

Public health

innovation and
intellectual property rights

REPORT OF THE COMMISSION ON
INTELLECTUAL PROPERTY RIGHTS, INNOVATION
AND PUBLIC HEALTH



World Health
Organization

Public health, innovation and intellectual property rights

**REPORT OF THE COMMISSION ON
INTELLECTUAL PROPERTY RIGHTS, INNOVATION
AND PUBLIC HEALTH**

WHO Library Cataloguing-in-Publication Data

Commission on Intellectual Property Rights, Innovation and Public Health.

Public health, innovation and intellectual property rights: report of the Commission on Intellectual Property Rights, Innovation and Public Health.

1. Intellectual property . 2. Delivery of health care. 3. Patents. 4. Development
5. Research. 6. Research support. I. World Health Organization. II. Title. III. Title: Report of the Commission on Intellectual Property Rights, Innovation and Public Health.

ISBN 92 4 156323 0

(NLM classification: W 20.5)

ISBN 978 92 4 156323 9

© **World Health Organization 2006**

This publication contains the collective views of an independent international commission and does not necessarily represent the decisions or the stated policy of the World Health Organization.

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

All rights reserved. Publications of the World Health Organization can be obtained from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: bookorders@who.int). Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to WHO Press, at the above address (fax: +41 22 791 4806; e-mail: permissions@who.int).

Printed in Switzerland



Members of the Commission¹

Ms Ruth Dreifuss (Chairperson): President of the Swiss Confederation in 1999. From 1993 to 2002, member of the Swiss Government and Federal Minister of Interior where her responsibilities included, among others, public health and scientific research.

Dr Raghunath Anant Mashelkar (Vice-Chairperson): Director-General of India's Council of Scientific and Industrial Research.

Professor Carlos Correa: A lawyer and economist is Director of the Centre for Interdisciplinary Studies on Industrial Property and Economics Law at the University of Buenos Aires.

Professor Mahmoud Fathalla: Professor of Obstetrics and Gynaecology, former Dean of the Medical School at Assiut University, Egypt, and Chairperson of the WHO Advisory Committee on Health Research.

Dr Maria C. Freire: President and Chief Executive Officer of the Global Alliance for TB Drug Development, and previously Director of the Office of Technology Transfer at the United States National Institutes of Health from 1995 to 2001.

Professor Trevor Jones: Previously Director-General of the Association of the British Pharmaceutical Industry and, prior to that, Director of Research and Development at the Wellcome Foundation Limited.

Mr Tshediso Matona: Director-General in South Africa's Department of Trade and Industry.

Professor Fabio Pammolli: Full Professor of Economics and Management, Faculty of Economics, University of Florence. He is the Director of IMT Lucca Institute for Advanced Studies.

Professor Pakdee Pothisiri: Senior Deputy Permanent Secretary of Health, Government of Thailand, and Secretary General of the Thai Food and Drug Administration.

Professor Hiroko Yamane: Professor at the National Graduate Institute for Policy Studies, Japan.

¹ All Commissioners were appointed in their individual capacity and not as representatives of an institution or government. The Commissioners have disclosed any conflicts of interest to the other members and to the WHO Secretariat.



Terms of Reference

- Summarize the existing evidence on the prevalence of diseases of public health importance with an emphasis on those that particularly affect poor people and their social and economic impact;
- Review the volume and distribution of existing research, development and innovation efforts directed at these diseases;
- Consider the importance and effectiveness of intellectual property regimes and other incentive and funding mechanisms in stimulating research and the creation of new medicines and other products against these diseases;
- Analyse proposals for improvements to the current incentive and funding regimes, including intellectual property rights, designed to stimulate the creation of new medicines and other products, and facilitate access to them;
- Produce concrete proposals for action by national and international stakeholders.

ORIGINS

In May 2003, WHO Member States agreed at the World Health Assembly to set up a time-limited body to consider the relationship between intellectual property rights, innovation and public health. The operative part of the text of the resolution establishing the Commission (WHA56.27) reads as follows:

“...collect data and proposals from the different actors involved and produce an analysis of intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries...”

The Commission was established by the Director-General of WHO in February 2004.

The Commission was supported by a small Secretariat in WHO under the overall direction of Dr Tomris Türmen, representative of the Director-General. Dr Charles Clift was Secretary of the Commission.



Contents

Preface	ix
Chapter 1 The health innovation cycle: making it work for poor people	1
Introduction	1
Health, wealth and poverty	1
Changing disease trends	2
Many ways to better health	5
Health, development and the Millennium Development Goals	6
A moral imperative	8
A framework for analysis	11
Defining the problem	12
The types of disease	12
The economics of innovation and access	15
Demand	15
Supply	17
The role of patents	19
The innovation cycle	22
Changing players in the innovation process	24
Innovation systems in developing countries	27
The report	28
Chapter 2 The deep well of discovery: early stage research	33
Introduction	33
Early stage research	35
The impact of scientific advances	35
Institutional changes	37
Policy changes	40
Public funding and research priorities	41
Policy proposals: financing and priority setting	46
Policy proposals: intellectual property	48
Research tools and platform technologies	48
Changes in patenting policies	51
Patent pools	52
Research exemptions	53
Compulsory licensing	54
Public sector and university patenting	55
Developing countries	56
Developed countries	57

Chapter 3	The long road from discovery to development	65
	Introduction	65
	Scientific and technical issues	67
	The institutional framework	70
	The public and private sectors and partnerships	70
	Current funding arrangements	74
	Funding requirements	75
	Institutional challenges	78
	Regulation and clinical trials	79
	Incentives to develop new products	83
	The TRIPS agreement	83
	Special incentives to spur product development	86
	Orphan drug schemes	86
	Tax credits	86
	Scheme for transferable intellectual property rights	87
	Transferable fast-track review scheme	87
	Reward systems	87
	Medical R&D treaty	90
	Open source approaches	91
Chapter 4	Delivery: getting products to patients	97
	Introduction	97
	The determinants of availability	99
	Health delivery systems	100
	The determinants of acceptability	104
	Quality	104
	Suitability of products for use in poor settings	106
	The determinants of accessibility	108
	International pricing policies	109
	Company pricing policies	111
	Company donation programmes	113
	Public policy	114
	Intellectual property	116
	Prices and competition	116
	The Doha Declaration and compulsory licences	117
	Company patent policies	121
	Other patent-related schemes	122
	Parallel imports	123
	Test data protection and data exclusivity	124
	International purchasing arrangements	126
	Policies to promote competition	128
	Facilitating the entry of generic competition	
	on patent expiry	129
	Incremental innovation	130
Chapter 5	Fostering innovation in developing countries	141
	Introduction	141
	The development of innovative capacity	143
	Dimensions	143
	The policy framework	144
	Policy options	149

Education	149
Promoting networks	149
The role of the public sector	150
Technology transfer in production	151
Regulation and clinical trials	154
Regulation	154
Clinical trials	157
Traditional medicine	160
Discovery, development and delivery	161
Policies	164
Chapter 6 Towards a sustainable plan to promote innovation and access	171
A global challenge	171
A global responsibility	173
Our proposals	174
Chapter 2 – discovery	175
Chapter 3 – development	177
Chapter 4 – delivery	179
Chapter 5 – fostering innovation in developing countries	182
The way to support a sustainable global effort	184
Acronyms and abbreviations	189
Glossary	191
Acknowledgements	197
Visits	199
Commentaries	201

预览已结束，完整报告链接和二维码如下：

https://www.yunbaogao.cn/report/index/report?reportId=5_29845

