





# Promoting Access to Medical Technologies and Innovation

Intersections between public health, intellectual property and trade



# Promoting Access to Medical Technologies and Innovation

Intersections between public health, intellectual property and trade







### Disclaimer

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion on the part of the World Health Organization (WHO), World Intellectual Property Organization (WIPO) and World Trade Organization (WTO) concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

The mentioning of specific companies or products does not imply that they are endorsed or recommended by the WHO, WIPO or the WTO or preferred to others that are not mentioned. The names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the WHO, WIPO and the WTO 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 WHO, WIPO and the WTO be liable for any consequences whatsoever arising from its use.

#### © 2012 World Health Organization, World Intellectual Property Organization and World Trade Organization

All rights reserved. Reproduction or translation of the material contained in this document may be made only with the written permission of the WTO Publications Manager.

WTO ISBN 978-92-870-3839-5 WIPO ISBN 978-92-805-2308-9 WHO ISBN 978-92-415-0487-4

This publication can be obtained through:

#### World Health Organization

Department of Public Health, Innovation and Intellectual Property Avenue Appia 20 CH-1211 Geneva 27 Switzerland

Tel: + 41 22 791 21 11
Fax: + 41 22 791 31 11
Email: phidepartment@who.int
Web site: www.who.int/phi/en/

#### World Intellectual Property Organization

WIPO Publications Chemin des Colombettes 34 PO Box 18 CH-1211 Geneva 20

Switzerland

Tel: + 41 22 338 91 11 Fax: + 41 22 338 733 54 28 Web site: www.wipo.int

Online WIPO bookstore: www.wipo.int/ip-outreach/en/publications

#### World Trade Organization

WTO Publications 154 rue de Lausanne CH-1211 Geneva 21 Switzerland

Tel: + 41 22 739 52 08 Fax: + 41 22 739 54 58 Email: publications@wto.org Web site: www.wto.org

Online WTO bookshop: http://onlinebookshop.wto.org

A PDF version of this publication is available on the websites indicated above.

Printed by WTO Secretariat, Switzerland, 2013.

Publication designed by Book Now Ltd, London. Cover photo © Getty Images.

# **Contents**

Acknowledgements				
Foreword by the Directors-General				
Execu	ıtive	Summary	9	
I.	N	Tedical technologies: the fundamentals	16	
Α.	Public health and medical technologies: the imperative for international cooperation		18	
	1.	Policy coherence	18	
	2.	Scope of the study	19	
	3.	The need for this study	19	
	4.	The timing of the study	20	
	5.	Who should read this study?	20	
В.	Th	The cooperating agencies: the WHO, WIPO and the WTO		
	1.	World Health Organization	21	
	2.	World Intellectual Property Organization	22	
	3.	World Trade Organization	23	
	4.	Trilateral cooperation	23	
	5.	Other international key stakeholders	24	
C.	The global burden of disease and global health risks			
	1.	Defining the need	25	
	2.	Trends and projections: major cause groups contributing to the total disease burden	26	
	3.	Global health risks	28	
D.	Factors shaping public health policy			
	1.	Seeking effective outcomes within a complex policy environment	30	
	2.	Transforming policy intersections: from boundaries to synergies	30	
	3.	Building stronger links between local, national and global levels	32	
	4.	The empirical challenge: an accessible base for policy	32	
II.	Т	he policy context for action on innovation and access	38	
A.	Public health policy			
	1.	Health and human rights	40	
	2.	Access to essential medicines: an indicator for the fulfilment of the right to health	42	
	3.	Universal access and the UN Millennium Development Goals	42	
	4.	Public health, innovation and access in the WHO	43	
	5.	National health policies and health systems	46	
	6.	Regulation of medical technologies	47	
В.	Intellectual property, trade and other policy dimensions			
	1.	Intellectual property systems	53	
	2.	Competition policy	75	

	3.	Trade policy settings	77	
	4.	Government procurement	80	
	5.	Free trade agreements	83	
C.	Ec	onomics of innovation and access to medical technologies	86	
D.	Tra	aditional knowledge and traditional medicine	89	
-	1.	Traditional medicine knowledge systems	89	
	2.	Traditional medical knowledge in international health and IP policy	90	
	3.	Traditional medicines regulation	90	
	4.	Concerns about misappropriation of traditional medicines	91	
	5.	New approaches to IP protection of traditional medical knowledge	92	
III.	1\	Tedical technologies: the innovation dimension	100	
A.	Historical pattern of medical R&D			
	1.	Innovation for medical technologies in context	102 102	
	2.	From early discoveries to "wonder drugs"	102	
	3.	Growth and evolution of the modern pharmaceutical industry	102	
	4.	From non-exclusive licensing to restricted production	102	
	5.	R&D productivity: early gains, regulatory concerns	103	
B.		e current R&D landscape	<b>105</b> 105	
	1. 2.	A time of challenge for the pharmaceutical industry  Public-sector researchers play a key role in medical R&D	105	
	3.	Medical R&D costs	100	
	4.	Incentive models in the innovation cycle	107	
	5.	Registration of clinical trials in pharmaceutical product development	113	
		rercoming market failure: the challenge of neglected diseases	115	
	1.	Diseases disproportionately affecting people in developing countries: neglected diseases	115	
	2.	New approaches to innovation for neglected diseases	116	
	3.	WHO Expert Working Groups on R&D financing	119	
	4.	Product development partnerships: new pathways to innovation	120	
	5.	Research for neglected diseases: a growing role for pharmaceutical companies	121	
	6.	WIPO Re:Search: a new partnership to use intellectual property in public health	123	
	Int	ellectual property rights in the innovation cycle	125	
	1.	The role of international and national norms and IP management	125	
	2.	Intellectual property and the product development process	126	
	3.	Pre-grant issues: questions of patentability	126	
	4.	Post-grant issues: questions related to the use of patents	133	
E.	Sh	aring of influenza viruses and access to vaccines and other benefits	138	
	1.	WHO Global Influenza Surveillance and Response System	138	
	2.	Intellectual property rights in the context of PIP negotiations	138	
	3.	The PIP Framework	139	

IV.	Medical technologies: the access dimension	142		
A.	Access to medical technologies: the context			
	The WHO access framework for essential medicines	145		
	2. Access to medicines in specific areas	148		
	3. Access to medical devices	153		
B.	. Health systems-related determinants of access			
	Generic medicines policies, price controls and reference pricing	156		
	2. Differential pricing strategies	159		
	3. Taxes	160		
	4. Mark-ups	161		
	5. Effective and efficient procurement mechanisms	161		
	6. Local production and technology transfer	163		
	7. Regulatory mechanisms and access to medical technologies	165		
C.	IP-related determinants of access			
	Determinants of access prior to patent grant	172		
	2. Pre-grant and post-grant review procedures	173		
	3. Post-grant determinants of access	174		
	4. Patent information and its relationship with public health policy	185		
	5. Review of IP provisions in recent FTAs	186		
D.	Other trade-related determinants for improving access	191		
	International trade and tariff data of health products	191		
	2. Competition policy issues	198		
Anr	nex I. Overview of international key stakeholders	206		
A.	International organizations	208		
В.	Other international key stakeholders	213		
Anr	nex II. Special compulsory licences for export of medicines	222		
A.	Operation of the System: context and scope	224		
B.	Use of the System	225		
C.	Domestic implementation	229		
Riblia	ography	231		
	Bibliography Abbreviations			
List of figures, tables and boxes				
Extended Table of Contents				

# Acknowledgements

This publication is the product of extensive collaboration between the WHO, WIPO and WTO Secretariats, led by the Department of Public Health, Innovation and Intellectual Property in the WHO, the Global Challenges Division in WIPO and the Intellectual Property Division in the WTO. Research, authoring and substantive review was done by: Hans Georg Bartels, Peter Beyer, Roger Kampf, Anatole Krattiger, Zafar Mirza, Antony Taubman and Jayashree Watal.

The contributions of many others are warmly acknowledged, in particular: Marco Aleman, Robert Anderson, Philippe Baechtold, Andrew L. Ball, Raffaela G. Balocco, Maryam Bigdeli, Thomas Bombelles, Andrea Bosman, Marie-Charlotte Bouesseau, Mathew Bryan, Alexandra M. Cameron, Andrew K. Cassels, Jorge Castro, Miriam Clados, Mireille Cossy, Carlos Castro, Marti Darlan, Jonathan J. Darrow, Cornelis de Joncheere, Clemens Feinäugle, Carsten Fink, Martin Friede, Martha Friedli, Emmanuelle Ganne, Fiona Gore, Tom Goodwin, Louise Van Greunen, Intan Hamdan,

Matthias Helble, Ali Jazairy, Fei Jiao, Warren Kaplan, Matthew Kennedy, Mossahid Khan, Mary Kay Kindhauser, Irene Kitsara, Sabine Kopp, Angel Lopez Solanas, Richard Laing, Geidy Lung, Pacyinz T. Lyfoung, Lutz Mailänder, Yukiko Maruyama, Colin Mathers, Sophie Mayer, Anne Mazur, Shanti Mendis, Wolf Meier-Ewert, Lorraine Misquith, Tomoko Miyamoto, Joaquin Montes Rodriguez, Eun-Joo Min, Giovanni Napolitano, Boniface Dongmo Nguimfack, Nuno Pires de Carvalho, Anna Caroline Müller, Clive Ondari, Philippe Pelletier, Joseph H. Perriens, Lembit Rägo, Matthew Rainey, Alex Riechel, Suja Rishikesh Mavroidis, Debbie Roenning, Tavengwa Runyowa, Hanna Steinbach, Robert Terry, Raymundo Valdés, Adriana Velazquez, Berumen, Xavier Vermandele, Hannu Wager, Krisantha Weerasuriya, Wend Wendland, Heike Wollgast and Ning Xu.

Special thanks for editorial and administrative support are due to: Cathy Boyle, Anthony Martin, Ross McRae, Brenda O'Hanlon, Julie N. Reza, Karyn Russell and Gabriela Treso.

# Foreword by the Directors-General

Public health has been a priority for global action for many years. The right of everyone to the enjoyment of the highest attainable standard of physical and mental health is a universal human right, just as the burden of disease is shared by all humanity.

The constitution of the World Health Organization (WHO) underscores that achievements by any state in the promotion and protection of health are of value to all. In the age of globalization, progress made in public health in one country has an impact on the international community as a whole. Consequently, a compelling case can be made for effective international cooperation in public health, and such cooperation is an essential foundation for sustainable development.

Public health and medical technologies are an important focus of the international system, including in the system-wide work of the United Nations – most notably in the Millennium Development Goals (MDGs). The very founding objective of the WHO is the attainment by all peoples of the highest possible level of health. In addition, the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) – in line with the mandates given to them by governments and their respective areas of expertise – have increasingly stepped up their efforts to support global endeavours to improve health outcomes.

International cooperation on public health takes many forms. Recent years have seen an intensified focus on the role of medical technologies – both the innovation processes that lead to new technologies and the ways in which these technologies are disseminated in health systems. Access to essential medicines as a dimension of the right to health has been a major concern for several decades. Now, however, the focus has broadened to consider how to promote the requisite innovation, how to address neglected health needs, and how to ensure equitable access to all vital medical technologies, including

by the Declaration on the TRIPS Agreement and Public Health (Doha Declaration), adopted on 14 November 2001 at the Fourth Ministerial Conference of the WTO. That Declaration was followed by a number of significant developments:

- The creation of new and innovative financing and procurement mechanisms, leading to significantly increased funding for medicines procurement and vaccine development.
- An evolving and more diverse pharmaceutical industry, and increasing innovative capacity in some developing countries.
- Innovative approaches to medical research and development (R&D) and its financing – particularly for neglected diseases – with an emphasis on public-private initiatives to develop required medical technologies.
- Renewed attention to the cost-effectiveness of national health systems.
- Growing global awareness of the impact of noncommunicable diseases (NCDs) on health and socioeconomic development, especially in developing countries.
- Increasing recognition of the need to move towards universal health coverage.
- Insights into the intersections between public health, the IP system, trade and competition rules, and measures to promote innovation and access to medical technologies.
- Better, more comprehensive and more accessible data on prices, access, patents and trade, enhancing the empirical base for informed priority setting and policy decisions.
- Greater policy coherence and practical cooperation on the intersection of health policy, trade and IP issues within the broader perspectives established by the

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 28247



