

Local Production and Technology Transfer to Increase Access to Medical Devices

Addressing the barriers and challenges in low- and middle-income countries



IP
Intellectual
Property and Trade

R&D
Innovation

TT
Technology
Transfer

IA
Improving Access

FS
Financing

MR
Monitoring and
Reporting



**World Health
Organization**

Local Production and Technology Transfer to Increase Access to Medical Devices

Addressing the barriers and challenges in low- and middle-income countries



World Health
Organization

Prepared, developed and written by the Medical Devices Unit of the Department of Essential Medicines and Health Products, Health Systems and Services Cluster of the World Health Organization, under the coordination of Adriana Velazquez .

This report forms part of the project entitled "Improving access to medicines in developing countries through technology transfer and local production". It is implemented by the Department of Public Health Innovation and Intellectual Property of the World Health Organization (WHO/PHI) with funding from the European Union (EU).

All reports associated with this project are available for free download from the following websites: http://www.who.int/medical_devices/en and <http://www.who.int/phi/en>

This publication has been produced with the assistance of the European Union. The contents of this publication are the sole responsibility of the World Health Organization and can in no way be taken to reflect the views of the European Union.

Editing and design by Inís Communication – <http://www.iniscommunication.com>

WHO Library Cataloguing-in-Publication Data

Local production and technology transfer to increase access to medical devices: addressing the barriers and challenges in low- and middle-income countries.

1.Equipment and supplies. 2.Appropriate technology. 3.Technology transfer. 4.Biomedical technology. 5.Developing countries. I.World Health Organization.

ISBN 978 92 4 150454 6 (NLM classification: WX 147)

© World Health Organization 2012

All rights reserved. Publications of the World Health Organization are available on the WHO web site (www.who.int) or can be purchased 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 through the WHO web site (http://www.who.int/about/licensing/copyright_form/en/index.html).

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.

Photo: Design That Matters from one of the success stories, on neonatal equipment , see page 52.
Printed in France

Contents

Acknowledgements	1
Abbreviations	3
Executive summary	5
1. Introduction	7
1.1 Background	8
1.2 Medical devices – WHO perspective	8
1.3 Objectives	10
1.4 Methodology	10
1.5 Definitions	11
1.6 Need for this report	14
References	14
2. Scoping study on local production of medical devices	16
2.1 Global medical devices market	18
2.2 Innovation of medical devices	20
2.3 Research and development for medical devices	21
2.4 Local production	23
2.5 Technology transfer and intellectual property	24
2.6 Health system financing	25
2.7 Governance and regulation	26
2.8 Foreign technologies, local business capabilities and economic context	28
2.9 Country case studies	29
<i>a. Brazil Americas Region</i>	<i>29</i>
<i>b. China Western Pacific Region</i>	<i>34</i>
<i>c. Ethiopia Africa Region</i>	<i>38</i>
<i>d. India South-East Asia Region</i>	<i>41</i>
<i>e. Jordan Eastern Mediterranean Region</i>	<i>46</i>
2.10 Success stories	50
References	62
3. Challenges and barriers to local production	70
3.1 Literature findings	70
3.2 Health system challenges	71
3.3 Policy challenges	72
3.4 Organizational challenges	73
3.5 Partnerships and other challenges	74
3.6 Survey on access to medical devices	74
3.7 Relevant findings of the survey	75
3.8 Product development and technology transfer	76
3.9 Policies and partnerships	77
3.10 Regulations and intellectual property rights	77
3.11 Funding and financial mechanisms	78
References	79

4. Measuring the viability for local production of a specific medical device: A feasibility tool	80
5. Way forward: Overcoming barriers	84
5.1 General issues to consider in order to increase access to medical devices.	84
5.2 Stakeholder-specific suggestions resulting from committee discussion.	86
Annexes	91
Annex 1	
Survey on access to medical devices in low-resource settings: results . . .	92
Annex 2a	
Feasibility tool: A usage exercise	109
Annex 2b:	
Feasibility tool: Specific sections	125
Annex 3	
Consultation on barriers and opportunities for improved access to medical devices by technology transfer and local production.	133

Acknowledgements

Local production and technology transfer to increase access to medical devices: Addressing the barriers and challenges in low- and middle-income countries is the result of collaboration between the Department of Public Health Innovation and Intellectual Property, and the Medical Devices Unit of the Essential Medicines and Health Products Department of the World Health Organization (WHO). The project is in the context of the *Global strategy and plan of action on public health innovation and intellectual property*. The report was developed and completed from January to June 2012, and was supported with funding from the European Union under EU Agreement PP-AP/2008/172-129. Thanks to Kees de Joncheere, Zafar Ullah Mirza and Robert Terry for guidance and support through the project.

The report was written under the supervision of Adriana Velazquez Berumen, Coordinator, Medical Devices Unit, with the contribution of the following people: Clara Aranda, Jennifer Barragan, Geoffrey Graham, Dr Heike Hufnagel, Einstein A. Kesi, Dr Jitendar K. Sharma, Dr Ricardo Martinez, Albert Poon, Dr Niranjana Khambete, Victoria Gerrard, and support from the following interns: Luz Elena Aguirre Algara, John Akrofi, Dan Azagury, Ashley Crasto, Carolina Lourenco, Cai Long, Matt Kukla, Richard Mudd, Shreesh Naik, Hamza Obaid, Xiaoyu Nie, Xuedan Yuan, Bryan Ranger and Rahul Rekhi.

Thanks to Clara Aranda, Ajanthy Gaya Arasaratnam, Geoffrey Graham, Dr Heike Hufnagel, Dr Ricardo Martinez and Dr Jitendar K. Sharma for their editing.

Thank you to all the participants of the Survey on Access to Medical Devices, as listed in the survey annex.

Thank you also to Einstein A. Kesi, Tony Easty, Rebeca Richards-Kortum, K. Siddique-e Rabbani, Samantha O'Keefe, Howard Weinstein, Gregory Dajer and Rick Kearns for providing case studies to test the medical devices feasibility tool.

We are also grateful to the advisers and participants of the stakeholder meeting convened on 4–5 June, 2012 in Geneva, Switzerland. Participants included: clinical engineers from ministries of health: Nicholas Adjabu (Ghana) and Sam Wanda (Uganda); representatives of innovators in academic institutions: Aya Caldwell, Victoria Gerrard (Singapore); Einstein A. Kesi, Dr Niranjana Khambete, Professor Anuraq Mairal, Dr K. Siddique-e Rabbani; representatives from nongovernmental organizations: John Anner, Rick Kearns, Jorge Ernesto Odon, Howard Weinstein; technical advisers: Clara Aranda, Michael Cheng, Dr Heike Hufnagel, Albert Poon, Dr Jitendar K. Sharma; United Nations organizations: Dr Lutz Mailander (WIPO), Dr Helene Moller (UNICEF), João Paulo (UNCTAD), Ermias Tekeste Biadgleng (UNCTAD); WHO Regional Offices: Dr Adham Ismail (EMRO); WHO headquarters: Dr Kees de Joncheere, Dr Peter Beyer, Dr Mario Meriardi, Francis G. Moussy, Dr Clive Ondari, Robert Terry, Adriana Velazquez-Berumen, Ajanthy Gaya Arasaratnam, Rahul Rekhi, Bryan Ranger, Hamza Obaid,

John Akrofi, Luz Elena Aguirre Algara, Catherine Shih, Shreesh Naik, Jonathan Darrow, and Matthew Novak. Participation via teleconference with Diana Calva from Mexico and Howard Weinstein from Brazil; observers and representatives from medical devices trade associations DITTA and GMTA: Christine Muzel, Tatjana R. Sachse, Maurizio Suppo and Jennifer Brant.

We would also like to thank Chandrika Rahini John, Gudrun Ingolfsdottir, Karina Reyes Moya for administrative support throughout the project.

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_28565

