and poisoning
 - Increase in poverty leading to higher demands for health care and lower affordability
 - Low levels of health care financing
 - Lack of coverage by health insurance or reimbursement systems meaning high patient payments
 - Young population in the central Asian republics, decreasing birth rates in the Russian Federation.
 - Health care restructuring in most of the NIS.
-

3.2 Pharmaceutical sector reform – current status

GLOBAL DEVELOPMENT OF THE PHARMACEUTICAL SECTOR

Since the early 1990s, the main changes in almost all the NIS have been the introduction of market-oriented drug distribution systems and the diminishing budget allocations for health care. The pace of these developments has, however, varied from country to country: pharmacies are still largely state-owned in the Russian Federation and centralized systems still prevail in Tajikistan and Turkmenistan. Budget problems also differ (see Annex B): they are severe in all the NIS, but least so in the industrial urbanized regions of the Russian Federation.

Key words: *market development, diminishing budgets, increased control, improved availability, decreased affordability.*

⁶ WHO health for all database. Copenhagen, WHO Regional Office for Europe, 1997.

⁷ See Annex A for a comparison of selected health indicators in the NIS, countries of central and eastern Europe and the European Union.

⁸ See also: *Trends in health status, services, and finance – the transition in central and eastern Europe*. World Bank Technical Paper 341, 1996.

The transition to a market-oriented drugs supply is leading to growths in imports as the markets open up, in the number of wholesalers and pharmacies (except in the Russian Federation) and in the number of products available. The rapid increase in availability after only a few years is being matched by improved quality control.

Budget problems have seriously affected the provision of free drugs, while the fall in incomes (due *inter alia* to unemployment and negative economic growth) in combination with large patient (co-)payments have made drugs less and less affordable, even in hospitals. Old financing mechanisms are being revised or new (insurance-based) ones are slowly evolving. This takes time and cannot be done unless economic developments are generally positive.

LEGISLATION AND REGULATION

In the former Soviet Union, pharmaceuticals were regulated by a large number of unified centrally developed regulations, not by law.

Key words: *drug law, sub-regulations, price regulation, licensing, advertising and marketing of drugs*

Now, the importance of a proper legislative framework for the pharmaceutical sector has been strongly recognized in all the NIS; most have either adopted drug and pharmacy laws and subsequent regulations or are discussing drafts. In some countries the adoption of pharmaceutical legislation has been a long and thorough process with many different interests involved.

All the NIS are facing serious difficulties in law enforcement, since after a period of unlimited freedom several unwanted practices have grown. The role of drug regulatory authorities in the implementation of the new laws has been recognized and all countries have now established such agencies, albeit with different tasks and capacities. These agencies come under the respective ministers of health and focus on the control of medicines for human consumption (despite pressure from external lobbies to separate them from the health care system and make them profit centres).

Those countries where proper legislation was in place before the pharmaceutical sector was privatized are now in a better position to keep the sector under control. Others lost control and now have to bring order out of chaos. Licensing of pharmaceutical enterprises is now the rule in all countries, although the quality of this licensing could be improved.

Regulatory agencies in NIS are turning into centres of expertise for the pharmaceutical sector, and also cover economic market regulation and the design and preparation of legislation and drug policy (in many western countries these functions are performed by other authorities). Regulating a market and dealing with issues such as the regulation and monitoring of prices are new for the NIS and difficult to implement. It takes time before it is recognized that pharmaceuticals are part of health care – an understanding that is not yet common in the private sector or in much political thinking.

The largely uncontrolled and unregulated advertising and marketing of drugs are giving rise to unethical practices which will gradually have to be eliminated.

QUALITY ASSURANCE

In the NIS, as in several other parts of the world, the quality of drugs on the market is sometimes questionable. Several factors encourage the import and production of low quality drugs in NIS:

Key words: *regulatory agencies, quality assurance, inspection, registration, laboratory, GMP, GPP*

- there are almost no GMP⁹ standards in domestic production;
- low priced drugs are more affordable for a vast majority of the population: price rather than quality is the major selection criterion;
- the population is not sensitive towards quality, efficacy and safety – several of these drugs were “successfully” consumed in the former supply system;
- quality control and inspection capacity are unsatisfactory;
- the open borders between countries lead to illegal imports and imports of counterfeit drugs.

Drug regulatory authorities are aware of these problems and try to handle them in daily practice. Significant steps have already been taken, such as the introduction of drug registration and import/export licensing, the establishment of national quality control laboratories and the drawing up of plans for the implementation of GMP standards. However, while some countries are working on an overall concept of quality assurance and how to implement it, others continue to focus on strict control procedures that generate a lot of bureaucracy. Strict batch-by-batch control will become increasingly difficult for these agencies to carry out or for importers to afford. Given the open borders, the lack of GMP in production and the need for cheap imports, improved quality assurance needs a common strategy. Until this is in place, countries continue batch-by-batch control of domestic (non GMP) products.

Another quality element in drug dispensing is good pharmacy practice. In those NIS where unregulated privatization has taken place, professional standards of pharmacy practice have been sacrificed and should be upgraded.

PROCUREMENT AND DISTRIBUTION

Almost all the NIS have abandoned central procurement. Even for hospital care many countries now have to rely on the private sector, although this market segment is mostly dominated by former state-owned suppliers. Central procurement by the state occurs mostly for state-financed programmes. The lack of reliable and regular funding makes hospitals very unreliable payers, and as a result the availability of drugs in hospitals diminishes.

Key words: *procurement, privatization, pricing, production, donations, hospital supply*

Privatization of the wholesale sector is almost complete in the NIS, with the majority of pharmacies either being privatized or new private companies. The negative effects of early, rapid and unregulated privatization have been softened in some countries, and the positive effects of increased availability of drugs are visible. The problem now is their affordability. A frequent obstacle to government regulation of prices is pressure from the new private sector.

⁹ GMP: Good manufacturing practice. Quality standards for drug production.

Although competition at wholesale level is strong, the growth of these new markets and the relatively high profit margins keep a large number of wholesalers in the various markets. Intermediate trade is also common.

Several NIS are investigating the possibility of creating or increasing domestic production. However, only a few countries appear to have the infrastructure, knowledge and trade connections to maintain or develop a competitive pharmaceutical industry.

Donations have been a major source of drugs for the last five years in several, but not all, NIS. There are now fewer donations and countries are having to rely on their own supply systems, which puts an additional financial burden on citizens (both in- and outpatients) and governments (hospitals).

DRUG FINANCING

The financial crisis in the public sector in the NIS, caused by a lack of productivity and a large grey sector, leaves governments with very small budgets for public goals such as health care. In addition, health care is not a political priority in many countries, while a huge overcapacity in health care facilities and the number of health workers further dilutes the available budgets.

Key words: *health care budgets, hospital budgets, drug reimbursement, health insurance, co-payments, cost containment*

Most countries are building up a new health insurance system that should be able to attract new sources of income. At the same time a rationalization of the hospital sector should keep the costs under control. But these demanding and time-consuming transformations are either not yet ready or have not yet borne fruit. Most hospitals do not have budgets for drugs (except for essential drugs, donations and emergency supplies) and it has become common practice to ask patients to buy their own drugs. Outpatients in most NIS have to pay for their drugs themselves, although some relief in the form of free drugs is given to patients who are chronically ill or have specific diseases or to vulnerable social groups.

Modern drug reimbursement systems, which work on direct compensation of pharmacies, are either not implemented or are unreliable. Pharmacies finding themselves with unpaid debts thus lose trust in or even ignore these systems.

Although budgets are limited, cost containment is almost entirely limited to drug prices and standard treatment protocols for calculating levels of reimbursement or free drugs, which are not very accurate or effective. Other measures, such as generic prescribing, volume reducing measures and incentives to purchase low priced drugs are gradually becoming known but are not yet widespread.

The lack of available funds for health and drugs (low if measured¹⁰ per capita, per GDP and as a percentage of the state budget) is a major concern. In particular, it is difficult to raise money from the healthy and wealthy as there are only a few redistribution mechanisms in place. It is the sick and the poor who have to pay the bill (as far as they can), which means that growing proportions of the population cannot afford essential care and drugs. Treatments are postponed until the complaints become more severe and hospitalization is necessary.

¹⁰ See Annex B for indicators.

RATIONAL DRUG SELECTION AND USE

The rational selection of drugs is almost the most difficult element of a national drugs policy to implement in all the NIS. This is

Key words: *drug lists, prescribing, drug information, therapeutic committees, utilization reviews, OTC, traditional medicine*

due to the fact that discussions on rational prescribing were initiated at times of dramatic budget cuts, and to a negative attitude towards rationalization where it limits the prescribing freedom of the doctor. Physicians, having to shift from almost unlimited professional freedom to prescribe drugs "at no cost", consider rational selection a temporary *force-majeure* situation because the country is poor – an attitude which they often communicate to their patients. It is therefore difficult to change the structure of prescribing practices. In some cases better selection and prescription is working in state systems when hospital managers so request, but these limitations are often irrationally "corrected" by the patients being asked to buy drugs privately outside the hospital.

There is also little scope for correcting bad prescribing practice due to limited drug utilization studies, a lack of mechanisms for adverse drug reaction monitoring, and insufficient statistical information on drug-related problems.

Despite the above, many countries are promoting better selection and use of drugs through reimbursement systems and the new medical insurance schemes, as well as establishing national essential and life-saving drug lists and formularies. Some countries are conducting drug utilization studies, and establishing hospital drug and therapeutic committees which are involved in selecting drugs for the hospital supply while implementing treatment guidelines.

It is not yet widely understood that monitoring doctors' prescribing practices and conducting drug utilization reviews are very strong instruments in advocating evidence-based prescribing (output measurements). A strong reliance on treatment guidelines (input focus) prevails. In many NIS there is a focus on locally made traditional medicines, which are not always supported by relevant safety and efficacy studies.

In most NIS every drug can be obtained from a private pharmacy without prescription, including antibiotics, psychotropics and hospital drugs. In many cases patients cannot afford to go to the doctor and choices are not based on professional advice. In addition, there are contradictory developments – more new drugs are becoming available and there is less information. This is a big problem for both prescription and over-the-counter drugs used in self-medication.

HUMAN RESOURCE DEVELOPMENT

It is clear that all NIS have a huge human and intellectual potential in health care and in the pharmaceutical sector. But knowledge and skills are often outdated or inadequate in the new circumstances and future development and needs of the pharmaceutical sector, and the authorities and key experts are struggling with issues related to training and re-educating staff at all levels and in all areas of the pharmaceutical sector.

Key words: *the role of the pharmacist, curricula development, continuing education, training*

Compared with the drastic changes that are taking place in other sectors within the NIS, the relative stability of staff in the pharmaceutical sector is remarkable. Although there have been huge organizational changes, many experts are still in place, although sometimes in a new setting. Technical assistance programmes

have gained by this continuity. The training provided has therefore been fruitful, perhaps even more than could have been expected. In several instances trained individuals are acting as resource persons for other local staff.

Training of teachers is taking place with varying degrees of intensity under a range of support programmes. However, where formerly a few good centres were accessible to all NIS, these centres now serve nationals only. In some countries the lack of qualified teachers, training materials, textbooks, etc. is a major obstacle. A number of initiatives, such as study tours, conferences and meetings, are now taking place in all NIS. Changes in the curricula for medical and pharmacy students are being implemented in a few countries. Still there is much to do as new educational methods are needed at all education levels in all NIS.

Staff of the ministries of health and of the drug regulatory authorities also need new knowledge, vision and experience to meet the changing needs of the pharmaceutical sectors. Special attention should be given to transferring information and knowledge to national and regional politicians and managers, who can either block or encourage new initiatives and reform processes.

Patients' attitudes and the freedom of choice strongly influence drug prescribing and use, but patients are not being made aware of the rationale for proper drug treatment.

NATIONAL DRUG POLICIES

Several NIS have described their drug policy objectives and strategies in national policy documents. Some of these documents were

Key words: *policy development, adoption and dissemination, operational implementation plans, monitoring*

developed at an early stage of the transition process and have been helpful in achieving consensus within the sector and attracting the attention of politicians. Discussions about the drug laws have also triggered a wide debate about the place of pharmaceuticals in the health care system, the level of private interest to be allowed and how the sector should develop in the future.

Not many countries have implemented these policies in a structured way. Rapid political changes and the lack of capable people at the initial stages have resulted in frequent changes of plan. Today there is more room for structural development, as several questions of principle have been answered and the number of trained people is gradually increasing. Also the first "wild" stages of market development have passed and the young private sector may now become more receptive to public health goals and more patient-oriented.

Those NIS that have developed drug policy documents have usually kept them for central level purposes and have not disseminated or communicated them sufficiently to regional health and pharmaceutical authorities. Most national drug policies lack an operational implementation plan or adequate monitoring mechanisms. Some countries already see the need to update their drug policies, including operational plans. A few began this process in 1997.

3.3 A new transition phase: changed conditions for reform

Today the conditions for further reform of the pharmaceutical sector in the NIS are different from those prevailing at the beginning of the 1990s: new prospects are emerging and new problems have to be faced. Not all developments in the NIS are conducive to a smooth reform; new obstacles occur or old ones remain. Below is an overview of the major trends in care and their effects on the pharmaceutical sector.

<i>External developments and their effect on pharmaceutical sector reform</i>	
<i>Economy</i>	
• Slow, but positive economic growth	+ Increased financial resources
• Development of a more mature attitude in the private sector	+ Increased availability of drugs; improved collaboration between private and public sectors
• Low payment levels of officials	- Unattractive employment conditions for trained and talented people, potential brain drain
• Decentralization	+ Room for new developments and initiatives based on regional and local needs
	- Re-address pharmaceutical reform in regions; increasing budget problems; information gaps
<i>Health and health care</i>	
• Low priority for health and health care (% GDP, % budget)	- Underfunding due to insufficient budget allocations; affordability problems due to low income levels
• Rediscovery of social orientation and public health values	+ Potential for speeding up health care reform and a higher place on the political agenda; better availability of funds
• Gradual implementation of health care reform	+ Greater effectiveness of health care systems; focus on priority areas; mixed funding of drug bill
	- The slow pace of reform dilutes budgets and leads to inadequate drug selection; continuous reliance on inadequate state budgets
• Slow development of the drug production sector	- Continuous delivery of non-GMP and non-registered products; dependence on imports
• Continued reliance on traditional systems and habits (prescribing, quality control, education)	- Innovation and reform proceed slowly starting in selected central level facilities, spreading later to other facilities and regions
<i>Other</i>	
• Improved capabilities and skills, as well as awareness and knowledge	+ Creative solutions, better exchange of opinions and information, better targeted interventions
• Underdeveloped information systems for management and decision-making capacity	- Decisions and interventions are not evidence-based; positive and negative developments are not recognized; incomparability

The balance between positive and negative influences will differ between countries, but a strategy for reform in the pharmaceutical sector, as well as its actual implementation and expectations about its impact and results, should take these forces into account. It is clear that the NIS will remain in a transitional stage for several years, and that the environment for change and innovation will not always be positive or stable.

3.4 Summary of developments and conclusions

Since the beginning of the 1990s, and especially during the last two to three years, there have been many positive developments in the pharmaceutical sector in the NIS, although these have often been overshadowed by temporary setbacks and the effects of negative or slow economic growth.

- Legislation has been drafted or adopted and appropriate regulations are partly ready or under development.
- Regulatory authorities have been established. Their tasks and activities are being developed and their functioning will improve, including with the help of outside support.
- The quality of drugs is slowly improving due to better regulation, improved functioning of agencies and tighter import/export licensing.
- Privatization has made drugs more widely available throughout the countries.
- Consciousness of the essential drugs concept and rational prescribing is slowly spreading within the health profession.
- Knowledge of new financing mechanisms and cost containment instruments is growing, along with the recognition of the need to restructure the hospital sector.
- The new circumstances and future needs require different knowledge and skills. Training of key persons is delivering the first (albeit very isolated) results.
- Drug policies have proved to be a useful tool in reforming the pharmaceutical sector, by contributing to better awareness and knowledge within the sector and among politicians.
- Networking and assistance are contributing to new solutions, supporting decision-makers, and improving problem-solving capacities and adequate capacity building.

At the same time there are several barriers to further or faster development, due partly to the lasting economic difficulties and partly to long-standing practices and traditions.

- Lack of access to drugs due to low levels of affordability is a major problem, especially for the growing numbers of people who use health care regularly.
- In most countries prescription drugs can be bought in community pharmacies without prescription.
- Inadequate budgets in hospitals induce large private payments, have a deleterious effect on the functioning of hospital pharmacies and encourage irrational prescribing.
- There are major problems with the enforcement of new laws and regulations regarding drugs and services.
- Professional levels of work in health care and pharmaceuticals are inadequate: either profit becomes more important, or lack of motivation hinders the rendering of a proper service.
- Universities and continuing education programmes need new methods and visions to train and educate teachers, professionals and students.
- Rapid developments in the private sector have led to a lack of information on markets and on drugs.

From the point of view of the regulator, many things have improved. For health professionals the situation concerning drug treatment has become more complex; on the one hand availability has improved, but on the other affordability has decreased. For the patient the situation largely depends on a person's or family's income. Given the economic hardship of large groups in the population, it is clear that access to quality drugs is no longer within reach of many of them.

CHALLENGES FOR THE SECTOR

Within the changing economic and political environment the pharmaceutical sector will have to take up the challenges that lie ahead. The responsibilities laid down in new structures and organizations should be used to carry positive developments forward, increase efficiency, deliver better quality services and improve the effectiveness of interventions.

4. Strategic vision and priority-setting

4.1 Our mission

The objective of continued reform of the pharmaceutical sector in all the NIS should be to:

- **Ensure affordable access to good quality drugs and their appropriate prescription and use.**

In view of the apparent challenges and the changing conditions for reform, successful improvement depends on many factors. Most NIS face similar problems, although these might differ in depth and intensity. Solutions might also differ. There is much to gain from combining strength, exchanging knowledge and learning from each others' successes and failures. This calls for collaboration, coordination, information exchange and development of networks.

FIVE PRIORITIES

The challenges facing the pharmaceutical sector in the NIS can be grouped into five major priority areas: access, management, quality, rational use and education.

In the following paragraphs these challenges are briefly discussed for the NIS as a group. Individual countries may prefer to order their own priorities in accordance with their specific situations and national conditions. All countries, however, need to put improvements in access to essential drugs high on their agenda.

The knowledge, expertise, skills and authority of several key persons in the sector are essential if the challenges are to be met in the next few years. Encouragement and support of these persons and organizations in networks and through assistance programmes is a necessary precondition for successful reform.

Priorities for the pharmaceutical sector

- **Access**
Improve the affordability of drugs, especially for hospital patients (make more funds available, spend scarce resources more effectively); encourage more efficient and effective procurement and distribution of low priced good quality drugs.
 - **Sector management**
Move from paper regulation to implementation and enforcement; Improve information flows for better management and involvement of all stakeholders in the sector, taking into account decentralization.
 - **Quality**
Enhance professional levels throughout the sector, both private and public; move from quality control to quality assurance (including GMP).
 - **Rational drug use**
Set up sustainable, comprehensive programmes for rational prescribing and use of drugs, inform the patient; make better use of the pharmacist in the health care system.
 - **Education**
Reform basic education programmes; set up continuing post-graduate education programmes; train key people and opinion-formers.
-

4.2 Why these priorities?

IMPROVE ACCESS: FOCUS ON THE PATIENT

The *highest priority* should be given to the question of access: it affects the patient immediately, has a big political and social impact, improves doctors' prescribing practices (treatment and selection) and has the potential to create sustainable and visible improvements for the many stakeholders involved.

Affordability, or economic access to drugs, has two components: financing and demand. Governments should ensure that sufficient funds are made available for patients in need, either through budget allocations or through the organization of reimbursement systems in collaboration with other sources of finance such as insurance systems. At the same time demand should be optimized in both quantity (better targeted drug selection and prescribing) and in value (price levels, generic substitutes, procurement). Priorities should be set at hospital and polyclinic level and collaboration intensified within regions to achieve better results.

Improving access to drugs also requires stronger management to improve the organization of the supply of drugs through collaboration and higher efficiency.

The rationalization of treatment, drug selection and prescribing is another necessary precondition for improving access. A focus on lists of effective, safe and good quality drugs will avoid the waste of scarce resources, both governmental (hospital budgets) and patients' contributions.

Problems with access, particularly affordability, are strongly connected to health care reform and the economic development of a country. So far these areas are not developing fast enough to provide solutions. Improvement of access will therefore have to come from innovative ideas and solutions within the sector (e.g. group purchasing, non-profit suppliers, generics, mixed payment/reimbursement).

This has some impact in the short term (ideas, pilot schemes, expectations) but a greater impact for patients and professionals in the medium and long term.

Linked priorities
Management
Rational drug use

Impact
Short, medium
and long term

STRENGTHEN SECTOR MANAGEMENT (DRUG POLICIES, REGULATION, ENFORCEMENT, INFORMATION)

Improving the management of the sector is important if the best use is to be made of efforts and investments in different areas. Already much has been invested in establishing new structures. Now management needs to be strengthened and sustainability created as well as the necessary conditions for other systems and efforts to be successful. Development and implementation, including enforcement, of proper regulations and standards play a central role in establishing or maintaining authority in the sector. In this context (revised) national drug policies can play a stimulating strategic role.

A further strengthening and improvement of public sector structures, processes and people are also needed to match the increasing strength and capacity of the rapidly growing private sector. Collaboration in certain areas should be sought.

Substantial improvements are needed in the flow and exchange of information on issues such as market developments, drug use, independent drug information, rational selection and prescribing, and structural and regulatory changes. Exchanges between regions and health professionals will strengthen their own knowledge and position, and improve the knowledge of ministries and agencies and their authority and visibility in the country.

Linked priorities
Education
Rational drug use
Quality

This activity will have an immediate effect and spread the reform of the sector into the health profession and regions.

Impact
Short and medium
term

QUALITY DRIVE (QUALITY ASSURANCE, GMP, GPP)

The third priority is quality improvement, not only of the drugs on the market but of the profession as well. This component should create sustainability in this area, build effectively on the investments of recent years and encourage the implementation of the regulations that have been developed.

Improvements in the control systems aimed at guaranteeing the quality of the drugs will have to be supplemented by attention paid to higher professional quality levels at each stage of the supply chain, from production to distribution, dispensing, pharmacy services and information.

Gradually, while strengthening the quality control function, the focus should be shifted towards quality assurance programmes. Countries must collaborate on this because of the intensive cross-border trade. Education and training, standards and implementation programmes, and certification (including GMP, GDP, GLP, GPP) according to quality standards are all necessary elements in this process.

Linked priorities
Education
Management

The improvements in quality control will have an immediate effect, while quality assurance programmes will deliver better results over time.

Impact
Short and long
term

ENCOURAGE APPROPRIATE DRUG USE (SELECTION, PRESCRIBING, CONSUMPTION)

The rational selection and prescribing of drugs is an important issue everywhere. In the NIS, however, it is especially critical because of prescribing practices inherited from the time of free health care and drugs and the current lack of money. Experience shows that changing prescribers' behaviour is very difficult, and even a comprehensive approach using drug and therapeutic committees, drug lists or formularies and standard treatment guidelines takes a long time to achieve tangible results.

Better prescribing and use of drugs is highly beneficial for the patient and for cost containment, but health professionals must be provided with the tools and information to make the right decisions. The task is to increase awareness of these problems, collect and exchange information about current and preferred practice and results (drug prescribing, utilization) and provide better methods and tools for drug selection and prescribing.

It is clear that rational drug use cannot be achieved without proper access to safe, available and affordable quality drugs or quality guarantees (quality control, sector organization, adequate information). Furthermore, an essential role is played by education and training both of new students and, even more, of the large number of practising health professionals – doctors, nurses and pharmacists.

Linked priorities
Access
Management
Quality
Education

Given the huge task in this area and the dependence on issues such as access and quality, positive results may only be anticipated in the medium to long term.

Impact
Medium and long
term

EDUCATION AND TRAINING: MOTIVATING VIEWS

Fundamental changes in the educational system are necessary as a result of the shift in the pharmaceutical market from supply-oriented to needs-driven, and from product- and process-oriented to patient- and health outcome-oriented. Changing education should start with the training and education of opinion-makers and

academics and the redefinition of curricula. Initially, changes could be made in the training curricula for physicians, pharmacists, clinical pharmacologists, pharmacotherapists and pharmacy technicians in the areas of: clinical pharmacy, patient orientation, patient communication, social and administrative pharmacy, financial management, pharmacy management and sector development.

Special attention is needed to improve teaching in drug selection and prescribing at university level (doctors, pharmacists) and for selected groups of practising doctors in continuing education programmes (see the fourth priority – rational drug use).

Linked priorities
Management
Quality
Rational drug use

Training and education of these professionals should take into account a redefinition of their tasks and function in the future health care and drug supply system. A more prominent role should be anticipated for pharmacists, and standards and procedures defined with respect to quality assurance.

Education is a very important issue, but can only have a more long-term impact on the creation and development of excellent health professionals. In that context emphasis should be put on continuing education programmes. In the mean time, intensive workshops dedicated to the main problem areas may be effective.

Impact
Medium and long
term

5. From vision to action!

The previous section sets out the strategic directions and priorities for the next few years in pharmaceutical policy terms. In addition one should be aware of the objectives that are to be reached. Only with well defined goals reform becomes a meaningful exercise.

5.1 The Patient in Focus – objectives

Towards the next millenium, the focus of pharmaceutical sector reform in newly independent states will shift from product and regulation oriented towards patient oriented. What then, are the objectives of reform from a patient's point of view?

- Guaranteed quality of all products on the market (control, registration, inspection).
- Access to these quality products that improve treatment results and health outcomes, regardless of financial or social circumstances of the patient (availability, compensation mechanisms).
- Qualified doctors and pharmacists that are able to advise the most appropriate and effective treatment based on up-to-date information (education, training, rational selection and use, information).
- Doctors and pharmacists are able to provide adequate information in order to maximize patients' compliance (information, promotion, patient orientation).
- Reliable drug supply systems that are able to deliver quality products at the lowest possible price in hospitals and for outpatient care, throughout the entire country (availability, price competition or regulation, hospital drug management).

From these reform objectives one can derive the relevant objectives for the defined five priority areas.

These objectives and intermediate targets are presented in Annex D.

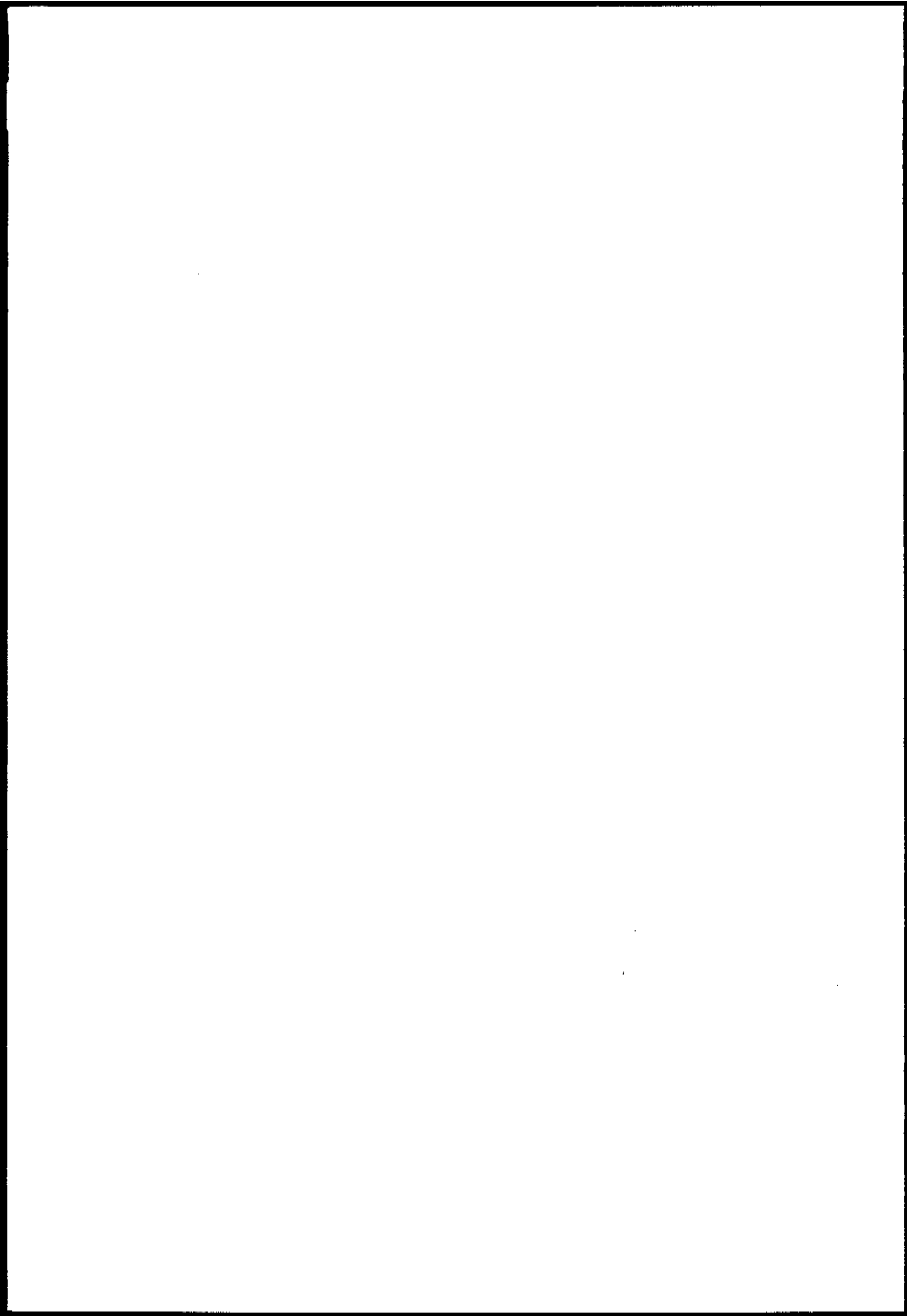
5.2 Action plan

The operational implications will differ from country to country, although the NIS have a lot in common. In order to assist countries translate these strategies and priorities to a more detailed operational level, some ideas and indications on how to reach the objectives are presented in Annex E.

For each of the five priority areas (access, management, quality, rational use, and education and training), the country's needs in operational terms, possible interventions and activities and which organizations may be involved or in charge are shown. Countries may wish to use this framework for their own implementation plans. Actions, interventions and activities may then be planned in more detail depending on the national situation and capabilities, with sub-targets and follow-up actions for each activity.

It should be noted that activities may have different effects and need different time frames to deliver tangible results. The development of an implementation plan calls for a balance to be found between the achievement of quick results and gradual improvements. Finally, the available financial and human resources must be taken into account when the workload is distributed.

Copenhagen, February 1998



Annex B Economic indicators, health care and drug expenditure and pharmaceutical sector structure NIS (1996-1997)

Country	Population Million	GDP		Health care expenditure		Drug expenditure per capita 1996 USD	Average monthly wage ('97) USD	Number of registered drugs ('97) nr.	Establishments in the sector (1-1-97)			Kiosks per pharmacy	
		1996 USD	1996 %	1996 USD	in % of GDP				Production plants nr.	Full assorted wholesalers nr.	Pharmacies nr.	Sep. '97 nr.	Sep. '97 nr.
Armenia	3.5	\$450	4.2	\$19	4.2	\$16	\$80	1,200	10	6	600	120	5,800
Azerbaijan	7.6	\$451	2.8	\$13	2.8	\$7	\$20	6,000	3	2	1,000	200	7,600
Belarus	10.3	\$1,308	5.1	\$67	5.1	\$16	\$145	3,000	5	10	1,250	4,000	8,200
Georgia	5.4	\$841	4.5	\$38	4.5	\$12	\$90	1,500	20	7	850	600	6,400
Kazakhstan	16.4	\$1,278	2.0	\$26	2.0	\$12	\$100	2,000	22	130	1,700	1,220	9,700
Kyrgyzstan	4.6	\$379	3.4	\$13	3.4	\$8	n.a.	830	9	20	260	500	17,700
Moldova	4.4	\$443	3.9	\$17	3.9	\$10	\$40	3,500	5	10	680	0	6,500
Russian Federation	147.5	\$2,985	2.8	\$84	2.8	\$40	\$155	11,000	370	10	16,000	25,000	9,200
Tajikistan	6.0	\$177	8.0	\$14	8.0	\$2	\$90	n.a.	1	1	507	n.a.	11,800
Turkmenistan	4.6	\$461	5.0	\$23	5.0	\$5	n.a.	665	1	2	390	120	11,800
Ukraine	50.9	\$864	3.3	\$29	3.3	\$10	n.a.	5,000	22	10	n.a.	n.a.	n.a.
Uzbekistan	22.7	\$391	3.4	\$13	3.4	\$3	\$60	1,920	16	20	5,200	0	4,400
Average	23.7	\$836	4.0	\$30	4.0	\$12	\$87	3,051	40	19	2,585	3,176	9,000
Total	283.9								484	228	28,437	31,760	

Sources

- economic data: EBRD, EIU, BCE, IMF;
- health care expenditure: WHO Health for All database;
- sector data and drug expenditure: Ministries of Health and Drug Agencies of NIS countries.

Annex C Abbreviations

CAR	Central Asian Republics
CEE	Central and Eastern Europe
DAP	Action Programme on Essential Drugs (WHO)
DRA	Drug Regulatory Authority
DTC	Drug and Therapeutic Committee
EU	European Union
EURO	Regional Office for Europe (WHO)
GDP	Gross Domestic Product or Gross National Product
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
GPP	Good Pharmacy Practice
MoE	Ministry of Economics
MoF	Ministry of Finance
MoH	Ministry of Health
MoJ	Ministry of Justice
NDP	National Drug Policy
QA	Quality Assurance (prevent errors)
QC	Quality Control (measure errors)
STG	Standard Treatment Guideline
WEU	Western Europe
WHO	World Health Organization

NIS	Newly Independent States
ARM	Armenia
AZE	Azerbaijan
BEL	Belarus
GEO	Georgia
KAZ	Kazakhstan
KGZ	Kyrgyzstan
MDA	Moldova
RUS	Russian Federation
TJK	Tajikistan
TKM	Turkmenistan
UKR	Ukraine
UZB	Uzbekistan

Annex D Targets per priority area

<i>Item</i>	<i>Intermediate target for NIS</i>	<i>Ultimate objective</i>
1) Access targets		
a) Availability	<ul style="list-style-type: none"> • All necessary WHO Essential drugs available in hospitals and for primary care in the entire country • Generic alternatives widely available in all major therapeutic classes • Generic substitution possible 	<ul style="list-style-type: none"> • Extended list of drugs widely available throughout the country • Generic prescribing and substitution arranged by law
b) Affordability	<ul style="list-style-type: none"> • No direct patient payments for drugs in basic package health care in hospitals • At least 50% compensation of outpatient essential drug (on a list) for chronic patients and groups of poor and vulnerable people (children, elderly and people under the poverty line) • Pricing mechanisms that favour sales of low priced drugs 	<ul style="list-style-type: none"> • No direct patient payments for all hospital drugs • 90% compensation of outpatient essential drugs (on a list) for chronic patients and groups of poor and vulnerable people (children, elderly and people under the poverty line) • Over 70% coverage of all Rx-drugs by a comprehensive reimbursement system (health insurance, state budget or other)
2) Management targets		
a) Regulation	<ul style="list-style-type: none"> • Drug laws and ub-regulations adopted and in force 	<ul style="list-style-type: none"> • Full enforcement of adopted laws and regulations • Regulations in compliance with maximum benefits for patients
b) Policy, communication, information	<ul style="list-style-type: none"> • National Drug Policy defined, operational plan in action, supervisory committee active • Interactive communication lines within the sector (public institutes, private business, associations, production) • Information collection and dissemination within the country about pharmaceutical sector development, reforms, results, relevant indicators, products and treatments • Involvement of pharmacise in health promotion and disease prevention programs for selected high priority areas • Adequate information for the public on self medication and OTC drugs 	<ul style="list-style-type: none"> • Progress reports based on monitoring of objective indicators for each drug policy item • Full participation of the sector in its development and reform • Wide access to all information about sector development, products, markets, regulations, treatments. • Healthy life styles and a decrease in the prevalence of certain diseases as a result of health promotion and disease prevention programs • Wide availability of relevant information for patients
c) Procedures	<ul style="list-style-type: none"> • Review of all customs, regulatory and control procedures on necessity and effectiveness • Reintroduction of prescription forms for Rx drugs 	<ul style="list-style-type: none"> • Transparent and non-bureaucratic customs, regulatory and control procedures • Use of prescription forms for Rx drugs obligatory by law

Targets per priority area (cont'd)

<i>Item</i>	<i>Intermediate target for NIS</i>	<i>Ultimate objective</i>
3) Quality targets		
a) Licensing	<ul style="list-style-type: none"> • All pharmacies, distributors and producers licensed • No unlicensed kiosks • No Rx drugs in kiosks, but only to be sold by licensed pharmacies 	<ul style="list-style-type: none"> • All licensed pharmacies comply with international quality standards and deal with registered products only • No kiosks
b) Quality control	<ul style="list-style-type: none"> • Drug Agencies adequately funded and at full capacity in their essential functions • Reduce number of non-registered drugs with 20% per year • Plan developed to move from control to quality assurance • Plan developed to introduce GMP, GDP, GCP, GPP • Inspectors trained and skilled with up-to-date knowledge 	<ul style="list-style-type: none"> • Drug Agencies able to play a strong independent role in quality control • No non-registered drugs on the market • Quality assurance focused on error prevention instead of error detection • GMP, GDP, GCP, GPP compliance within the entire sector • Inspection at international level, member of PIC
4) Rational use targets	<ul style="list-style-type: none"> • Rational drug use principles based on essential drugs communicated to facilities, doctors and pharmacists • Standard Drug Treatment Guidelines developed for priority diseases • Drug formularies for different health care levels • Therapeutic committees introduced in all major hospitals • Independent drug information centres established • Design programs for better prescribing • Assess prescribing habits on a sample basis 	<ul style="list-style-type: none"> • Maximum compliance with rational drug use principles in facilities and by all doctors and pharmacists • Mechanism to review Standard Drug Treatment Guidelines developed • System of feed back and periodical updating of drug formularies • Active net of therapeutic committees operational in all major hospitals • Independent drug information centres play a key role in information exchange to and from therapeutic committees and with pharmacies • Full involvement of doctors and pharmacists in prescribing improvement • Regular monitoring of prescribing behaviour and feed back
5) Education and training targets		
a) Basic education	<ul style="list-style-type: none"> • Review curricula of pharmacists and doctors • Train teachers and professors in new methods and skills • Exchange experiences with other NIS 	<ul style="list-style-type: none"> • Revised curricula operational • Keep teachers up-to-date in continuous training • Exchange of teachers outside NIS
b) Continuous training	<ul style="list-style-type: none"> • Develop continuous training programs • Select priority areas and target groups for continuous training 	<ul style="list-style-type: none"> • Full participation of doctors, nurses, pharmacists and pharmacy technicians in continuous training programs every 5 yrs.

Annex E Implementation plans: country needs, approaches and organizations involved

Suggestions for implementing priority I: Access (affordability)

<i>Country needs</i>	<i>Possible approaches</i>	<i>Involved organizations</i>
1. Improve the availability in specific areas		
a) Increase the availability of drugs in hospitals	<ul style="list-style-type: none"> • Develop viable solutions and concepts combining direct supply, generic prescribing, common drug lists, group purchasing, tendering, inventory control, automation. • Strengthen the role of hospital pharmacy • Try different ideas for improvement in pilot projects; implement positive results on larger scale 	MoH, DRA, Hospitals, Suppliers, Hospital pharmacies, Hospital managers
b) Improve the availability of drugs in rural areas	<ul style="list-style-type: none"> • Ensure a minimum assortment to be available in all pharmacies through regulation, reimbursement, licensing or incentives 	Pharmacies, MoH, Inspection
2. Increase the general affordability of drugs		
a) Better protection of poor and vulnerable groups	<ul style="list-style-type: none"> • Create or redesign separate compensation mechanisms for poor and vulnerable groups and provide sufficient funds to make it sustainable; give a role for new financing structures like insurance funds 	MoH, MoF, Govt., Insurance, Parliament
b) Develop new compensation mechanisms: i.e. insurance, drug reimbursement	<ul style="list-style-type: none"> • Include drugs in health insurance schemes – at least essential drugs in hospitals • Create separate drug reimbursement systems for certain groups or diseases if budget or health insurance cannot deliver 	MoH, MoF, Govt., Insurance, Parliament
c) Review current price regulation policy (incl. Taxation benefits)	<ul style="list-style-type: none"> • Develop and implement comprehensive cost containment measures which keep market forces intact • Introduce margin systems that provide incentives for selling low priced drugs; for example: decreasing or flat rate margin systems 	MoH, DRA, MoF, Tax dept., Parliament
3. Invest in better supply systems for low priced quality drugs		
a) Domestic production	<ul style="list-style-type: none"> • Large scale production when feasibility study results are positive; develop realistic plans • Encourage small scale production and joint ventures for essential drugs or for the final production phase (tableting, packaging) 	MoH, MoIndustry, Govt., Suppliers, Foreign Investment Agencies
b) Assortment in pharmacies	<ul style="list-style-type: none"> • Introduce requirements for the available assortment of drugs in pharmacies, which should include cheaper alternatives • Introduce incentives for pharmacists for providing information about low prices alternatives to doctors and patients. 	MoH, DRA, wholesalers, pharmacies, health authorities
c) Drug procurement concept	<ul style="list-style-type: none"> • Increase effectiveness of drug procurement by encouraging competition (tendering), pooling resources, increasing purchase power, less intermediaries • Encourage creation and wide dissemination of formularies and lists to focus procurement 	MoH, MoEconomics, Hospitals, wholesalers, pharmacies, regional health authorities
d) Promotion of generic drugs	<ul style="list-style-type: none"> • Simplify and encourage generic registration • Stimulate the knowledge about generics of doctors and pharmacists • Encourage prescribing by generic name 	MoH, DRA, Hospitals, pharmacies

Suggestions for implementing priority II: sector management (drug policies, regulation, enforcement, information)

<i>Country needs</i>	<i>Possible approaches</i>	<i>Involved organizations</i>
1. Improve the management capacity of public structures		
a) Departments of pharmacy in MoH (DoP)	<ul style="list-style-type: none"> Strengthen the policy making and legislative capacity within the Dept. of Pharmacy Ensure good collaboration between departments in the ministry and the drug agency. 	MoH, (DRA)
b) Regulatory agencies	<ul style="list-style-type: none"> Work with a clear mission, functions and tasks Improve the management capacity within the agency and its units Increase cohesion between different people and units of the Agency Improve information exchange within the agency Set limits to the number of registered drugs Make inspection and laboratories operational; focus on priority areas; improve enforcement 	DRA, (MoH)
2. National drug policies	<ul style="list-style-type: none"> Develop a national drug policy or revise the existing ones according to today's situation and requirements Make an action programme for implementation Create a Drug Policy Council to monitor, steer, lobby and measure progress. 	MoH, DRA, associations, key persons, politicians
3. Simplify and streamline regulatory processes & procedures	<ul style="list-style-type: none"> Improve transparency of regulations, rights and duties. Diminish bureaucracy: introduce time limits for control procedures, abolish superfluous paperwork Limit control to the necessary by sampling; give incentives to good behavior; publish repeated bad behavior Shorten processing time and decrease cost for applicants 	DRA, legislation, regulations, Inspection, customs
4. Create and share adequate and up-to-date sector information	<ul style="list-style-type: none"> Set up drug information centers either within the MoH or within the Agency for priority information and communication tasks Collect and disseminate relevant information <ul style="list-style-type: none"> on sector development, available drugs, prescribing and use communicate to policy makers, hospitals, doctors, pharmacies and the public Create a communication network (contacts, newsletters, etc.) within the health sector and with regional health authorities 	MoH, DRA, Hospitals, regional health authorities
5. Human resources: strengthen capabilities of staff in the public sector	<ul style="list-style-type: none"> Encourage personal development by sharing information and experiences, training. Focus on personal, managerial and communication skills and not only on knowledge Motivate and refresh people regularly Encourage and organize in-house training, exchange within NIS, study tours to Central or Western Europe or other developed systems 	MoH, DRA, Universities, Schools of Pharmacy, Schools of Medicine, Schools of Public Health, Schools of Management

Suggestions for implementing priority III: Quality (quality assurance, GMP, GPP)

<i>Country needs</i>	<i>Possible approaches</i>	<i>Involved organizations</i>
1. Further improve the quality control (QC) system		
a) Develop basic functions of a good QC system	<ul style="list-style-type: none"> • Make transparent procedures and tariffs • Pay more attention to counterfeit drugs • Develop regulatuon on drug advertising and promotion • Train managers, staff and upgrade equipment • Exchange approaches with other NIS 	DRA, Drugnet-network, MoH, Customs, regulations, laboratories
b) Focus QC on essential functions	<ul style="list-style-type: none"> • Create a reasonable balance between sampling and batch control • Reward good behavior, be strict on repeatedly non-compliance with regulations or quality • Diminish bureaucracy; improve response times; decrease costs 	DRA, MoH, Customs, Inspection, laboratories
c) Find ways to improve the enforcement	<ul style="list-style-type: none"> • Collaborate with Min. of Justice and Min. of Economics to implement laws and regulations • Involve local authorities in enforcement 	MoH, MoJ, MoEc., regional and city authorities, Police
d) Follow and implement common standards	<ul style="list-style-type: none"> • Develop standards and implementation guidelines; • Exchange these with other NIS and aim for common standards throughout the continent 	DRA, Suppliers, pharmacies
2. Prepare a plan to introduce a quality assurance (QA) system in due time	<ul style="list-style-type: none"> • Develop a conceptual approach to go from QC to QA and a gradual implementation • Improve the quality of domestic production (GMP) • Improve the quality of distribution (GDP, GPP) 	DRA, Lab's, producers, distributors, pharmacies
3. Ask attention for and stimulate the quality focus of practising professionals	<ul style="list-style-type: none"> • Introduce quality standards in licensing (inspection) • GPP programmes • Introduce simple quality checks and measure • Remove unqualified pharmacies from the market (accreditation) • Initiate quality awards 	DRA, Inspection, regional and local health authorities and inspection,

Suggestions for implementing priority IV: Rational drug use (selection, prescribing)

<i>Country needs</i>	<i>Possible approaches</i>	<i>Involved organizations</i>
1. Encourage the rational drug treatment of common diseases		
a) Standard (drug) treatment guidelines (STG's)	<ul style="list-style-type: none"> • Develop STG's for major diseases in collaboration with similar hospitals and experts • Disseminate STG's and treatment information • Monitor prescribing practices • Exchange information on STG's with other NIS • Introduce and/or promote use of Essential drugs • Encourage generic prescribing • Publish and discuss new STG's 	MoH, DRA, Hospitals, Doctors, H-pharmacies, retail pharmacies
b) Drug and therapeutic committees (DTG's)	<ul style="list-style-type: none"> • Encourage and develop function of therapeutic committees • Involve and train wide range of professionals in rational drug use • Define a clear role for the pharmacists • Improve the information flows on essential drugs 	MoH, DRA, Hospitals, Doctors, H-pharmacies, retail pharmacies
2. Develop and offer tools to improve a better selection of the most adequate and effective drugs	<ul style="list-style-type: none"> • Define a clear role for the pharmacists • Improve the information flows on essential drugs • Training and education in rational drug use for doctors and pharmacists • Drug lists per health care level • Formularies 	MoH, DRA, Hospitals, Doctors, H-pharmacies, retail pharmacies
3. Introduce incentives for rational dispensing focused on a good quality/price ratio	<ul style="list-style-type: none"> • Clear rules for generic substitution • (Re-)introduce use of prescription forms • Training and standards for GPP • Information on OTC's (in writing and in person) 	MoH, DRA, Hospitals, H-pharmacies, retail pharmacies
4. Create better information:		
a) for patients	<ul style="list-style-type: none"> • Drug utilization reviews • Monitoring systems at pharmacy level 	MoH, DRA, Hospitals, H-pharmacies, retail pharmacies, Press, RTV
b) drug utilization of patients	<ul style="list-style-type: none"> • Improve access to up-to-date drug information • Patient education and information 	

Suggestions for implementing priority V: Education

<i>Country needs</i>	<i>Possible approaches</i>	<i>Involved organizations</i>
1. Upgrade the curricula of pharmacists with new knowledge and learning methods		
a) Graduate courses	<ul style="list-style-type: none"> • Less focus on chemicals and products; more on patient orientation, information, management, GPP, quality, economics ... • Include Drug policies and organization of the pharmaceutical sector in curricula • Introduce new programmes and methods 	Universities, Schools of Pharmacy, Cont. Education Programmes
b) Postgraduate & continuous training	<ul style="list-style-type: none"> • Condensed postgraduate courses • Make a programme for all existing (licensed) pharmacists to attend 	Universities, MoEducation, Schools of Pharmacy
c) Train the teachers	<ul style="list-style-type: none"> • Workshops for opinion leaders in universities in modern pharmaceutical management, economics, pharmacotherapy, etc. 	Universities, MoEducation, Schools of Pharmacy
2. Intensify education and training of various players		
a) Managers	<ul style="list-style-type: none"> • Focus on new management techniques, accounting, communication, information, IT. • Modern pharmaceutical sector management 	MoH, DRA, Universities, Schools of Pharmacy
b) Health care professionals	<ul style="list-style-type: none"> • Workshops on STG, DTC • Provide regular information • Involve in DTC's 	MoH, DRA, Universities, Schools of Pharmacy, Hospitals
c) Pharmacists	<ul style="list-style-type: none"> • See 1.1 and 1.2 • Define role and function of staff in coming years • Include regular training in license • Provide regular information 	MoH, DRA, Universities, Schools of Pharmacy, associations
d) Patient education	<ul style="list-style-type: none"> • Through mass media, at pharmacy • Public health promotion programmes 	MoH, DRA, Universities, Schools of Pharmacy, pharmacies, press, RTV