

Ten best readings in . . . essential medicines

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The essential medicines concept has become an established approach in international public health – a vital component for combating HIV/AIDS, tuberculosis, malaria, respiratory infections, other communicable diseases and the vast majority of non-communicable diseases. But the survival and global dissemination of the essential medicines concept were by no means assured at the outset. Looking back at the experiences of Costa Rica, Cuba, Egypt, India, Mexico, Mozambique, Pakistan, Peru, Sri Lanka and other countries in the 1960s and 1970s, **Drugs Policy in Developing Countries**¹ traces the often contentious and sometimes uncertain evolution of essential medicines policy over the 15 years following the 1975 World Health Assembly resolution that introduced it. Kanji and colleagues provide what remains the best available introduction to the public health crisis, political dynamics, pharmaceutical industry reactions and international response which characterized the formulation and first 15 years of the essential medicines policy. In 1992 they correctly predicted that financing, rational use and consumer choice would be the three major medicines themes in the 1990s. On these and related themes, much work remains to be done. The authors conclude with the hope that ‘the essential drugs movement can no longer be stopped’. Indeed, the movement is more vital than ever.

A national drug policy is a crucial ingredient in every country's national health policy, as it provides the strategic framework to identify national goals and commitments. **How to Develop and Implement a National Drug Policy**² is the most concise overview of the process of developing such a policy and monitoring its impact. This publication includes summary descriptions of all components of a drug policy and relevant World Health Organization (WHO) technical advice. These components are: selection of essential medicines, affordability, drug financing, supply systems, drug regulation, rational use, research, human resources development, and monitoring and evaluation. The strength of the publication lies in its very systematic approach, its clear language and the full references it gives to all relevant WHO publications in each of the technical areas.

Most countries require a pharmaceutical product to be approved on the basis of efficacy, safety and quality before it can be prescribed. In addition, the majority of health care and insurance schemes cover only the costs of medicines on a selected list. The WHO Model List of Essential Medicines (the ‘Model List’) is an example of such a list. The first Model List of 1977 is widely seen as a revolution in public health. The Model List has been updated every 2 years since then.

By the end of 1999, 156 countries had a national list of essential medicines. In 2002 the procedures for updating the Model List have been drastically improved, moving towards a transparent and independent decision-making process based on a systematic review of evidence, external review and closer links to clinical guidelines. The first meeting of experts held in accordance with the new methods took place in April 2002 and the report of the meeting, **The Selection and Use of Essential Medicines**³, contains the best description of the new procedures. This book also includes the latest Model List of Essential Medicines, as well as cross references to the Anatomical Therapeutic Chemical (ATC) classification and Defined Daily Dosage which are used in drug utilization studies.

When it came out in 1981 **Managing Drug Supply**⁴ was the first of its kind, and it remained so useful for so many years that it has been dubbed ‘the yellow bible’. In 1997 a revised and expanded edition was produced, again by Management Sciences for Health (a not-for-profit international consultancy group); this time in close collaboration with WHO. This very practical book remains the standard reference on the management of medicine supply and largely reflects the international consensus on all subjects covered. Structured around the ‘drug management cycle’ of selection, procurement, distribution and use, the publication also includes detailed coverage of drug financing, human resources management, information management and legal aspects of drug management. Numerous country studies, checklists, assessment guides together with further readings, all add to the usefulness of this important book.

Debates over affordability and innovation have become perhaps the most contentious in the area of national medicines policies. **Globalization and Access to Drugs**⁵, first published in 1997 and revised in 1999, provides an essential and authoritative introduction on the World Trade Organization (WTO), the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and their relevance to public health. The TRIPS Agreement establishes the minimum patent requirements for 144 WTO member countries; among these, the obligation to recognize product and process patents, and 20 years minimum patent coverage. Of particular concern for developing countries is the effect of TRIPS on prices of newer essential medicines and generic competition. Subsequent publications in the WHO *Health Economics and Drugs* series provide indicators for monitoring the TRIPS Agreement, an analysis of the Doha Declaration on the TRIPS Agreement and Public Health, and a

comprehensive annotated bibliography of relevant publications.

Just as the first large tenders for East Africa in the late 1970s considerably reduced the international world market prices for generic essential medicines, the recent price information services on antiretroviral medicines have contributed to the reduced prices for these drugs. Several price information services are now available, but one of the most comprehensive is the annual **International Drug Price Indicator Guide**⁶, issued by Management Sciences for Health in Washington in collaboration with WHO and covering most of the items on the WHO Model List. This information service is also available on their very user-friendly web site (www.msh.org). The Guide, which was initiated in the late 1990s, is now complemented by price information on active ingredients for essential medicines, HIV-related medicines, and medicines against tuberculosis; details of all of these and more are available from WHO's medicines website (see below).

National medicines policy usually includes activities to ensure the quality, safety and efficacy of all medicines available in the country. **Effective Drug Regulation**⁷ provides an analysis of how 10 countries from different regions and different levels of economic development have organized, financed and implemented their drug regulatory functions. It addresses legislation, human resources, licensing, inspection, product registration, surveillance, control of promotion and advertising, and quality control laboratories. Equally important, it provides tools for assessing regulatory performance with respect to effectiveness, efficiency, accountability and transparency. Combined with the extensive WHO normative guidance on a wide range of regulatory matters, the book provides a solid base for strengthening vital regulatory functions.

Irrational prescribing is a widespread problem, leading to suboptimal treatment and economic waste. **Ten Recommendations to Promote Rational Drug Use in Developing Countries**⁸ by Laing et al. is probably the most comprehensive review of developments in the field since the groundbreaking International Conference on Rational Drug Use in Nairobi in 1985 and the launch of the WHO/INRUD indicators for measuring rational drug use in 1993. The paper examines all available evidence on educational, managerial and regulatory approaches to promoting rational use of medicines in developing countries, in order to identify the most effective interventions. Proven effective interventions are the development of standard treatment guidelines, essential medicines lists, pharmacy and therapeutics committees, and problem-based pharmacotherapy teaching. The paper is recommended because it is very practical and specifically aimed at health policy-makers.

Clinical guidelines on diagnosis and treatment of choice for common conditions are the basis for the selection of essential medicines, and also help turn the concept into clinical practice. WHO has developed clinical guidelines for over 100 diagnoses, complaints and preventive needs. One of the first efforts to combine field experience and most of these guidelines into one single volume is provided by Médecins Sans

Frontières in their **Clinical Guidelines, Diagnostic and Treatment Manual**⁹, now in its fifth edition. Today about 135 countries have developed clinical guidelines appropriate to their health care services. In 2002 the first **WHO Model Formulary**¹⁰ was published, which presents standard medicine information on all 325 essential medicines on the WHO Model List. The Formulary is recommended because it is now the most comprehensive summary of WHO's clinical guidelines, and because it is also available in electronic form for use as the basis for national and institutional formularies.

In addition to these 10 best readings, the world wide web offers access to a vast amount of information on medicines, though only a small portion is directly related to essential drugs. The main WHO website has sections for disease-specific information and treatment guidelines. The website of the WHO Department of Essential Drugs and Medicine Policy presents nearly all relevant WHO medicines documents and publications of the last decade, including those mentioned in this review. For example, the WHO Policy Perspectives on Medicines present summaries of important policy topics with their key references. A recent addition is the WHO Essential Medicines Library presenting the WHO Model List of Essential Medicines, key supporting evidence, links to WHO clinical guidelines and a searchable version of the WHO Model Formulary. Other useful web sites include those of Management Sciences for Health, Médecins sans Frontières, the British National Formulary, and the International Pharmacy Federation. The most relevant internet-based discussion network on essential drugs and intellectual property issues are respectively **e-drug** and **IP-Health**. Pharmaceutical industry perspectives on essential drugs are available from the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

Websites

- e-drug – Registration by email to majordomo@usa.healthnet.org
- IFPMA [<http://www.ifpma.org>]
- IP-Health [<http://lists.essential.org/mailman/listinfo/ip-health>]
- Management Sciences for Health [<http://www.msh.org>]
- Médecins sans Frontières [<http://www.msf.org>]
- The British National Formulary [<http://www.bnf.org>]
- The International Pharmacy Federation [<http://www.fip.org>]
- World Health Organization [<http://www.who.int>]
- WHO Department of Essential Drugs and Medicines Policy [<http://www.who.int/medicines>]

Readings

- (1) Kanji N, Hardon A, Harnmeijer JW, Mamdani M, Walt G. **Drugs policy in developing countries**. London and New Jersey: Zed Books, 1992. [<http://www.zedbooks.demon.co.uk/home.htm>]
- (2) **How to develop and implement a National Drug Policy**. Geneva: WHO, 2001.
- (3) **The selection and use of essential medicines**. Report of the 12th Meeting of the Expert Committee on the

- Selection and Use of Essential Medicines, April 2002. Geneva: WHO, Technical Report Series 914 (in print).
- (4) Quick JD, Rankin JR, Laing RO, O'Connor RW, Hogerzeil HV, Dukes MNG, Garnett A (eds). **Managing drug supply**, 2nd ed. West Hartford, CT: Kumarian Press, 1997. [<http://www.kpbooks.com/details.asp?title=Managing+Drug+Supply>]
- (5) Velasquez G, Boulet P. **Globalization and access to drugs**. Geneva: WHO, 1999. Health Economics and Drugs DAP Series, No.7; WHO/DAP/98.9 Revised.
- (6) **International Drug Price Indicator Guide**. Boston, MA: Management Sciences for Health, 2001. [<http://erc.msh.org/mainpage.cfm?file=1.cfm&id=1&temp-title=Introduction&module=DMP&language=English>]
- (7) Ratanawijitrasin S, Wondemagegnehu E. **Effective drug regulation – a multi-country study**. Geneva: WHO, 2002.
- (8) Laing RO, Hogerzeil HV, Ross-Degnan D. **Ten recommendations to promote rational drug use in developing countries**. *Health Policy and Planning* 2001; **16** (1): 13–20.
- (9) Médecins Sans Frontières. **Clinical guidelines, diagnostic and treatment manual**, 4th ed. Paris: ISI, 1999 (5th ed. in print). [www.msf.org]
- (10) Couper MC, Mehta D (eds). **WHO Model Formulary**. Geneva: WHO, 2002.

Note that readings from WHO can be obtained by contacting:

Documentation Centre
 Department of Essential Drugs and Medicines Policy
 World Health Organization
 CH-1211 Geneva 27
 Switzerland
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