



International Cooperation for Registration of Medicines

Opportunities for India

ALI MEHDI, VASUDHA WATTAL, PALLAVI JOSHI, AASHNA ARORA

2017 • PB • 8½ X 11 • 84P
ISBN 13: 9789332704251
Rs. 1295; US\$ 69.95

Published by :



ACADEMIC FOUNDATION

4772 / 23 Bharat Ram Road, (23 Ansari Road), Darya Ganj, New Delhi - 110 002, India.

Tel: +91-11-23245001 / 02 / 03 / 04.

Fax: +91-11-23245005.

e-mail: booksaf@gmail.com

website: www.academicfoundation.org

and

INDIAN COUNCIL FOR RESEARCH ON INTERNATIONAL ECONOMIC RELATIONS (ICRIER)

Core 6A, 4th Floor India Habitat Centre, Lodhi Road, New Delhi 110003

ABOUT THE BOOK:

To tackle the rising burden of disease, disability and premature deaths, the demand for newer and better treatment is more than ever. Drug registration is a critical step for the introduction of medicines in a country. There has been a great deal of international interaction and cooperation in the area of public health, particularly since the conception of the Millennium Development Goals. However, international cooperation vis-à-vis mechanisms to achieve shared goals of public health are still very limited. Regulation of drugs, more specifically drug registration, is one such neglected area. This report, the first-of-its-kind, based on extensive desk and field research in 4 Indian states—Maha-rashtra, Karnataka, Gujarat and Telangana—and 7 countries—USA, UK, Switzerland, Germany, South Africa, Singapore and Indonesia—incorporates views of more than 150 stakeholders to identify lessons as well as opportunities for the Government of India in its effort to address challenges of drug regulation in particular, and public health more generally, in the country.

PRAISE FOR THE BOOK:

“Through a thoughtful review of various countries’ drug registration procedures, this report summarizes international cooperation initiatives, and various opportunities critical in reestablishing India as a leader in pharmaceutical development. This report will be vital for government and private sector efforts to modernize India’s drug registration processes.”

— **Mark Barnes, J.D., LL.M**

Barbara Bierer, M.D.,

Multi-Regional Clinical Trials Center of Brigham and Women’s Hospital and Harvard University

“This is an excellent and timely report from an expert group that should be very useful to the Indian government as it considers possible improvements in its systems for review and approval of drug products.”

— **Richard Kingham**

Senior Counsel of Covington & Burling LLP in Washington, DC,

and London and Adjunct Professor at the Georgetown University Law Centre

CONTENTS

List of Tables, Figures and Appendix

List of Abbreviations

Foreword

Acknowledgements

Executive Summary

1. Introduction

1.1 Importance of the Subject—Rationale

1.2 Major Pathways of International Cooperation for Registration of Medicines

1.3 Need for India to Respond from a Public Health Perspective

2. Research Methodology

3. Analysis of Drug Registration Procedures and International Cooperation Initiatives

3.1 India

3.2 United States

3.3 Europe

3.4 ASEAN

3.5 South Africa

4. Cross-Country Implications for Stakeholders

4.1 Public Health

4.2 Regulator

4.3 Industry

5. A Game Theoretic Approach to Understanding International Cooperation

6. Policy Recommendations

6.1 International Cooperation

6.2 Drug Registration Procedures: Dossier Submission and Review

6.3 Addressing Additional Gaps

7. Conclusion

*Appendix
Bibliography*

TEAM LEADER:

Ali Mehdi established and leads the Health Policy Initiative at ICRIER. His research interests include—the process, design and assessment of health policies; prevention of chronic diseases along with policy instruments and institutional design for its promotion; social determinants of health; metrics of health inequities; health financing, governance and manpower; fertility and mortality; demographic dividend; drug regulation. A couple of his books are in the pipeline—India Health Report 2018 (Oxford University Press), A Shot of Justice (2 volumes) (Oxford University Press), Chronic Diseases in South Asia (Springer), Freedoms and Fragility: The Challenge of Job Creation in Kashmir, India (Routledge). Ali did his MA at the University of Freiburg, Germany and completed his PhD at Humboldt University in Berlin. He can be reached at amehdi@icrier.res.in.

AUTHORS:

Vasudha Wattal is a Research Associate at ICRIER, and has been associated with the Health Policy Initiative since its inception in 2014. She is specifically involved in the drug regulatory project and has contributed to various publications developed under this research program. She has also co-authored a number of opinion pieces and journal articles on several policy issues such as drug regulation, economics of drug pricing and air pollution. Her research interests include, economics of competition, economics of health and behavioural economics. Vasudha holds a Masters and an M.Phil. Degree in Economics.

Pallavi Joshi is a Research Associate at ICRIER, and is working on governance and regulatory aspects of healthcare sector and pharmaceutical industry, for publications under Health Policy Initiative. Previously, she has worked with Competition Commission of India, where she was involved in analysing competition issues in various sectors, in particular—healthcare sector, and pharmaceutical industry. She has also worked with Standard & Poor’s Capital IQ, a business research firm. Her core areas of interest include development economics, health economics, pharmaceutical regulation, behavioural economics, and competition law. She holds a Masters degree in Economics.

Aashna Arora is a Consultant at ICRIER under the Health Policy Initiative. Her interest areas include health economics, environmental economics, trade and economics, public policy and ethics in policymaking. She has a passion to work for policy oriented research on issues that impact public health and access to health and medicines in India. Previously, she has worked at KPMG as a Business Associate in the Research, Analysis and Knowledge unit and interned with the Ministry of Health and Family Welfare. She holds a Masters degree in Economics.

ORDER FORM

To,

**Academic Foundation,
4772-73 / 23 Bharat Ram Rd.
(23 Ansari Road), Darya Ganj,
New Delhi - 110 002. INDIA.**

Tel : 23245001 / 02 / 03 / 04.
Fax : 011-23245005.
e-mail: books@academicfoundation.com
www.academicfoundation.com

Dear Sir,
Please supply at the address mentioned alongside, your publications as listed in the enclosed sheet with their respective quantities as specified by us. (List to be enclosed by the buyer).

Discount applicable
to educational / research institutions :
10% on below 5 copies
15% on 5 copies & above

Note: Only 'US Dollar Price' applicable for copies to be shipped outside the Indian subcontinent.

Box-packing & courier delivery FREE (within India). Outside India: No extra charge for ordinary surface mail delivery. For express delivery by air, add USD 15.00 extra, per copy. **PAYMENT TERMS:** Full payment in ADVANCE by Banker’s Cheque / Demand Draft in favour of **Academic Foundation payable at Delhi** For cheques payable outside Delhi, kindly add Rs. 100 (INR) or USD 5.00 to the final amount.

Accordingly, enclosed please find our payment:

Demand Draft / Cheque No.
Dated..... amounting to
favouring **Academic Foundation** and preferably payable at Delhi.

Books to be sent at the following address :

NAME.....
DESIG.
DEPT.
ORG.
ADDRESS
CITY.....
STATE.....
PIN..... COUNTRY.....
TEL
FAX.....
E-MAIL