

International Political Economy Series

# The New Political Economy of Pharmaceuticals

Production, Innovation and TRIPS in the Global South

Edited by

Hans Löfgren and Owain David Williams



# The New Political Economy of Pharmaceuticals

Production, Innovation and TRIPS in the  
Global South

Edited by

Hans Löfgren

*Associate Professor, School of Humanities and Social Sciences, Deakin University, Australia*

and

Owain David Williams

*Research Fellow, Centre for Health and International Relations, Aberystwyth University, UK*



palgrave  
macmillan



Editorial matter, selection, introduction and conclusion © Hans Löfgren and Owain David Williams 2013

Individual chapters © Respective authors 2013

All rights reserved. No reproduction, copy or transmission of this publication may be made without written permission.

No portion of this publication may be reproduced, copied or transmitted save with written permission or in accordance with the provisions of the Copyright, Designs and Patents Act 1988, or under the terms of any licence permitting limited copying issued by the Copyright Licensing Agency, Saffron House, 6–10 Kirby Street, London EC1N 8TS.

Any person who does any unauthorized act in relation to this publication may be liable to criminal prosecution and civil claims for damages.

The authors have asserted their rights to be identified as the authors of this work in accordance with the Copyright, Designs and Patents Act 1988.

First published 2013 by  
PALGRAVE MACMILLAN

Palgrave Macmillan in the UK is an imprint of Macmillan Publishers Limited, registered in England, company number 785998, of Houndmills, Basingstoke, Hampshire RG21 6XS.

Palgrave Macmillan in the US is a division of St Martin's Press LLC, 175 Fifth Avenue, New York, NY 10010.

Palgrave Macmillan is the global academic imprint of the above companies and has companies and representatives throughout the world.

Palgrave® and Macmillan® are registered trademarks in the United States, the United Kingdom, Europe and other countries.

ISBN 978–0–230–28463–0

This book is printed on paper suitable for recycling and made from fully managed and sustained forest sources. Logging, pulping and manufacturing processes are expected to conform to the environmental regulations of the country of origin.

A catalogue record for this book is available from the British Library.

A catalog record for this book is available from the Library of Congress.

## *International Political Economy Series*

Series Editor: **Timothy M. Shaw**, Visiting Professor, University of Massachusetts Boston, USA, and Emeritus Professor, University of London, UK

The global political economy is in flux as a series of cumulative crises impacts its organization and governance. The IPE series has tracked its development in both analysis and structure over the last three decades. It has always had a concentration on the global South. Now the South increasingly challenges the North as the centre of development, also reflected in a growing number of submissions and publications on indebted Eurozone economies in Southern Europe.

An indispensable resource for scholars and researchers, the series examines a variety of capitalisms and connections by focusing on emerging economies, companies and sectors, debates and policies. It informs diverse policy communities as the established trans-Atlantic North declines and 'the rest', especially the BRICS, rise.

### *Titles include:*

Caroline Kuzemko

THE ENERGY SECURITY-CLIMATE NEXUS

Hans Löfgren and Owain David Williams (*editors*)

THE NEW POLITICAL ECONOMY OF PHARMACEUTICALS

Production, Innovation and TRIPS in the Global South

Timothy Cadman (*editor*)

CLIMATE CHANGE AND GLOBAL POLICY REGIMES

Towards Institutional Legitimacy

Ian Hudson, Mark Hudson and Mara Fridell

FAIR TRADE, SUSTAINABILITY AND SOCIAL CHANGE

Andrés Rivarola Puntigliano and José Briceño-Ruiz (*editors*)

RESILIENCE OF REGIONALISM IN LATIN AMERICA AND THE CARIBBEAN

Development and Autonomy

Godfrey Baldacchino (*editor*)

THE POLITICAL ECONOMY OF DIVIDED ISLANDS

Unified Geographies, Multiple Polities

Mark Findlay

CONTEMPORARY CHALLENGES IN REGULATING GLOBAL CRISES

Nir Kshetri

CYBERCRIME AND CYBERSECURITY IN THE GLOBAL SOUTH

Kristian Stokke and Olle Törnquist (*editors*)  
DEMOCRATIZATION IN THE GLOBAL SOUTH  
The Importance of Transformative Politics

Jeffrey Wilson  
GOVERNING GLOBAL PRODUCTION  
Resource Networks in the Asia-Pacific Steel Industry

---

**International Political Economy Series**

**Series Standing Order ISBN 978-0-333-71708-0 hardcover**

**Series Standing Order ISBN 978-0-333-71110-1 paperback**  
(outside North America only)

You can receive future titles in this series as they are published by placing a standing order. Please contact your bookseller or, in case of difficulty, write to us at the address below with your name and address, the title of the series and the ISBN quoted above.

Customer Services Department, Macmillan Distribution Ltd, Houndmills, Basingstoke,  
Hampshire RG21 6XS, England

---

# Acknowledgements

We are grateful for comments and high-quality copy-editing by Alison Caddick, Crissene Fawcett and Michael Leahy, and to Colleen Keane for her fine proof-reading. We are also thankful to Palgrave Macmillan for their support and professionalism. Hans Löfgren would like to acknowledge financial support from the Centre for Citizenship and Globalisation, Deakin University. Owain David Williams' time and research were made possible through funding from the European Research Council under the European Community's Seventh Framework Programme – Ideas Grant 230489 GHG. All views expressed remain those of the contributors, to whom we are indebted for their critical and constructive engagement with the themes and problems addressed in this volume.

# Contributors

**Zaheer-Ud-Din Babar** is a senior lecturer and Head of Pharmacy Practice, School of Pharmacy, University of Auckland, New Zealand.

**Sudip Chaudhuri** is Professor of Economics, Indian Institute of Management Calcutta, India.

**Anwarul-Hassan Gilani** is the Noor Mohamed Shamji Professor of Pharmacology, Department of Biological and Biomedical Science, Aga Khan University, Karachi, Pakistan.

**Andrew L. Gray** is a senior lecturer in the discipline of pharmaceutical sciences, University of KwaZulu-Natal, Durban, South Africa.

**Mohamed Azmi Hassali** is an associate professor and Programme Chair for Social and Administrative Pharmacy, School of Pharmaceutical Science, Universiti Sains Malaysia.

**Chee-Ruey Hsieh** is a research fellow in the Institute of Economics, Academia Sinica, Taipei, Taiwan.

**Richard Husada** is a senior lecturer at Universitas Surabaya, Indonesia.

**Dina Iskander** works for Oxfam Novib as the Policy and Campaigning Officer for Egypt and Yemen, based in Cairo.

**Shazia Qasim Jamshed** is an assistant professor at the International Islamic University, Kuantan, Malaysia.

**Hye-young Kwon** is a pharmacist and PhD in health economics at the Seoul National University.

**Hans Löfgren** is an associate professor in the School of Humanities and Social Sciences, Deakin University, Melbourne, Australia.

**Muhammad Ashar Malik** is a senior instructor in the Department of Community Health Sciences, Aga Khan University, Karachi, Pakistan.

**Shankaran Nambiar** is a professor in the School of Business at Manipal International University, Kuala Lumpur, Malaysia.

**Jens Plahte** holds a PhD in economic geography. His dissertation was on the Cuban biotechnology sector. He operates a consultancy business in Oslo, Norway.

**Simon Reid-Henry** is a lecturer in geography at Queen Mary, University of London.

**Asrul Akmal Shafie** is Associate Professor of Social and Administrative Pharmacy, Universiti Sains Malaysia.

**Cassandra M. Sweet** is Assistant Professor of Public Policy, the Institute of Political Science, PUC, Santiago, Chile.

**Jayabalan Thambyappa** is a member of the Governing Council of Health Action International, a Technical Committee member of the Malaysian Health Promotion Board and a member of the Academy of Occupational and Environmental Medicine, Malaysia.

**Raymond R. Tjandrawinata** is the executive director of Dexa Laboratories of Biomolecular Sciences (DLBS), Tangerang, Indonesia.

**Yousuf A. Vawda** is Professor of Law at the University of KwaZulu Natal, South Africa.

**Ipek Eren Vural** is Assistant Professor of Political Science in the Department of Political Science and Public Administration, Middle East Technical University (METU), Ankara, Turkey.

**Owain David Williams** is a research fellow in the Centre for Health and International Relations, Aberystwyth University, Wales.

**Bong-min Yang** is Professor of Health Economics, School of Public Health at the Seoul National University, South Korea.

# Acronyms and Abbreviations

ACTA	Anti-Counterfeiting Trade Agreement
ACTD	ASEAN Common Technical Dossiers
AFTA	Asian Free Trade Area
AIDS	Acquired Immune Deficiency Syndrome
AIOCD	All Indian Origin Chemists & Distributors
ANVISA	Brazilian National Health Surveillance Agency
API	Active Pharmaceutical Ingredient
ARV	Anti-Retroviral Medicines
ASEAN	Association of Southeast Asian Nations
ASJII	<i>Asuransi Jiwa Inhealth Indonesia</i> (subsidiary PT of Askes)
Askes	<i>Asuransi Kesehatan</i> (Malaysian National Health Insurance scheme)
Askeskin	<i>Asuransi Kesehatan bagi para miskin</i> (scheme for free medication for the lowest-income groups through Askes)
BNDES	Brazilian National Development Bank
BPOM	<i>Badan Pengawas Obat dan Makanan</i> (see NAFDC)
BRIC	Brazil, Russia, India and China
CBD	Convention on Biological Diversity
CDSO	Central Drugs Standard Control Organization (India)
CECMED	Cuban National Drug Regulatory Agency
CESCR	International Covenant on Economic, Social and Cultural Rights
CIGB	Centre for Genetic Engineering and Biotechnology (Cuba)
CIM	Cuban Centre for Molecular Immunology
CIPHI	Commission on Intellectual Property Rights, Innovation and Public Health
CLs	Compulsory Licences
CMIE	Central Monitoring for Indian Economy
CMS	Cooperative Medical Scheme
CNS	Central Nervous System
CPT	Consumer Project on Technology
CQB	Cuban Centre for Biomolecular Chemistry
CRAMS	Contract Research and Manufacturing Services
CSDH	Commission on the Social Determinants of Health
CVS	Cardio Vascular System
DAF	Department of Pharmaceutical Assistance and Strategic Raw Materials
DBF	Dedicated Biotechnology Firm

DNDi	Drugs for Neglected Diseases Initiative
DOEN	<i>Daftar Obat Esensial Nasional</i> (see NELM)
DPHO	<i>Daftar Plafon Harga Obat</i> (list and ceiling of drug prices – Malaysia)
EC	European Commission
ECU	European Customs Union
EFPIA	European Federation of Pharmaceutical Industries and Associations
EGF	Epidermal Growth Factor
EIPICO	Egyptian International Pharmaceutical Industries Company
EPC	European Patent Convention
EU	European Union
EUPI	Employers Union of the Pharmaceutical Industry
FAO	UN Food and Agriculture Organization
FATA	Federally Administered Tribal Areas
FDA	United States Food and Drug Administration
FDI	Foreign Direct Investment
FTA	Free Trade Agreement
FTAA	Free Trade Area of the Americas
G8	Group of Eight
G20	Group of Twenty
GATT	General Agreement on Tariffs and Trade
GAVI	Global Alliance for Vaccines and Immunisation
GCP	Good Clinical Practice
GDP	Gross Domestic Product
GHG	Global Health Governance (literature/discipline of)
GHP	Global Health Partnership
GISN	Global Influenza Surveillance Network
GLI	Green Light Committee Initiative
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GNI	Gross National Income
GSP	General System of Preferences
HAI	Health Action International
HCV	Hepatitis C Virus
HFA	Health for All
HHI	Herfindahl-Hirschman Index
HIV	Human Immunodeficiency Virus
HNP	Health, Nutrition and Population Partnership
HPTF	Health Policy Task Force
IAVI	International AIDS Vaccine Initiative
ICH	International Commission on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

IDR	Indonesian Rupiah
IDSC	Information and Decision Support Centre
IEIS	Pharmaceutical Manufacturing Association of Turkey
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IIPA	International Intellectual Property Alliance
IMC	Industrial Modernisation Centre (Egypt)
IMD	Incrementally Modified Drugs
IMF	International Monetary Fund
IMPACT	International Medical Counterfeiting Taskforce
IMR	Infant Mortality Rate
INN	International Non-proprietary Name
INPI	Brazilian Patent Office
IP	Intellectual Property
IPC	Intellectual Property Committee
IPE	International Political Economy
IPO	Intellectual Property Organization
IPR	Intellectual Property Rights
IR	International Relations
ISI	Import Substitution Industrialisation
ISO	International Standards Organization
Jamkesmas	<i>Jaminan Kesehatan Masyarakat</i> (social health security network – Malaysia)
KFDA	Korea Food and Drug Administration
KIPO	Korea Intellectual Property Office
KODC	Korea Orphan Drug Centre
KOR-US FTA	Korea-US Free Trade Agreement
KRW	Korean Won
LAS	Laboratory for Synthetic Antigens
LDC	Least Developed Country
LMIC	Low to Middle Income Country
M&As	Mergers and Acquisitions
MCC	Medicines Control Council
MDG	Millennium Development Goal
MFA	Multi-Fibre Agreement
MFN	Most Favoured Nation
MMV	Medicines for Malaria Venture
MNC	Multinational Corporation
MoH	Ministry of Health
MOPI	Malaysian Organization of Pharmaceutical Industries
MRP	Maximum Retail Price
MSF	Médecins sans Frontières
NAFDC	National Agency of Food and Drug Control (Malaysia)
NAFTA	North American Free Trade Agreement

NBE	New Biological Entity
NCD	Non-Communicable Disease
NCE	New Chemical Entity
NCMS	New Cooperative Medical Scheme
NEDL	National Essential Drugs List
NELM	National List of Essential Medicine (Malaysia)
NGO	Non-Governmental Organization
OECD	Organisation for Economic Cooperation and Development
OGB	<i>Obat Generik Berlogo</i> (unbranded generic medicines – Malaysia)
ONIITEM	Cuban National Office of Inventions and Trademarks
OTC	Over-the-Counter (medicines)
PCT	Patent Cooperation Treaty
PDP	Product Development Partnership
PEPFAR	President's Emergency Plan for AIDS Relief
PhRMA	Pharmaceutical Research and Manufacturers of America
PIC/S	The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme
PLT	Patent Law Treaty
PPMA	Pakistan Pharmaceutical Manufacturers Association
PPO	Pakistan Patent Office
R&D	Research and Development
RM	Malaysian Ringgit
SAAFTA	South Asian Free Trade Agreement
SAARC	South Asian Association of Regional Cooperation
SAC	Supreme Administrative Court
SACU	Southern African Customs Union
SAGMA	Southern African Generics Medicines Association
SIPO	State Intellectual Property Office of China
SJSN	National Social Security System – Indonesia
SPLT	Substantive Patent Law Treaty
Super 301	Section 301 of the US Trade Act of 1974
SUS	Sistema Única de Saúde (Brazilian healthcare system)
TAC	Treatment Action Campaign
TAN	Transnational Advocacy Networks
TB	Tuberculosis
TCM	Traditional Chinese Medicine
TNC	Transnational Corporation
TPI	Turkish Patent Institute
TPP	Trans-Pacific Partnership Agreement
TRIPS	Trade Related Aspects of Intellectual Property Rights
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development

UNDP	United Nations Development Programme
UNESCO	United Nations Educational Scientific and Cultural Organization
UNFPA	United Nations Population Fund
UNICEF	United Nations International Children's Emergency Fund
UPOV	International Union for the Protection of New Varieties of Plants Convention
USAID	United States Agency for International Development
USMFTA	US–Malaysia Free Trade Agreement
USTR	Office of the United States Trade Representative
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

# Contents

<i>List of Tables and Figures</i>	vii
<i>Acknowledgements</i>	ix
<i>Notes on Contributors</i>	x
<i>List of Acronyms and Abbreviations</i>	xii
1 The New Political Economy of Pharmaceuticals: Conformity and Resistance in the Global South <i>Owain David Williams and Hans Löfgren</i>	1
2 The Political Economy of Pharmaceutical Production in Brazil <i>Cassandra M. Sweet</i>	29
3 Pharmaceuticals, Health Policy and Intellectual Property Rights in China <i>Chee-Ruey Hsieh</i>	48
4 Immunity to TRIPS? Vaccine Production and the Biotechnology Industry in Cuba <i>Jens Plahte and Simon Reid-Henry</i>	70
5 TRIPS and Access to Medicines in Egypt <i>Dina Iskander</i>	91
6 The Pharmaceutical Industry in India after TRIPS <i>Sudip Chaudhuri</i>	111
7 The Healthcare System and the Pharmaceutical Industry in Indonesia <i>Richard Husada and Raymond R. Tjandrawinata</i>	134
8 TRIPS, Free Trade Agreements and the Pharmaceutical Industry in Malaysia <i>Mohamed Azmi Hassali, Jayabalan Thambyappa, Shankaran Nambiar, Asrul Akmal Shafie and Hans Löfgren</i>	152
9 The Pharmaceutical Industry, Intellectual Property Rights and Access to Medicines in Pakistan <i>Zaheer-Ud-Din Babar, Shazia Qasim Jamshed, Muhammad Ashar Malik, Hans Löfgren and Anwarul-Hassan Gilani</i>	167

10	TRIPS, Access to Medicines and Local Production in South Africa <i>Andrew L. Gray and Yousuf A. Vawda</i>	185
11	TRIPS and New Challenges for the Pharmaceutical Sector in South Korea <i>Bong-min Yang and Hye-young Kwon</i>	204
12	Neoliberalism, Intellectual Property Rights and the Turkish Pharmaceutical Industry in the 2000s <i>Ipek Eren Vural</i>	221
13	Conclusion: TRIPS, Drug Production in the Global South and Access to Medicines <i>Hans Löfgren and Owain David Williams</i>	246
	<i>Index</i>	251

# Tables and Figures

## Tables

2.1	Application of TRIPS changes to Brazilian IPR law	32
3.1	Health and economic indicators in China, 1978–2008	51
3.2	Market share of different drug types in China	58
3.3	Concentration indices of the pharmaceutical market in China	59
3.4	Selected indicators of the Chinese pharmaceutical industry by sector, 1997	60
3.5	Comparisons of R&D capability in China, US and Europe	61
3.6	Total production value of the Chinese pharmaceutical industry by type of products (in billions of RMB)	62
3.7	Ownership structure in China's pharmaceutical industry	65
3.8	Pattern of trade in the Chinese pharmaceutical sector (in billions of US\$)	66
4.1	Vaccines marketed by Cuban manufacturers	82
6.1	M&As and tie-ups in Indian pharmaceutical industry, 2006–2010	113
6.2	Patent status of new drugs marketed in India, 1995–2010	117
6.3	Market structure of new drugs, 2010	118
6.4	New drugs marketed by MNCs, 2010	119
6.5	Prices of MNC monopoly drugs	121
12.1	Overview of pharmaceutical IPR in Turkey	225
12.2	Transnational entry and acquisitions in the Turkish pharmaceutical market, 1999–2011	234
12.3	Pharmaceutical imports and exports, 1980–2010, in US\$ million	236
12.4	Percentage of imported and locally produced pharmaceuticals in the Turkish pharmaceutical market, 2005–2010	237

## Figures

2.1	Trends in trade: Brazil's pharmaceutical import and trade balance, 2005–2011	41
3.1	Number of foreign pharmaceutical patents in China, 1985–2006	50
3.2	Sources of healthcare financing in China, 1978–2008	53
3.3	Percentage of health expenditure spent on pharmaceuticals	55

3.4	Drug expenditure as a percentage of GDP in China, 1990–2008	57
3.5	Pharmaceutical price index, 1990–2005	64
10.1	Percentage private sector market share by volume (packs), 2006–2010, based on year to September data	198
10.2	Percentage private sector market share by value (single exit price), 2006–2010, based on year to September data	199
11.1	South Korea's pharmaceutical industry outputs	214
11.2	Changes in proportions of over-the-counter and prescription-only medications, 1995–2007	215
11.3	Percentage of foreign manufactures in numbers and in drug expenditure, 2002–2005	216
11.4	Share of generic drugs in pharmaceutical expenditure (quantity, value)	217
12.1	Total public health and drug expenditures, 2002–2010, in US\$ million	231
12.2	Turkish prescription market sales, 2003–2010, in US\$ billion	232
12.3	Turkish prescription market sales, 2003–2010, in volume of million boxes	232
12.4	Pharmaceutical patent applications to the Turkish Patent Institute, 2004–2010	239