如何制定和实施国家药物政策

How to develop and implement a national drug policy

第二版

Second edition

国家食品药品监督管理局国际合作司　译

世界卫生组织　日内瓦

中国医药科技出版社

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第二版　更新和替代

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感谢

这些指导原则是通过一系列的活动来制定的。1995 年 6 月 WHO 国家药物政策专家委员会举行会议，更新了 1988 年制定的《国家药物政策指南》。[1] 从国际团体、组织和专家，以及基本药物和药物政策司（EDM）和 WHO 地区办事处的工作人员那里得到了建议和帮助。最后的版本由 C. Hodgkin, E. D. Carandang, D. A. Fresle 和 H. V. Hogerzeil 编辑。

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Contributors

These guidelines were developed through a series of activities. In June 1995 a meeting of the WHO Expert Committee on National Drug Policy was held, to update the 1988 *Guidelines for Developing National Drug Policies*.[1] Comments and contributions on successive drafts were received from international groups, organizations and individual experts, as well as from staff members from the Department of Essential Drugs and Medicines Policy (EDM) and WHO Regional Offices. The final text was edited by C. Hodgkin, E.D. Carandang, D.A. Fresle and H.V. Hogerzeil.

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缩略语

AIDS	获得性免疫缺陷综合征
ASEAN	东南亚国家联盟
DRA	药品监督管理机构
EDM	基本药物和药物政策司
EU	欧盟
GMP	药品生产质量管理规范
HIV	人类免疫缺陷病毒
INN	国际非专有名称
INRUD	药物合理使用国际网络
MoH	卫生部
MSF	无国界医生组织
MSH	卫生管理科学
NDP	国家药物政策
NGO	非政府组织
OAU	非洲统一组织
OTC	非处方药物
TRIPS	与贸易相关的知识产权协议
TFHE	卫生经济学专门工作组
UNAIDS	联合国 HIV/AIDS 联合项目
UNICEF	联合国儿童基金
UNFPA	联合国人口基金
WHA	世界卫生大会
WHO	世界卫生组织
WTO	世界贸易组织

Abbreviations and acronyms

AIDS	Acquired immunodeficiency syndrome
ASEAN	Association of South-East Asian Nations
DRA	Drug regulatory authority
EDM	Department of Essential Drugs and Medicines Policy
EU	European Union
GMP	Good manufacturing practices
HIV	Human immunodeficiency virus
INN	International nonproprietary names
INRUD	International Network for Rational Use of Drugs
MoH	Ministry of Health
MSF	Médecins Sans Frontieres
MSH	Management Sciences for Health
NDP	National drug policy
NGO	Nongovernmental organization
OAU	Organization of African Unity
OTC	Over-the-counter (drug)
TRIPS	(Agreement on)Trade-Related Aspects of Intellectual Property Rights
TFHE	Task Force on Health Economics
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
UNFPA	United Nations Population Fund
WHA	World Health Assembly
WHO	World Health Organization
WTO	World Trade Organization

序　言

1975 年，世界卫生大会 WHA28.66 决议要求 WHO 拿出办法来帮助成员国制定国家药物政策。同时，也敦促 WHO 帮助各国实施战略，例如基本药物的遴选和根据卫生需求对质量保证的药品的适当采购，以及对药物规划各要素提供教育和培训。此项决议后续的一系列事件，标志着在 WHO 的帮助下国家药物政策的演变。

第一个 WHO 基本药物示范目录于 1977 年出版。一年以后，在阿拉木图召开“WHO/UNICEF 初级卫生保健会议”，将可获得基本药物作为初级卫生保健八大要素之一。1979 年，WHO 基本药物行动规划建立。另一个促进改善国家药品状况战略的里程碑是 1985 年在内罗毕召开的合理用药专家会议。转年的世界卫生大会通过了反映该会议推荐的关于促进合理用药的决议。同样在 1986 年，一个 WHO 国家药物政策专家委员会开会为成员国制定实践指南，出版了制定国家药物政策的指导原则。这一出版物经多年来证明是非常有用的。

各国和 WHO 以及其他机构的努力已经有相当的影响。获得基本药物的人数由 1977 年的约 21 亿增长到 1999 年估算的 38 亿。到 1999 年，与 1989 年的 14 个国家相比，在过去的 10 年中已有 66 个国家制定或更新了国家药物政策。到 1999 年底，已有 156 个 WHO 成员国拥有了国家基本药物目录，其中 127 个目录在过去 5 年中已被修订。[2]

然而，可获得质量保证的药物和合理使用的问题仍然存在。尽管只有很少可用的实际数据，但有可能在最贫穷的非洲和亚洲地区，超过半数的人口仍旧缺乏可获得的基本药品。现在又有一些新的挑战对可获得性构成了冲击，例如私立部分在药品领域的作用在扩大，医疗卫生领域的改革，以及全球化的影响。另一些因素是疾病谱的变化，细菌耐药性，以及出现的一些新的疾病。特别重要的是，尽管医疗需求在增加，但由于资源匮乏政府目前的

Preface

In 1975, the World Health Assembly in resolution WHA28.66 requested WHO to develop means to assist Member States in formulating national drug policies. It also urged WHO to assist countries in implementing strategies, such as the selection of essential drugs and appropriate procurement of quality drugs based on health needs, and in providing education and training in various elements of pharmaceutical programmes. This resolution was followed by a series of events that marked the evolution of country drug programmes with the assistance of WHO.

The first WHO Model List of Essential Drugs was published in 1977. A year later the WHO/UNICEF Conference on Primary Health Care at Alma-Ata included access to essential drugs as one of the eight elements of primary health care. In 1979, the WHO Action Programme on Essential Drugs was established. Another landmark in promoting strategies to improve the pharmaceutical situation in countries was the 1985 Conference of Experts on Rational Use of Drugs in Nairobi. The following year's World Health Assembly adopted resolutions that reflected the Conference recommendations on promoting rational use. Also in 1986, a WHO Expert Committee on National Drug Policies met to develop practical guidance for Member States, published as *Guidelines for developing national drug policies.*[1] This publication has proved very useful over the years.

The efforts of countries, WHO and other agencies have had a considerable impact. The number of people with access to essential drugs has grown from roughly 2,100 million in 1977 to an estimated 3,800 million in 1999. By 1999,66 countries had formulated or updated a national drug policy within the previous 10 years, compared with 14 countries in 1989. By the end of 1999, 156 WHO Member States had a national essential drugs list; 127 of the lists had been revised within the previous five years.[2]

Nevertheless, problems of access to quality drugs and rational use persist. Although few hard data are available, it is likely that in the poorest parts of Africa and Asia more than half the population still lacks access to essential drugs. And there are new challenges that may have an impact on access, such as the expansion of the private sector's role in pharmaceuticals, health sector reforms and the effects of globalization. The changing pattern of diseases, antimicrobial resistance and emerging new diseases are other factors. Particularly important is the current trend of governments to reduce health care spending because of inadequate resources,despite increasing health needs.

趋势仍是减少医疗开支。

经过十年，随着一些新问题的提出，修改1988年的指导原则势在必行。国家药物政策专家委员会1995年开会，评估当时的药品状况，以开始更新工作步骤。根据他们评估结果产生的一项报告成为现行指导原则的基础。[3]

这些更新的指导原则注重国家药物政策的过程、战略和可被成员国及在药品领域活跃的组织使用的各种选择。每个政策要素的讨论都强调现存的问题和新的挑战，各章均提供了可用于改进现状的战略和实际方法。所有章节都包括可提供另外的技术和实际细节的参考文件的出处。

（常文佐译）

After a decade, and with new problems to be addressed, there was a clear need to revise the 1988 guidelines. The Expert Committee on National Drug Policies met in 1995 to review the current pharmaceutical situation and to start the updating process. Their deliberations resulted in a report that became the basis of the present guidelines.[3]

These updated guidelines focus on the national drug policy process, strategies and options which can be used by Member States and organizations active in the pharmaceutical sector. Each policy component is discussed, with a focus on current problems and new challenges. And each chapter presents strategies and practical approaches that can be used to improve the situation. All chapters include references to publications that provide additional technical and practical details.

目录

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