EUR/ICP/QCPH 06 22 02(A)
ENGLISH ONLY
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REGIONAL OFFICE FOR EUROPE

ACCESS TO DRUGS IN THE NEWLY INDEPENDENT STATES: TOWARDS SHARING THE PATIENT'S BURDEN

Report on a WHO Seminar

London, United Kingdom
13–14 October 1997

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1998 EUR/HFA target 16

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MANAGING FOR QUALITY OF CARE

By the year 2010, Member States should ensure that the management of the health sector, from population-based health programmes to individual patient care at the clinical level, is oriented towards health outcomes

(Adopted by the WHO Regional Committee for Europe at its forty-eighth session, Copenhagen, September 1998)

ABSTRACT

The WHO Regional Office for Europe organized a Seminar for the newly independent states (NIS) to analyse the increased cost of pharmaceuticals to patients and the effect of this on access to health care and to discuss successes and failures in the various countries. The aims of the seminar were to develop strategies and programmes aimed at providing political awareness of this problem, to suggest new approaches and concepts and to make policy-makers as well as government officials aware of the effect of their decisions on the accessibility, and especially the affordability, of health care and drug treatment for the entire population.

The Seminar was attended by deputy ministers of health responsible for pharmaceuticals and heads of drug regulatory agencies. The Seminar provided an overview and basic information from the NIS on the role of national authorities, hospital managers, physicians and pharmacists in improving access to drugs in hospitals and primary health care. The Seminar provided participants with different mechanisms to increase access, such as improving methods of procurement, drug selection and prescribing, budgeting, drug reimbursement and regulatory measures. Examples of successful initiatives and approaches in different NIS were presented and discussed.

As a result of the Seminar, the participants became more aware of the serious consequences of the declining affordability of drugs on the access to health care and its effect on the health of the population. The complex and political character of the problem is an additional hurdle in finding sustainable solutions. Practical and feasible recommendations were given, and the implementation of these recommendations at country and intercountry level will be followed up with the assistance of the pharmaceuticals programme.

Keywords

PATIENT ADVOCACY
HEALTH SERVICES ACCESSIBILITY
DRUGS – supply and distribution
DRUG COSTS
ECONOMICS, PHARMACEUTICAL
ESSENTIAL DRUGS – economics
DRUG UTILIZATION
COMMONWEALTH OF INDEPENDENT STATES

Acknowledgements

This seminar was organised by the WHO Regional Office for Europe through financial contributions from the UK Know How Fund and USAID

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INTRODUCTION

The World Health Organization Regional Office for Europe held a seminar on the accessibility of drugs in the newly independent states (NIS), in London, United Kingdom, 13 and 14 October 1997.

Beginning in 1994, through the **Special Project for NIS**, the Programme for Pharmaceuticals at the World Health Organization Regional Office for Europe (WHO/EURO), in collaboration with the Action Programme on Essential Drugs (WHO Headquarters, Geneva), has provided technical assistance to reform the pharmaceutical sectors in the Newly Independent States (NIS). This assistance was provided through the development of comprehensive national drug policies in these countries, and by targeted interventions in specific problem areas. implemented within the framework of the Special Project for NIS in the area of pharmaceuticals. These drug policies are both a guide for action and the expression of the governments commitment towards the goal of assuring access of the whole population to essential, effective, safe and good quality drugs and promoting their rational use - all within the context of health care reform, democratisation and the transition towards a market economy.

At present, the above described collaboration is being actively developed within the framework of the above mentioned project with the governments of Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russian Federation, Uzbekistan, Ukraine, Tajikistan and Turkmenistan. Although the NIS countries have many common problems in the areas of access to drugs, drug regulation, quality assurance, supply, financing and rational use of drugs, priorities and methods used in reforming pharmaceutical sectors vary from country to country. As a consequence, each country practices different approaches, based on their national situation and infrastructure and concrete realities.

SCOPE AND OBJECTIVE

Today all the NIS have established their own new health care and drug sector management structures and are gaining expertise in defining directions for their national drug policy development. This focuses first of all on the development and implementation of appropriate legislation, but should also include development of strategies and solutions in improving access to drugs in hospital settings, as well as in primary health care.

The problems related to availability of drugs in the community pharmacies are increasingly being resolved. However, the issue of economic access to drugs and equity of access is not. Very frequently, economic interests are overpowering the social importance of pharmaceutical sector and, as a result, the interests of the vulnerable groups of the population are being forgotten. Many countries have insufficient financial resources for covering the population needs in pharmaceuticals. At the same time, the cost of drugs is increasing and patients can hardly afford them. The treatment guidelines used in hospitals are often outdated or not cost-effective. The privatisation of the pharmaceutical sector in the majority of the countries has already been accomplished, however, in many cases this process has had unfavourable influence on the access of population to essential, good quality drugs. Thus, politicians and managers are

becoming increasingly looking for the ways to share patient's burden. These and other problems are common to most NIS.

This seminar was organized within the framework of the above described collaboration between NIS and WHO. It was attended by the deputy ministers of health responsible for pharmaceutical sector and the heads of national drug regulatory authorities. The seminar has to be seen as continuation of an ongoing discussion and exchange of experiences initiated during the seminar on the "Current Status of Pharmaceutical Sector Reform in the NIS and the Baltic States", held in Hilleroed, Denmark, on 14-16 October 1996. At this stage, when much has been done for establishing regulatory agencies and development of an appropriate legislative framework, the main goal of the seminar is to define strategic directions for the continuation of pharmaceutical sector reform and the development of an action plan for the coming 5 years. Discussions focused on finding ways to improve access to drugs both in hospital and primary health care settings.

As an additional outcome of the seminar, major strategic directions were adopted for the development of the pharmaceutical sector in NIS in the coming five years. These strategies are outlined in separate paper '**The Patient in Focus**, *a strategy for pharmaceutical sector reform in Newly Independent States'*, published by WHO/EURO, Programme for Pharmaceuticals.

SUMMARY OF ISSUES DISCUSSED

The seminar presentations and discussions on improving access to drugs under the title 'Towards sharing the patient's burden' were focused around hospital drugs (inpatients) and drugs in primary health care (outpatients). In this report each chapter will point out the major problems, give the results of a small survey among policymakers, present case studies and give a summary of the discussion.

I. ACCESS TO DRUGS FOR HOSPITAL PATIENTS

1.1 Problems of primary concern

The main problem of the accessibility of drugs in hospitals is the serious lack of drugs - only for a few priority programmes public resources are sufficiently available. Due to this low availability many hospitalised patients are forced to buy their medicines on the private market which diminishes access, leads to higher costs and low compliance. In addition, new insurance systems for hospital treatment are many times not in place or not complete enough and this induces a tremendous shift in the burden of financing drugs from the state to patients.

Due to the low availability of drugs, the hospital pharmacy system is at risk of collapsing. A decrease in donations tends to worsen the situation.

The hospital drug supply situation is very serious in all NIS and increased efforts should be made to raise the attention of politicians, international organisations and possible donor countries to this problem, and also to assist countries to develop appropriate and sustainable strategies and systems that ensure adequate drug treatment in hospitals.

1.2 Survey results 'Overcoming obstacles for a better access to drugs in hospitals'

Counterparts in all 12 NIS were asked to indicate which instruments and measures they consider to be most useful in improving access to drugs in hospitals and primary care. The results of this limited survey are presented in Annex 2. A summary of these results is given below:

THE ROLE OF MANAGERS, DOCTORS AND PHARMACISTS	***THE ROLE OF NATIONAL AUTHORITIES***
It was felt that the most effective way to improve access (and especially the affordability) of drugs for hospitals is to use the available resources better by improving drug selection and appropriate prescribing. Key elements to improve this are: • Drug committees that define lists of preferred drugs and hospital formularies for procurement and prescribing and give these committees drug budget responsibility • Monitoring and feed back of prescribing practices • Better compliance with national standard treatment guidelines Less effective or even counterproductive was considered the option of having the ward or the chief physician decide about a drug list or procurement.	Also national authorities put high emphasis on better selection and prescribing. Highly valued tools are: • A National Essential Drug List • Frequent monitoring of drug committees in hospitals and prescribing practice by national authorities National authorities valued less the option of encouraging generic prescribing by doctors or to give the health insurance funds a role in better drug selection and prescribing.

Better ways of hospital drug procurement were considered to be less effective, although bulk purchasing and procurement for all hospitals in a region received positive marks. Putting the complete procurement responsibility to the wards or hospital departments is expected to have a negative effect.

In general the respondents did not consider budgeting an effective way of improving access to drugs in hospitals, except for the fixation of drug budgets at all levels to avoid these to be spent on other priorities.

Least effective was considered to decentralise drug budgets to regional or hospital level, while also making insurance funds responsible was not favoured.

1.3 Case studies

ZHITOMIR, UKRAINE – HOSPITAL SUPPLY

The health authorities of Zhitomir, Ukraine, consider the central and regional budget contributions to hospital care as minimal and insufficient to deliver appropriate care. The hospital management, in strong agreement and collaboration with the health authorities, took the following measures:

- Reorganisation of the hospital, decentralisation of budget responsibility and delegation of responsibilities to the wards. Wards were given the freedom to make their organization more cost effective and to attract outside resources to improve services.
- Essential packages of health care were defined to be delivered for free to all cases. These packages include drug treatment. Essential may be treatment of the first week, or the entire treatment of a more severe case. Only intensive treatment is given in the hospital, follow-up treatment or revalidation may be done in a separate building, making that part of the treat-

ment less costly, and in some cases open for patient co-payment. Poor patients receive their treatment for free

- Non-essential functions of the hospital were outsourced to the community. Where possible, local producers deliver food, beverages, furniture, etc. for free or at very low cost. Patients' relatives also bring in food. The donations and community contributions account for app. $3000 per month.
- Drug management is done according to the essential care packages (for free), additional drugs needed for inpatient treatment require co-payment or full patient payment depending on their disease and economic situation. Procurement is done by the hospital (together with other smaller hospitals in the region according to a list) directly from importers or from manufacturers in neighbouring countries. This new way of procurement resulted in savings of app. 25-40%.

The result is: free health care for essential treatment, co-payments or full patient payment for drugs for less essential care unless it is clear that people cannot afford that.

1.4 Discussion - Options to improve drug supply in hospitals

All players in the health care and pharmaceutical sector should contribute to improve access to good quality drugs. Coordinated efforts at different levels are needed to take on this important challenge. The following options for improvement were discussed:

A. MAKE BETTER USE OF AVAILABLE FUNDS

- Selection and use of drugs. Follow vigorously the basic principles of rational selection and prescribing of drugs, e.g. together with prescribers develop lists of essential drugs at each level of the health care sector, drug formularies, standard treatment guidelines and establish drug and therapeutic committees and make preference to essential drugs. Focus should be on groups with high cost drugs (20% of the drugs consume 80% of the budget).
- Procurement. Formulate an overall procurement policy: Issue guidelines on when and how to tender. Make the tendering process transparent. Design a pilot group procurement process for hospitals for selected essential drugs.In addition, countries should reconsider to lower or abolish the VAT on essential drugs, promote procurement of generic products, and buy drugs in hospital packages. The domestic manufacturing of drugs is another option, although some caution is needed (quality, cost price), as there are many low cost good quality drug producers in the world.
- Distribution. Firstly the efficient use of resources, i.e. rationalise all elements in the drug distribution process (efficient procurement, effective storage and distribution, reduce waste and loss). Secondly, illegal trade is a barrier to normalise the drug supply system. The role of the Drug Regulatory Agencies in supervising, monitoring and controlling all elements of the distribution chain should therefore be strengthened.

B. REORGANIZE THE ROLE AND FUNCTIONS OF HOSPITAL PHARMACIES

- Find ways to make hospital pharmacies more functional and patient- and doctor-oriented. Hospital pharmacies should also function as an advisor on pharmaceutical issues to the management of the hospital.
- Develop and use the expertise of the hospital pharmacist in the Drug and Therapeutic Committees and define the tasks and responsibilities of hospital pharmacies in providing information to prescribers.
- The hospital pharmacy should be the key player in drug procurement. A function now many times taken over by the chief physician.

C. STIMULATE COOPERATION BETWEEN HOSPITALS AND WITHIN REGIONS

- Group procurement, common drug lists and formularies, exchange of knowledge and experiences are essential. Economies of scale and a stronger negotiation power can reduce procurement cost substantially.
- Health authorities could perform co-ordinating and secretarial functions like support to inter-institutional co-operation.

D. MAKE THE PATIENT THE FOCAL POINT.

- Review of regulations by the Drug Regulatory Agency in view of potential improvements for the patient. Reconsider the need and usefulness of regulations which hinder access to drugs.
- Give special attention to vulnerable groups of patients or diseases with expensive or chronic drug treatment.
- Improve training at all levels of the drug supply and drug use system: the focus of the training curriculum for pharmacists should be shifted from product and supply oriented to more patient oriented (clinical pharmacy).

II. BUILDING ACCESS TO DRUGS IN PRIMARY HEALTH CARE

2.1 Problems of primary concern

The main problem in the outpatient drug supply is the lack of modern reimbursement systems that should have replaced previous systems of ‘free’ drugs in parallel with the privatisation of the drug supply system.

The largest part of drug consumption in a country is related to treatment of non-hospitalised patients. Poor patients - elderly patients - patients with chronic diseases - people living in rural areas - handicapped patients are victims. Problems occur from postponing treatment and/or with taking only partial treatment. Increasingly patients in the NIS are not be able to buy the drugs they need. Patients may even not be able to afford a doctor’s visit and self-medication using OTC drugs or even prescription-only drugs (without prior consulting a physician) is becoming common practice. This subsequently leads to serious problems, such as: increased resistance (antibiotics) and wrong or unnecessary treatment (plus side effects and adverse effects), which will inevitably lead to increased health care cost on the long term.

An additional problem is the current prescribing practice, which is many times not rational nor cost-effective and focused on brand names. Doctors and pharmacists have not always enough understanding of the concept of rational prescribing and use of drugs. This is partly due to weaknesses in disseminating objective key-information on drugs and weak communication lines between doctors, pharmacists and patients. Doctors, nurses and pharmacists are "easy victims" of aggressive promotion of drugs.

Illegal drugs and low quality drugs on the market in addition hinder an effective drug treatment and worsen health outcomes.

2.2 Survey results 'Primary health care can only work with reliable access to drugs'

Participants of the seminar also gave their opinion about the role of key players in the health care system to improve access to drugs for outpatients and about the effectiveness of certain interventions aimed at improving the affordability of drugs in primary health care settings.

THE ROLE OF POLYCLINICS, FAMILY DOCTORS AND PHARMACIST	***THE ROLE OF NATIONAL AUTHORITIES***
In general respondents felt that polyclinics, family doctors and pharmacists can do quite a lot to improve the accessibility of drugs for outpatients. Most favoured solutions are: • Standard treatment guidelines and strict monitoring of doctors' compliance • Analyse (cost-effectiveness of) prescribing of doctors • Generic prescribing and prescribing less or no drugs when that is possible. • Pharmacies should buy generic forms, inform doctors about cheaper alternatives and analyse prescribing based on received prescription forms.	National authorities can improve access to drugs for outpatients by: • Reimbursement systems: (1) compensate the complete treatment including drugs, (2) focus reimbursement on diseases and drugs instead of on social groups, and (3) include outpatient prescription drugs in health insurance schemes. • Improved drug selection: (1) reimbursement strictly on treatment guidelines and drug lists, (2) monitoring prescribing, incl. treatment outcomes. • Price regulation that makes the earnings of wholesalers and pharmacists not dependent on the price of a drugs. I.e. flat rate or fixed fee, or decreasing margin systems.

Referring patients to hospitals to receive free treatment was the least favoured option. Less preferred options for the respondents were also the ones which include patient co-payments. One could not see how co-payments might contribute to better access. Any payment is considered as a barrier for obtaining the necessary drugs.

2.3 Case studies

KUBA, AZERBAIJAN – HEALTH CENTRE REVOLVING FUND

With assistance from UNICEF, the Kuba region has established a revolving drug fund for health centres (outpatient care). The drugs are delivered by UNICEF and given for free to well-defined groups of patients (poor, or chronic or for certain diseases) or sold to the other patients with a small mark-up. The mark-up is used to finance the free drug delivery for the first group.

The system is based on the essential drug list and run by the health centres (special drug delivery window) separately from the (private) pharmacies. Prices from UNICEF are sometimes 5-6 times lower than average market prices and even with a small mark-up patients pay far less than

in the community pharmacies. Participation in this system is large among poor and chronic patients.

The chosen approach in Kuba applies for a narrow range of products, functions outside a normal market development and is dependent on one single vendor. The revolving fund had some problems in keeping the fund revolving, as there were too little people buying drugs for the full price compared to the large number of people entitled to receiving the drugs for free.

KUTAISI, GEORGIA – DRUG REIMBURSEMENT SYSTEM

With assistance from WHO/EURO, Programme for Pharmaceuticals, a pilot drug reimbursement system was set up in the city of Kutaisi. This voluntary system is designed to compensate high drug costs per patient on an annual basis. The benefits for members are:

- 20% reduction on the doctors fee in contracted polyclinics
- 10% discount on all R_x drugs in affiliated pharmacies
- 50% reimbursement on R_x drugs after a patient has exceeded 100 Lari on drug costs.
- Free inclusion of children under 16 years of age.

One can become a member by buying a booklet at the price of 2 lari per adult. Companies and public servants may obtain booklets collectively at a reduced fare.

The pilot has started in October 1997 and will initially run until the end of 1998. Results are not yet available. One of the major problems to overcome seems to be the lack of trust of the population in financing and insurance systems provided by state or government.

2.4 Discussion - Options to improve access to drugs for outpatients

Access to drugs for outpatients is a major problem in all NIS. Large out-of-pocket payments and co-payments are common practice. Only limited groups of patients are covered by so-called 'free drugs'. In general this problem can only be solved by improving or introducing better reimbursement systems, ensuring affordable price levels and by improving the selection and prescribing of drugs by physicians. The discussion about which options there are to improve access to drugs for outpatient care takes place around the following key points:

A. ACCESS HAS TO DO WITH THE WILL TO RESTRUCURE FINANCING MECHANISMS

- Old systems of state provided free drugs have disappeared (due to insufficient state budget). New ways of financing through premium based health insurance or drug reimbursement systems may ensure that scarce resources are spent in a better and more transparent way and will allow a diversification of funding (central and local government budget, employers premiums, employee premiums, patient co-payments).
- Redesigned systems of free drugs and new reimbursement systems should be in line with national priorities on health and health care. Systems should be able to keep their promises and be transparent for users and health professionals. Monitoring (accessibility, prices) and control mechanisms (cost containment, rational use) play an essential role that is very often forgotten in most NIS.

- Focus on vulnerable groups of patients. It should be taken into account that these groups accumulate high expenditure on health care, while already deprived of sufficient income.
- Decentralisation of the responsibility to organize the pharmaceutical sector and health care (incl. drug treament) to local level authorities may improve the situation, provided budgets are equally transferred. The same holds for special state and municipality programmes for selected diseases/patient groups.

B. RATIONAL PRESCRIBING AND USE OF DRUGS MAY HAVE A HUGE EFFECT, BUT IS DIFFICULT TO ACHIEVE.

- Strengthening or developing a rational drug use programme is a very decisive and important factor. Not only to avoid waste of scarce resources, but also to improve health outcomes of treatment.
- Independent drug information will remain a government responsibility. Part of that being the control of promotion and advertising of drugs.

C. THE QUALITY OF CARE AND OF PROFESSIONAL SERVICES NEEDS TO BE IMPROVED

- to avoid substandard products, inadequate advice, inappropriate prescribing, dispensing and use and to enhance patient compliance.
- By regulation: developing standards for professional practice, licensing or certification schemes of health professionals and institutions, and by stricter control and inspection.
- By knowledge transfer: education, training and retraining programmes.

CONCLUSIONS

The conclusions of the seminar are presented separately for hospitals and outpatient care, as these areas contain different options for intervention, while the role of health authorities and health professionals also differs. General conclusions about priorities, concepts and approaches that may affect both levels of health care are presented in a separate final paragraph (III).

I. CONCLUSIONS REGARDING ACCESS TO DRUGS FOR HOSPITAL PATIENTS

MOST FAVOURED SOLUTIONS BY COUNTRIES

Countries favour a number of different measures to improve access to drugs in hospitals. Equal importance is given to measures that improve the situation within the hospitals (treatment guidelines, committees, lists, procurement) and to conditions imposed upon the hospitals (procurement, budget, rules, taxation). This implies:

- Inside the hospitals, procedures, responsibilities and focus may be improved. Instruments are: lists, committees and guidelines. Commitment of the hospital management and health authorities is a necessary condition. A bigger role of the hospital pharmacy as the manager of drug supply, as the centre of drug information and as adviser on drugs and drug treatment to physicians is required.
- The relation of the hospital with the outside world can be improved in two ways. Firstly by improving the conditions for hospitals through: stricter budgeting, keeping budgets on targets,

tax reliefs, regulation (for example to allow direct procurement). Secondly rationalisation of drug purchases by group procurement, generics, procurement lists, hospital or bulk packages and tendering can greatly improve the efficiency and contain costs.

CONCLUSIONS AND RECOMMENDATIONS TO IMPROVE ACCESS TO DRUGS IN HOSPITALS

1) Health authorities in NIS have a strong believe in the positive effects of rationalisation of drug selection and prescribing on the accessibility of drugs for hospitals. Support in this area is very encouraging and should be promoted.

2) At the same time one observes some reservation about the effectiveness of measures that can be taken by the health authorities themselves. In general these measures were valued as less effective, although it became clear that large improvements may be achieved. This reluctance may have to do with difficulties encountered in reorganizing hospitals: a very sensitive issue in many countries. Continued efforts seem necessary to convince, support and assist countries in redesigning their hospital care. But one should not wait with interventions regarding common drug formularies and drug procurement (pooling and direct procurement) as these can be effective regardless of the hospital structure.

3) The discussions and case studies show that creative measures at regional or municipal level can be very successful. This calls for:

   a) Sharing positive results and achievements with regional and local health authorities and hospital managers.

   b) Delegation of certain tasks to lower level authorities. Give them room within clear borders to create their own solutions. To achieve that a change in budgeting and control of hospitals is needed: output steered and not input (capacity) oriented.

4) The dilution of hospital budgets over too many facilities with too low occupancy has severe consequences for drug supply (and probably for other cost components and management as well). The following measures could bring improvements (cost saving or higher benefits):

   a) Reorganize hospitals in viable units with a reasonable occupancy rate or group hospitals in clusters for pooling of procurement, common formularies or drug lists. Also other purchases (equipment, medical supplies, etc.), central facilities and services or costs may be shared.

   b) Give strict minimum budgets for drug procurement to prevent that the money is used for other purposes.

5) It is clear that many countries cannot afford to cover all hospital drugs for patients. Therefore countries may prioritise diseases and population groups according to the following categories:

   a) Full coverage of the drug treatment (at least for a certain period of time) for life threatening diseases, emergencies and for vital or chronic treatment. Certain priority diseases containing high cost drug treatment may be added.

   b) Partial coverage of drug costs, complemented by patient payments for less essential drugs or treatments or for short term treatments.

   c) Drugs fully paid by patients (non-essential drugs or low cost drugs).

6) The role of the hospital pharmacy and pharmacist in improving drug management, drug selection (formulary, lists) and procurement is of vital importance. Hospital managers should be made aware of the substantial improvements that may be achieved in this area. Training, collaboration, knowledge transfer, hospital pharmacy practice guidelines, information and technical assistance are needed.

   Stronger pressure is needed to focus hospital managers on better selection, generics, hospital packages, and the role of the pharmacists as an adviser to physicians.

7) An important issue, besides ineffective procurement and organization, is the corruption related to hospital drug procurement. Inproper mixing of public and private interests, leakage of drugs to private kiosks, nurses selling drugs on wards, sales of drugs that should be given for free, etc. are barriers to a proper access to drugs. These illegal and inproper practices need to be abolished by proper regulation, enforcement, management control and transparency (patients should know their benefits and rights).

8) The serious situation with regard to the inaccessibility of drugs for hospital patients should be brought to the attention of politicians, in order to receive a higher priority for hospital and drug budgets. International agencies should support ministries of health in this respect. Decision makers and influencials should also be convinced about the severe consequences of denying patients access to drugs (and by that many times to health care). The cost of which may be unmanageable in the near future.

II. CONCLUSIONS REGARDING ACCESS TO DRUGS IN PRIMARY HEALTH CARE

MOST FAVORED SOLUTIONS BY COUNTRIES

Again countries want a mix of measures, which are more diverse in the case of outpatient drugs.

- Setting standards and guidelines. The use of essential drug lists and treatment standards is one method of focusing outpatient care on appropriate drug treatment. The introduction of (regional) drug committees was not taken into consideration.
- Generics. Generic prescribing from approved lists was mentioned by several countries as an appropriate instrument to reduce the burden of the outpatients.
- Pricing and financing are both mentioned by many countries. A national drug pricing policy should favour the sales of low priced drugs (particularly mentioned were regressive margin systems). The creation of health insurance funds should include drug treatment for outpatients. These funds may then be given full responsibility to deliver reimbursement according to certain priorities set by the state, s.a. priority diseases and population groups.

CONCLUSIONS AND RECOMMENDATIONS TO IMPROVE ACCESS TO DRUGS FOR OUTPATIENTS

9) The most problematic interventions are the ones where the new market freedom (often misinterpreted) is contradicting the need to introduce guidelines and regulation. In addition, in the current economic environment it is difficult to create financing mechanisms that allow diversification of funds.

10) A strong reliance on centralised or top-down approaches by health authorities can be observed, especially when concerning drug selection and prescribing. This is contrary to the

world experience that bottom-up and decentralised, local initiatives provide the best results. Therefore greater emphasis is needed on these local committees and initiatives, that together with improvements in information exchange are indispensable elements to achieve changes in drug prescribing and use.

11) The wish to promote generic prescribing and use is encouraging. In daily practice however a lot of work needs to be done to achieve that goal, as there is a general focus on brand names and branded products (a generic name is many times considered to be just another brand name). The concept of generics should be made clear to all levels of health care, doctors, pharmacists and patients and replace the common opinion that these drugs represent lower quality.

12) Again, as is the case with hospital drugs, there is a strong believe that rational drug therapy through treatment guidelines will be the most effective approach to improve access. Evidence shows that prescribing habits of doctors change only gradually on the long run. Recognising this implies that short term changes can only be achieved through other measures - basically the ones to be taken by regulatory authorities, politicians and ministries of economy and finance. Examples are:

    a) Price regulation (maximum or regressive margins, flat rates) favouring low priced drugs.

    b) Drug reimbursement systems using drug lists and reference prices for priority diseases and priority population groups (elderly, children, poor, chronic patients).

    c) Speeding up of health insurance programmes that enable coverage of outpatient care (and fairly should include certain drug costs).

    d) Special state programmes for costly treatments, including drugs.

13) The re-introduction of prescription forms is an absolute necessity. The current practice of uncontrolled dispensing of R_x drugs is endangering patients, leads to increased resistance levels and prevents health authorities from having a clear picture about the current development. In addition patients avoid doctors' visits also for serious illnesses, encourages irrational drug treatment, or diminishes its curative effect. Efforts should be intensified to curb this undesirable development.

III. GENERAL OBSERVATIONS AND CONCLUSIONS

14) As a result of the privatisation of the drug supply system and diminishing health care budgets, previously subsidised drugs are no longer available for free. New mechanisms to replace this full coverage are slowly being introduced, but the pace of this development is unsatisfactory. Therefore, patients' access to drug treatment is largely depending on disposable income, which, given the slow economic growth and increasing poverty, is cutting of growing groups of people from (drug) treatment and (indirectly) from health care.

15) The low affordability of drugs leads to postponed treatment and an increased number of severe or emergency cases. This does not only worsen the health of large groups of people, but also directs patients away from less costly forms of health care (primary health care), and increases the total health care cost. Initiatives to create sustainable primary health care systems are in vain if access to drugs is not guaranteed.

16) There is a growing understanding of the access problem amongst health authorities, including ministries of health. However, budget allocations are made by other ministries where the voice of health authorities is hardly heard. Broadening the awareness of the situation to other government levels and by international agencies is needed to achieve public health objectives and to prevent a further worsening of the situation for patients. It is clear that the current health care expenditure of less than 4% of GDP is insufficient to provide a basic package of health care and a minimum of access.

The discussions and examples have shown that the lack of access to drugs is a complex problem, that can be solved only when all involved authorities are determined and committed to do so. There is a need to convince government officials (at all levels), politicians, economists, the health profession, health care managers and many other stakeholders of the severity of the problem, as many of them have a stake in minimising it.

The access problem is of a complex character and its effects and the changes in health status and patient behaviour are difficult to measure. WHO/EURO will try to initiate a multi-country study on the extend of the access problem, its consequences for the health status of certain population groups and the potential long term effects.

WHO/EURO
Programme for Pharmaceuticals
Special Project for NIS
Copenhagen, June 1998

ANNEXES

Annex 1

Seminar programme

Sunday, 12 October

19.00 **Welcome dinner and official opening**

Monday, 13 October

09.00 - 10.30 **Summary of key issues from the seminar on "Current status of pharmaceutical sector reform in NIS and three Baltic states",** Denmark, October 1996
Mr Kees de Joncheere

Overview of major developments and problem areas in pharmaceutical sector reform in NIS.
Objectives of the meeting.
Dr Nata Menabde

Plenary discussion: "View from NIS"
Chairman: Mr Kees de Joncheere

11.00 - 12.30 **Hospitals - overcoming obstacles for better access to drugs**
What can managers, doctors and pharmacists do at hospital level?
- *Proper budgeting and planning?*
- *Better ways of procurement?*
- *Drug committees*
- *Selection and formularies*
- *Drug management*

Introduction to the problem: Paul Spivey
Case study: Zhitomir, Ukraine
Chairman: Jan Svihovec

13.30 - 15.00 **Hospitals- bridging policies and activities to improve access to drugs**
What can national authorities do to improve access to good drugs in hospitals?
- *Which national policies encourage hospitals?*
- *Which policies are effective?*
- *What in relation to health care policies?*
- *The role of domestic and hospital drug production?*

Introduction to the problem: M.Magdei (Moldova)
Case study: Russian Federation (E.Nekrasov)
Chairman: Kees de Joncheere

15.30 - 17.00 ***"Access to drugs for hospital patients - options and solutions"*** Concluding discussion
Chairman: Nata Menabde

17.00-17.30 **Guest speaker**: John Ferguson, Secretary and Registrar, Royal Pharmaceutical Society of Great Britain

Tuesday, 14 October

09.00 - 10.30 **There is no primary health care without reliable access to drugs**

What can polyclinics and pharmacies do?

- *Interrelationship between government, doctors, pharmacists and patients*
- *Better ways of procurement?*
- *How can all stake-holders match public health goals?*

Introduction to the problem: Jan Svihovec
Case study: Azerbaijan
Chairman: Paul Spivey

11.00 - 12.30 **Building access to drugs in primary health care - policies**

What can national authorities contribute to improve access to adequate drugs for outpatients?

- *Which policies are effective?*
- *What in relation to health care policies?*
- *Drug reimbursement systems that work*
- *What about vulnerable groups of patients?*
- *Selection and procurement*
- *How to influence or stimulate the private sector?*

Introduction to the problem: Emil Gabrielian (Armenia)
Case study : Kutaisi (R.Makharadze)
Chairman: Kurt Fonnesbaek Rasmussen

13.30 - 14.30 **Access to drug for outpatients- options and solutions**

Concluding discussions:
Chairman: Frans Stobbelaar, WHO/EURO

15.00 - 16.30 **Meeting the 21st century - Improved access to drugs in NIS**

Defining priorities and ways to go .
Open discussion on the future strategy
Chairpersons: Jonathan Quick, Paul.Spivey and Nata Menabde

Annex 2

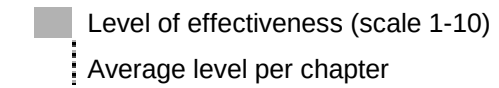
What are the most effective ways to improve access to drugs in Newly Independent States?

RESULTS OF A SURVEY AMONGST POLICY MAKERS AND KEY OFFICIALS (PARTICIPANTS OF THE SEMINAR)

OVERCOMING OBSTACLES FOR A BETTER ACCESS TO DRUGS IN HOSPITALS
ПРЕОДОЛЕНИЕ ПРЕПЯТСТВИЙ ДЛЯ УЛУЧШЕНИЯ ДОСТУПА К ЛС В БОЛЬНИЦАХ

What can managers, doctors and pharmacists do at hospital level?

Что могут менеджеры, врачи и фармацевты сделать на уровне больницы?

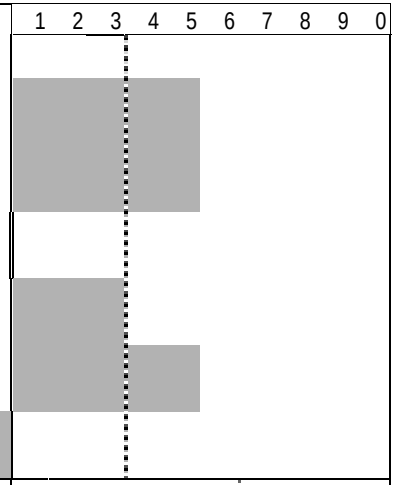


1. *Better ways of procurement*

a) Buy all drugs in bulk through centralised state procurement and distribute to hospitals?
b) Decentralise procurement to regional level from regional budgets for all hospitals in that region?
c) Give drug procurement completely in the hands of hospitals without further instructions or conditions?
d) Give drug procurement completely in the hands of hospitals with instructions and strict budget conditions?
e) Make drug and therapeutic committees of hospitals completely responsible for the drug budget and
f) Make the wards of hospitals completely responsible for the drug budget and procurement?

1. *Наилучшие способы закупок*

a) Покупать все ЛС в виде “англо”через государственные централизованные органы и
b) Децентрализованные закупки на региональном уровне из регионального бюджета для всех больниц региона?
c) Передать все вопросы закупок в ведение больниц без каких бы то ни было дальнейших инструкций или
d) Передать все вопросы снабжения в ведение больниц с четким инструктажем в жестких рамках бюджета?
e) Сделать больничные лекарственные комитеты полностью ответственными за закуп ЛС и бюджет?
f) Сделать больничные палаты полностью ответственными за их закуп ЛС и бюджет?

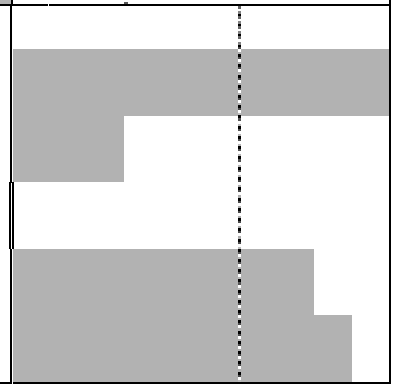


2. *Improve drug selection and prescribing*

a) Drug committees (cooperation of chief physician, doctors, pharmacist) should define the list or formulary for
b) Per ward the doctors should define the list or formulary for procurement and prescribing
c) The chief physician should define the list or formulary for procurement and prescribing
d) Drug prescribing by doctors should be monitored intensively
e) Drug lists should be followed strict according to national standard treatment guidelines and a national list

2. *Улучшение отбора и назначения ЛС*

a) Комиссии по ЛС (в составе главврача, врачей, фармацевтов) должны определять перечень ЛС для
b) Врачи каждой палаты должны определять перечень ЛС для закупок и лечения
c) Главврач больницы должны определять перечень ЛС для закупок и лечения
d) Процесс назначения ЛС врачами должен наблюдаться и контролироваться более интенсивно
e) Перечни ЛС должны жестко соблюдаться согласно национальным руководствам по лечению и нац.



What can national authorities do to improve access to drugs in hospitals?

Что могут сделать национальные регулирующие органы для улучшения доступности ЛС в больницах?

1. *Budgeting*

a) Will centralised budgets at Ministry of Health be more effective?

b) Is the decentralisation of budgets to regional level leading to better results?

c) Is decentralisation of budgets to hospitals better?

d) Make the health insurance funds or companies responsible?

e) Fix the amount of money to be spend on drugs for each budget level to avoid that it is given to other priorities?

1. *Бюджет*

a) Будет ли бюджет Министерства Здравоохранения более эффективным когда он централизован?

b) Ведет ли децентрализация бюджета на региональном уровне к лучшим результатам?

c) Ведет ли децентрализация бюджета на уровень больниц к лучшим результатам?

d) Сделать страховые фонды и компании ответственными за бюджет?

e) Зафиксировать денежный суммы на ЛС на каждом уровне бюджета во избежании их траты на другие

2. *Improve drug selection and prescribing*

a) Is the establishment of a national drug list effective?

b) Is monitoring of prescribing practises effective?

c) Should hospital drug committees regularly be evaluated by national authorities on their selection measures and

d) Do patient co-payments help in rational prescribing and consumption?

e) Are national publicity and promotion campaigns effective?

f) Would it help to stimulate doctors to prescribe generics?

g) Should health insurance play a key role in better selection and prescribing?

2. *Улучшение отбора и назначения ЛС*

a) Эффективна ли мера создания национальныго перечня ЛС?

b) Является ли мониторинг практики назначения ЛС эффективным?

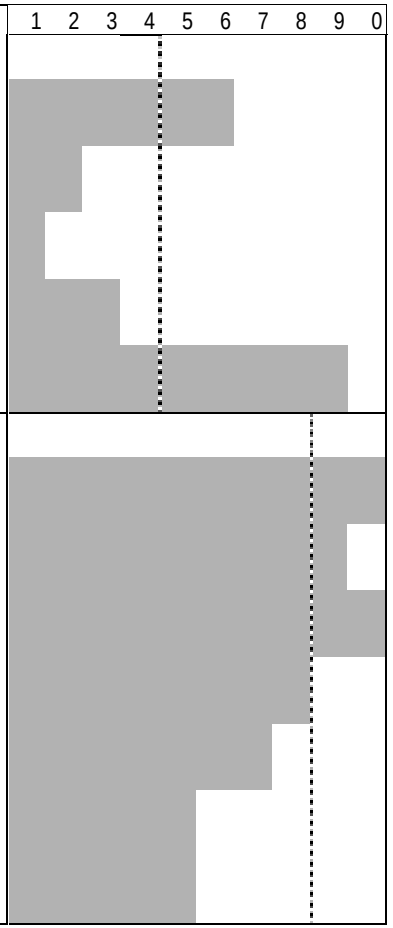
c) Должна ли работа больничных лекарственных комитетов регулярно оцениваться на предмет

d) Содействует ли механизм доплаты за лекарства больными более рациональному назначению и

e) Эффективны ли национальные комании по рациональному использованию ЛС?

f) Эффективны ли меры по стимулированию врачей к назначению дженериков?

g) Должно ли мед.страхование играть ключевую роль в улучшении отбора и назначения ЛС?

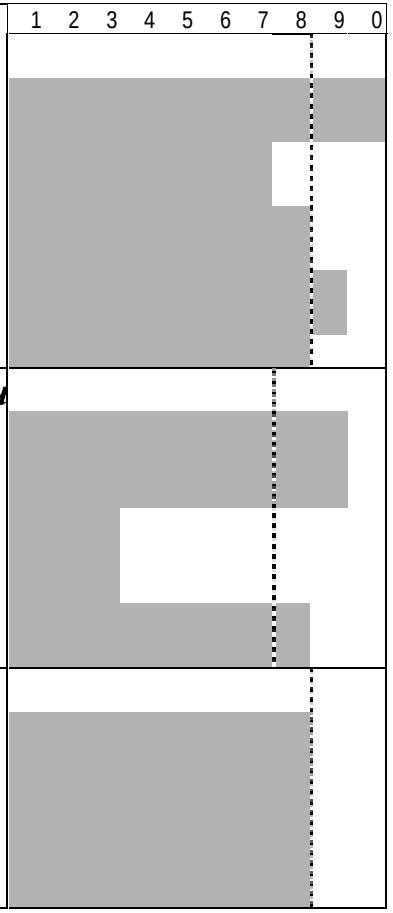


PRIMARY HEALTH CARE CAN ONLY WORK WITH RELIABLE ACCESS TO DRUGS
ПЕРВИЧНОЕ ЗДРАВООХРАНЕНИЕ ФУНКЦИОНИРУЮТ ТОЛЬКО ПРИ НАДЕЖНОМ ДОСТУПЕ К ЛС

What can polyclinics, family doctors and pharmacists do?

Что могут сделать поликлиники, участковые врачи и фармацевты?

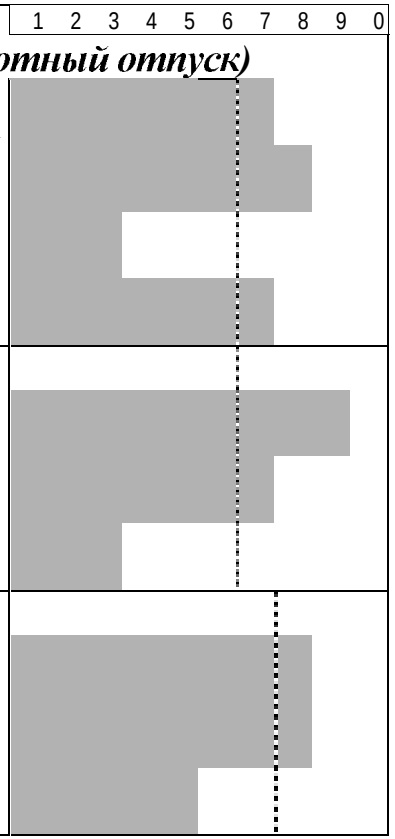
1. Polyclinics	***1. Поликлиники***
a) Develop, use and monitor standard treatment guidelines?	a) Разработка, использование и наблюдение за следование стандартам лечения?
b) Monitor prescribing of doctors in the polyclinic?	b) Наблюдение за назначениями врачей в поликлиниках?
c) Make the use of prescription forms obligatory?	c) Сделать использование рецептурных бланков обязательным?
d) Make cost effectiveness analysis of prescribing of doctors?	d) Проводить анализ назначений врачей с точки зрения эффективности затрат?
e) Reward doctors with good prescribing practice?	e) Поощрять врачей с хорошей практикой назначения?
2. General practitioners or polyclinic doctors	***2. Врачи широкого профиля или врачи поли***
a) Prescribe generic drugs; only in exceptional cases more expensive brands	a) Назначать дженерики; в исключительных случаях более дорогие препараты?
b) Do not prescribe drugs when that can be avoided	b) Не назначать ЛС когда этого можно избежать?
c) Refer patients with high drug costs to hospitals to receive free drugs	c) Направлять пациентов с высокой стоимостью лекарственного лечения в больницы для получения ЛС бесплатно?
d) Prescribe only from an approved list (national or regional)	d) Назначать ЛС только из утвержденного перечня (национального или регионального)
3. Pharmacies	***3. Аптеки***
a) Buy always generic forms in addition to branded drugs	a) Покупать всегда ЛС дженерики в дополнение к фирменным препаратам?
b) Inform doctors about cheaper forms and alternatives	b) Информировать врачей а наличии более дешевых лекарственных форм или альтернативах?
c) Analyse and report over-prescribing based on received prescription forms	c) Отслеживать, анализировать и информировать о чрезмерном назначении ЛС основываясь на



What can national authorities do to improve access to drugs for outpatients?

Что могут сделать национальные регулирующие органы для улучшения доступа к ЛС амбулаторных больных?

1. Drug reimbursement	***1. Возмещение затрат (бесплатный и льготный отпуск)***
a) Focus drug reimbursement on a combination of drug treatment and diseases and not on population groups?	a) Сконцентрировать систему возмещения затрат на лекарственной терапии и болезнях, а не на социальных
b) Make a reimbursement system that provides compensation for the complete treatment and not drugs	b) Создать систему возмещения затрат для компенсации стоимости всего курса лечения, а не только ЛС?
c) Give only compensation after a patient has reached a certain amount of co-payment in one year.	c) Предоставлять компенсацию только после того как пациент достиг определенной суммы затрат на ЛС в
d) Make the health insurance funds or companies responsible for outpatient drug reimbursement	d) Сделать страховые фонды и компании ответственными за компенсацию затрат для амбулаторного больного?
2. Improve drug selection and prescribing	***2. Улучшение отбора и назначения ЛС***
a) Restrict drug reimbursement to an approved (generic) drug list only, and exceptions only after separate approval	a) Ограничить возмещение затрат на ЛС утвержденные списком (дженерики) и делать исключения после
b) Is monitoring of prescribing practises effective?	b) Является ли мониторинг практики назначения ЛС эффективным?
c) Do patient co-payments help in rational prescribing and consumption?	c) Содействует ли мехнизм доплаты больными более рациональному назначению и потреблению?
3. Regulation	***3. Регулирование***
a) Make a fixed fee for pharmacies per prescription not depending on the price of a drug (no interest to sell	a) Ввести фиксированные гонорары для аптек за каждый отпущенный рецепт независимо от цены ЛС (не будет
b) Make a decreasing margin scale (low margin for expensive drugs, high margin for cheap drugs)	b) Ввести снижающуюся гибкую наценку (низкая наценка для дорогих ЛС, высокая для дешевых)?
c) Limit the number of drugs to 1 per prescription	c) Ограничить количество ЛС на один рецептурный бланк ?



The most successful measures to improve access to drugs in hospitals in NIS

Measure	*Effect*
• Planning of items for drug procurement in the hospital budget	⇒ *Better procurement*
• Control of drug procurement in hospitals	⇒ *To purchase essential and more effective drugs*
• National Programme for Rational Drug Use	⇒ *All essential drugs always exist on hospital stock*
• Fixed budget lines for drugs in different expenditure categories	⇒ *Better drug selection and prescribing*
• Drug prescribing monitoring on different levels of healthcare	⇒ *Avoid to spend money for other purposes*
• Formulary based on the list of essential and life-saving drugs	⇒ *Prescribing practice results were improving*
• Drug purchasing via tender	⇒ *More rational drug use*
• Creation of a commission for rational use and distribution of drugs	⇒ *More rational drug use*
• Creation of National list of essential drugs.	⇒ *More rational finance using*
• Approval and implementation of the law on health care and on drugs	⇒ *hospital patients receive drugs free of charge*
• Creation of in-hospital pharmacies, under direct hospital supervision	⇒ *hospitals patients receive drugs free of charge*
• Different joint ventures with foreign pharmaceutical companies	⇒ *Drug manufacturing in the country, availability*

The most successful measures to improve access to drugs in outpatient care in NIS

Measure	*Effect*
• Approval and introduction of List of Essential drugs	⇒ *Priority for drug procurement in pharmacies*
• Privatization of pharmacy network	⇒ *Better access to drugs and drug prices decreased*
• Limiting the margins on drugs	⇒ *Limits price increase*
• Development, use and monitoring of treatments standards	⇒ *Better drug selection and prescribing*
• Obligatory use of Rx forms	⇒ *Better drug prescribing*
• Informing doctors about cheaper generic drugs	⇒ *Better drug prescribing*
• List of drugs for free or reimbursement via Health Insurance System	⇒ *Drugs in guaranteed volume*
• Using generic drugs as much as possible in drug supply	⇒ *Expenditure decreased*
• Voluntary medical insurance for citizens	⇒ *Now patients pay only 10% of normal drug price*
• Definition of patient categories which receive free drugs	⇒ *Better access for poor and chronic patients*
• Ministerial focus on ensuring adequate drug budgets	⇒ *Better availability*
• Opening pharmacies branch offices in policlinics and in the hospitals	⇒ *Improved availability*

Annex 3

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Annex 4

List of background documents

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