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Issue Paper

Improving Access to Essential Pharmaceuticals

prepared by
IHCAR

SWEDISH INTERNATIONAL DEVELOPMENT
COOPERATION AGENCY

Department for Democracy
and Social Development
Health Division

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Introduction

The Health Division at Sida has commissioned IHCAR to prepare a background paper on pharmaceuticals in relation to development assistance. It has been prepared by Rolf Wahlström, in consultation with expert staff members at IHCAR.

Pharmaceutical technologies make a vital contribution to health. Access to essential drugs is fundamental to the good performance of health care delivery systems, and is part of the human right for health. The basis for a comprehensive and sustainable development of the use of pharmaceuticals is the existence of a National Drug Policy (NDP).

The use of pharmaceuticals involves much more than pharmacological issues. The provision of safe, effective and affordable medicinal drugs of good quality and in the right quantity to the whole population, but particularly the poor, and used rationally and appropriately, should be a priority in health and drug policies. Ongoing health care reforms, including privatisation of drug provision, underline the necessity to deal both with the private and public sector in the same policy. The presence of a large private sector, with, e.g., mushrooming of private pharmacies and bypassing of public health facilities, calls for a strong and extensive legislation and regulation with effective implementation strategies.

Sida has been actively involved on a global level in development within the drug sector since more than 15 years, and thus has a comparative advantage compared to countries where this interest is more recent. This support has previously mostly been channelled through the Action Programme on Essential Drugs at WHO, now since a few years the unit of Essential Drugs and other Medicines (EDM), but also through collaboration with other organisations like the World Bank, Health Action International (HAI) and the International Network for Rational Use of Drugs (INRUD). The experiences from bilateral support for development of essential drugs programmes in the 80s (e.g., Zambia) and for developing comprehensive NDPs in the 90s (e.g., Vietnam and Laos) have also built up a high competence in this field.

Health Development and Pharmaceuticals

Public health and Essential Drugs

Drugs should be seen in the context of the national health system and adapted to the general socio-economic situation and development of the country. A health system only functions well with sustained availability of essential drugs, as patients tend to bypass facilities that can not provide drugs. Essential drugs must also be affordable by low-income members of the population, and there must be mechanisms ensuring that even the poorest people have uninterrupted access to essential drugs (price reductions, prepayment mechanisms, waivers, beneficiary schemes, etc.).

The development and implementation of a National Drug Policy (NDP), is a complex process in any country, requiring a long time for development and implementation, a strong political will and a solid scientific basis in order to overcome resistance to change. Key stakeholders include Government departments, professional organisations and opinion-leading professionals, the pharmaceutical industry, multilateral and bilateral organisations (GOs and NGOs), consumer and patient organisations, and mass media representatives.

It is essential that national policies are based on scientific evidence and that their implementation is carefully monitored with performance indicators for both the public and private sector. The objectives of operational research/health systems research are to assist the decision-makers in identifying problems and evaluating effectiveness of performance in the health and pharmacy services. It should also give evidence for the need of future activities. Mechanisms for feedback of results should be further developed to inform policymakers and health personnel. In Laos, e.g., six health systems research projects, including experiments in both the public and private health sector, have generated data for informed decision-making.

In countries with an extensive burden of disease and a poor health services infrastructure there is both need for short-term interventions for supplying identified target drugs, and simultaneously strategic support to alleviate the situation regarding both economic and human resources. Examples of areas where access to essential drugs is critical are diseases like malaria, tuberculosis, acute lower respiratory tract infections in children and sexually transmitted diseases, including HIV/AIDS. These diseases constitute major threats to public health particularly among the poor and among children.

National Drug Policy development

It has been continuously observed that all components must be simultaneously developed in order to achieve the goals of an NDP: To ensure accessibility and rational use of essential and good quality drugs for the majority of the population. Important aspects that are often weak are the functioning of regulation of the market activities, and the capacity for inspection for quality assurance of the chains in the supply sector (procurement, distribution, purchasing, customer information). The regulation of the private market has been identified as a key is-

sue to avoid widespread misuse of drugs due to inadequate control of prescribing and dispensing practices, and lacking or insufficient information and communication to the customer.

Essential elements in an NDP are:

- Legislation and regulation
- Quality control
- Inspection systems (pharmacies, wholesalers, manufacturers)
- Procurement, supply and distribution
- Registration and licensing systems
- Prescribing regulations
- Financing systems
- Rational use of drugs
- Information, communication and education to professionals and the public
- Advertising and promotion
- Role of traditional and complementary medicine
- Monitoring and evaluation (supervision)
- Health Systems Research component (operational).

Rational use of drugs

To be used rationally, drugs must be made available in a context where all involved groups and individuals are aware of the benefits and hazards of modern drugs. The implications is that it is not defendable to promote improvements regarding fragmented aspects of drug use. A comprehensive approach should include support for the whole spectrum of activities to ensure rational use, like development and implementation of Standard Treatment Guidelines, establishment and optimal functioning of Drug and Therapeutic Committees (DTCs), optimising prescribing practices among prescribers at different levels, improving dispensing practices at pharmacies and drug outlets, using mass media for information and communication, etc. Professional training programmes after graduation, e.g., for doctors or pharmacists, are often lacking or inadequate, and need to be strengthened as part of human resources development. This should go hand in hand with consumer information and education. One example is a project funded by Sida/SAREC and EC, on shared care of under-5 children with malaria in Africa.

The concept of essential drugs has been predominant in the field of pharmaceuticals for 25 years. It is still valid in its basic components as it aims at addressing the major needs of the most vulnerable parts of the population. However, it also needs continuous revisions and modifications depending on the development of the disease pattern and economic growth. The essential drugs list (EDL) is partially based on cost awareness. Most new drugs have prices that exclude them from such a list in most developing countries. Depending on the economical situation in the countries, the number of new, innovative drugs that can be included in the list varies substantially.

In most developing countries the majority of decisions to treat with drugs are taken without consultation with a medical doctor. The crucial role of private pharmacies and other drug outlets needs thus to be taken into consideration, as well as the need to enhance public education regarding drug use. The Good Pharmacy Practice document provides an agenda for improving private pharmacy practice. An EC funded randomised controlled trial in Vietnam and Thailand has proven multi-component educational interventions to be effective, including regulatory enforcement, education, and peer influence.

Essential Drugs and Traditional Medicines

It is estimated that over one-third of the world's population lacks regular access to affordable essential drugs. For these people, modern medicine is not likely to be a realistic treatment option in the coming 5-10 years. In contrast, traditional medicine is widely available and affordable, even in remote areas, and generally accessible to most people. In the last decade there has been a global upsurge in the use of traditional medicine and complementary and alternative medicine in both developed and developing countries. As a consequence, traditional medicine today plays an increasingly important role in health care and health sector reform globally. Despite their often promising potential, however, untested traditional medicine and complementary and alternative therapies sometimes have negative health consequences. This problem is compounded by failure to support research in this area, resulting in lack of data and methodology at a time when both are urgently needed. There is a need to support research and policy development in this field towards better health systems performance.

Essential Drugs and and Sustainable Environment

The use of pharmaceuticals also has an environmental aspect as, e.g., widespread self-medication with antibiotics usually implies too few tablets during a too short period, thus risking development of antibiotic resistance. Not infrequently antibiotics are also used without proper indication, which also contributes to creation of resistance problems. The global problems with increasing resistance to life-saving anti-malarial and anti-tuberculosis drugs have created a worrying situation. Hence efforts are needed to increase the current understanding of anti-microbial use and resistance epidemiology in low-income countries and to contribute to evidence-based policy making both nationally and internationally. For example, a recent major EC financed project in South America will develop an intervention strategy regarding anti-microbial use and bacterial resistance involving local health services, and addressing the public in general.

Pharmaceuticals and Financing of Health Services

According to WHO access to essential drugs depends on: 1) rational selection and use of medicines; 2) sustainable adequate financing; 3) affordable prices; and 4) reliable health and supply systems. Since most poor people in low-income countries currently pay for drugs out of pocket, access to medicines is particularly sensitive to cost.

In most developing countries, the cost for drugs take up a great part of Government expenditure in the health sector. Still it is far from enough to fulfil the needs, and in most countries the proportion paid by the consumers is very high, up to 70–80 per cent, while it for example in Sweden is only about 25 per cent. Establishment of Drug Revolving Funds has been one way of ensuring availability of drugs at the respective public facilities (hospitals, health centres, etc.). However, the costs for these drugs may still be too high for large proportions of the poor population, calling for subsidies or other solutions.

Mechanisms for sustainable financing of the health system in general, and accessibility and rational use of essential drugs more specifically, need to be tested both in low-income countries and middle-income countries. Such mechanisms include taxes, different kinds of fees, and in particular insurance systems. Each country should aim at paying running costs for inspections and monitoring of the provision and prescribing of drugs by own resources generated from, e.g., registration fees.

Although the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement may reduce prices on already existing generic drugs, it will most probably increase the prices for new drugs in most developing countries. However, there is an exemption clause, which allows countries to make exceptions in case of an emergency situation. This has already been used by some countries with reference to the HIV/AIDS situation.

International Co-operation

Increasing efforts are underway to improve pharmaceutical sector performance in low- and middle-income countries. An essential tool for such work is an objective and standard method of assessment, which can be used to promote evidence based NDP development and implementation. Sida and WHO have supported a collaborative effort by which 13 developing countries were comparatively assessed. The outcome clearly showed that most efforts internationally have been devoted to availability and affordability and to a lesser extent to quality and rational use of drugs.

International organisations such as WHO, Unicef and the World Bank are expanding their joint efforts to support their member states in the area of pharmaceuticals through a well established co-operation (Interagency Pharmaceutical Co-ordination [IPC] Group). Donor co-ordination should be imperative and the IPC mechanism could be even further strengthened. The World Bank has recently presented an issue paper on pharmaceuticals where the first proposed target area is to strengthen policy analysis and dialogue, and another is to expand access to drugs through public-private collaboration. All multinational pharmaceutical corporations are trying to extend their influence and increase their sales in all countries, but only to a minor extent regarding essential drugs. Generally, they do not supply important drugs in countries or for diseases where a low sales profit is expected. The TRIPS agreement seems to imply even greater challenges on developing countries to find strategies to reduce the cost for drugs on the market.

Key Priorities for Swedish Development Co-operation

The future Sida support in the drug sector must observe the crucial role of drugs in a comprehensive health system. It must also assess the specific contexts for a national or regional support. Finally it must co-ordinate the support with other national activities and with other donor support.

1. Equity – Human rights – Poverty reduction

Sweden has a long history of building its health services on equity principles, based on political decisions. This has given health professionals and the scientific community a high competence for identifying needs and means of improving health care services towards equity (men-women, poor-rich, ethnic groups, remote areas, etc.), human rights, including the rights of the child, and democracy. Patient's rights is an important element of the Swedish Health legislation.

2. Policy and Institutional Development

To support and assist in a comprehensive development and implementation of evidence-based National Drug Policies drawing on experiences from on-going Sida supported programmes and lessons learned from other organisations and from international comparisons. Bilateral support should be concentrated to a few countries, while regional support could be focused on training or networking regarding specific issues. Support on a global level should focus on method development. Particularly important components of a comprehensive national drug policy could be supported on a bilateral, regional level:

- Human resources development through intervention programmes to ensure rational use of drugs both at public and private providers, and through media information and communication to consumers and the public.
- Establishment and development of effective quality control mechanisms, including regulations and inspections as parts of a comprehensive policy development.

3. Research collaboration with low-income countries

Operational and health systems research linked to NDP development and implementation. Human resources development is essential in relation to most elements of an NDP, and postgraduate education from Master of Public Health to doctorate studies is one way to improve human capacity in the pharmaceutical sector. The Swedish academic system is suitable for foreign students. Research collaboration is one tool for increasing human capacity on a long-term and sustainable basis. Several Swedish departments have this experience and can continue to contribute to such collaboration. Usually there are two components from which the developing countries can benefit: the outcome of the research itself , and the competence building that arises from research training.

4. Consensus building, net-working, teamwork

In Sweden there is also a long tradition of teamwork and net-working which is important for achieving widespread participation and ownership in development projects. Our experience and working habit of trying to achieve consensus in most situations, is also an advantage in this context. Peer influence and collaboration between health personnel is common in Swedish health care.

Collaborating Partners in Sweden

Sweden has a large cadre of highly skilled professionals in the field of pharmaceuticals, e.g., at the Medical Products Agency, at Apoteket AB, within the health services (e.g., Drug Therapeutic Committees), at SBU (Swedish Board for Health Technology Assessment), at the WHO Collaborating Centre on Monitoring of Adverse drug reactions in Uppsala, and at identified academic departments, like the Division of Clinical Pharmacology at Huddinge University Hospital (WHO Collaborating Centre on Drug utilisation and drug information), and IHCAR (Division of International Health, Department of Public Health Sciences, Karolinska Institutet). IHCAR has worked in a multidisciplinary way on the global arena with pharmaceutical issues, especially National Drug Policy development and Rational Use of Drugs, including regulation of the private sector and increased awareness of the role of traditional medicine. Research and development related to drugs is also performed at, e.g., Handelshögskolan (Stockholm School of Economics) and IHE (Institute for Health Economy) in Lund.

References

Cederlöf C, Tomson G. Private pharmacies and the health sector reform in developing countries – professional and commercial highlights. J Social Admin Pharmacy 1995;12:101–111.

Dag Hammarskjöld Foundation. Health and Drug Policies: Making them the Top of the Agenda. Developmetn Dialogue 1995;1:5–24.

Einarsson P, Byström M. TRIPS. Consequences for developing countries. Implications for Swedish development cooperation. Stockholm: Report; December, 2000.

Falkenberg T, Tomson G. The World Bank and pharmaceuticals. Health Policy & Planning 2000;15:52–58.

Falkenberg T, Nguyen TB, Larsson M, Nguyen TD, Tomson G. Pharmaceutical sector in transition – a cross sectional study in Vietnam. 2000;31:590–597.

Falkenberg, T. Larsson, M & Tomson, G. Towards Good Pharmacy Practice in Vietnam and Thailand. Brussels: Final report. EU 4th framework programme, ERB3514PL950674, 2000.

Falkenberg & Bartoloni. Towards controlling antimicrobial use and resistance in low-income countries. Brussels: Accepted project proposal, 5th Framework, 2001.

Govindaraj R, Reich MR, Cohen JC. World Bank Pharmaceuticals Discussion Paper. Washington: Human Development Network, The World Bank, September, 2000.

Helling-Borda M, Andersson G. Lao National Drug Policy Programme. Stockholm: Department for Democracy and Social Development, Sida 2000;Sida Evaluation 00/9.

Hogerzeil HV., Walker G.J.A., Sallami AO, Fernando G., Impact of an essential drugs program on availability and rational use of drugs, The Lancet, January 21,1989: 141–142.

Jerve AM (team leader), Krantz G, Bich San P, Spivey P, Tuan T, Örtendahl C. Tackling Turmoil of Transition: An evaluation of lessons from the Vietnam-Sweden Health Cooperation 1994 to 2000. Bergen: Chr. Michelsen Institute, 2001.

Laing RO, Hogerzeil HV, Ross-Degnan D. Ten recommendations to improve use of medicines in developing countries. Health Policy & Planning 2001;16:13–20.

Larson M, Kronvall G, Nguyen Thi KC, Karlsson I, Lager F, Hoang DH, Tomson G, Falkenberg T. Antibiotic medication and bacterial resistance to antibiotics: a survey of children in a Vietnamese community. Trop Med & Internat Health 2000;5:711–721.

Leon DA, Walt G, Gilson L. International perspectives on health inequalities and policy. BMJ 2001;322:591–594.

Paphassarang, C, Tomson G, Choprapawon C, Weerasuriya C. The Lao national drug policy: lessons along the journey. The Lancet: 1995;345:433–435.

Stenson B, Tomson G, Syhakhang L. Pharmaceutical regulation in context: the case of Lao People's Democratic Republic. Health Policy and Planning 1997;12(4):329–340.

Stenson B, Syhakhang L, Eriksson B, Tomson G. Real World Pharmacy: Assessing the Quality of Private Pharmacy Practice in Lao PDR. Social Science & Medicine 2001;52:393–404.

Tomson G, Jönsson C, Wahlström R, Jönsson K. How does research results influence health policy decisions? Use of evidence for for decision-making in implementing the Lao National Drug Policy. Project proposal accepted by Sida/SAREC 2000.

WHO. Comparative analysis of national drug policies. Geneva: Action Programme on Essential Drugs 1997;WHO/DAP/97.6.

WHO. Indicators for monitoring national drug policies. Geneva: Action Programme on Essential Drugs 1994;WHO/DAP/94.12.

WHO. Medicines Strategy: 2000–2003. Geneva, 2000, WHO/EDM/2000.1.

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