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978-1-107-07273-2 - Trade, Investment, Innovation and their Impact on Access to Medicines:

An Asian Perspective

Locknie Hsu

Excerpt

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Economic integration, Asia and medicines

1.1 Introduction – globalization and Asia

1.1.1 Asia in the twenty-first century

The last two decades have seen great economic change in many Asian states. Many have emerged from the post-World War II (and postcolonial) era to establish relatively successful economic and legal infrastructures. They have, to different extents, taken advantage of the globalization of supply chains and trade liberalization trends to become global providers (and consumers) of a variety of raw materials, processing input and finished goods. Many Asian states attract and host large numbers of transnational corporations that trade in goods and services due to the availability of labour (skilled and unskilled), land, physical and technological infrastructure, or a combination of these. Asian states are, with few exceptions, World Trade Organization (WTO) members and therefore participants in multilateral efforts at dismantling trade barriers. In the context of this book, the focus will be mainly on states making up the Association of Southeast Asian Nations (ASEAN) and their major trade partners, namely China, India, Korea and Japan.

With China joining the WTO in 2001, the number of people represented at the organization immediately grew by 1.5 billion, covering 97% of the world population.¹ The domestic economic reforms brought about by the entry of this economic juggernaut into the multilateral scheme of trade rules have helped to fuel trade and investment not only in China, but also in those countries that trade with it. India has developed into an economic powerhouse in parallel, with a series of significant economic reforms in the 1990s.²

¹ WTO, *Doha Declarations*, opening page, available at: www.wto.org/english/res_e/booksp_e/ddec_e.pdf (accessed 25 May 2015).

² See Shalendra D. Sharma, *China and India in the Age of Globalization* (Cambridge University Press, 2009).

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Within ASEAN, more recently, political and economic reforms occurring in Myanmar have led to a great deal of trade and investment interest in the country. More broadly, ASEAN is in the process of an ambitious regional integration exercise – the formation of an ASEAN Economic Community (AEC). This will see the formation of a single market and production base in a region with a 600-million strong population. The process began in earnest as early as in 1992, when ASEAN members resolved to establish an ASEAN Free Trade Area (AFTA). Since then, ASEAN has actively sought further integration on three fronts – economic, political-security and socio-cultural – with a target of establishing the ASEAN Economic Community (AEC) by the end of 2015.

At the WTO, a number of Asian states have become regular users of the WTO dispute settlement system – both as claimants and as respondents – including China and India. As one of two economic “powerhouses” with large economies in Asia, India has been active both in treaty and policy debate work in the area of trade. In particular, India has been emerging as a significant pharmaceutical producer, hosting a number of generic drug manufacturers and stoutly defending flexibilities under the WTO Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which allows members a certain amount of leeway in regulating pharmaceutical products.

The vexed question of access to affordable healthcare and medicines affects many countries, with those in Asia being no exception. A confluence of factors heightens the urgency of dealing with this question in Asia.

First, most countries in Asia are members of the WTO’s multilateral rules system. Apart from the trade liberalization work at the WTO, there has been a rapid emergence of free trade agreements (FTAs) in many Asian countries. FTA activity in Asia has been spurred in part by the interest of the US and EU, and by intra-Asia arrangements.³ ASEAN’s

³ The interest of the US in Asia was demonstrated during the administration of former US president George W. Bush. In 2002, about a year after taking office, Bush visited Asia twice in four months. The visit covered China, South Korea and Japan; see <http://fpc.state.gov/documents/organization/9185.pdf>. President Obama – continuing with the declared “pivot” to Asia – visited Southeast Asia recently during his second term in office, in November 2012, when he visited Myanmar amidst its implementation of various reform plans, as well as Cambodia and Thailand. The Bush Administration used the Trade and Investment Framework Agreement (TIFA) approach to trade and investment negotiations with Asia, as a preparatory step towards creating treaty arrangements with more concrete liberalization commitments. The US has signed TIFAs with ASEAN as a whole, and with Brunei Darussalam, Cambodia, Indonesia, Malaysia, Myanmar, the Philippines, Thailand and Vietnam. The US signed an FTA with Singapore in 2001. The EU, too, has separately

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individual members have been involved in a number of bilateral FTAs, and ASEAN itself has also entered into FTAs with several external trade partners. Some of these FTAs carry significant implications for trade in pharmaceutical products. At the moment, ASEAN is negotiating with six of these partners to form a Regional Comprehensive Economic Partnership (RCEP). Beyond ASEAN, Northeast Asian countries – China, Korea and Japan – are presently in negotiations for an FTA. In South Asia, India has also signed a number of bilateral FTAs and is currently negotiating one with the EU. Several Asian states, including Brunei Darussalam, Malaysia, Singapore and Vietnam, have been engaged in negotiations for the Trans-Pacific Partnership Agreement (TPP).⁴ According to the WTO, Asian members have been the most active participants in FTA negotiations.⁵

Secondly, rapidly aging populations and rising health costs in many parts of Asia – not necessarily all with high economic levels – are placing greater demands on healthcare systems. These factors contribute to increasing attention being paid to pressing healthcare needs and costs.⁶ The availability of affordable healthcare and pharmaceuticals for the aged and those requiring long-term medication will increasingly be a priority issue that Asian states have to handle, in order to meet domestic expectations and needs.

With ongoing economic integration, what are the implications for trade in pharmaceutical goods in Asia – is such trade affected adversely or positively? This is an important question as pharmaceutical companies look to Asia for growth opportunities and, in doing so, seek to influence the paradigm of regulatory rights over their products.⁷

embarked on trade and investment negotiations with ASEAN, with the result of completed negotiations for a bilateral FTA so far with Singapore; see generally, EU, available at: <http://ec.europa.eu/trade/policy/countries-and-regions/countries/singapore/> (accessed 19 March 2015).

⁴ The other eight negotiating parties are Australia, Canada, Chile, Japan, Mexico, New Zealand, Peru and the United States. In early October 2015, the parties announced that negotiations had been successfully concluded and that the TPP had been signed; next steps will include ratification and implementation by the parties.

⁵ WTO, *World Trade Report 2011*, p. 57; see also WTO Press Release, *Asia is at the Leading Edge of New Trade Pacts, Says World Trade Report 2011* (27 July 2011), available at: www.wto.org/english/news_e/pres11_e/pr635_e.htm (accessed 4 September 2014).

⁶ See J. Menon and A. C. Melendez, *Aging in Asia, Trends, Impacts and Responses*, *ASEAN Economic Bulletin*, Vol. 26, No. 3 (2009), 293–305. See also www.imf.org/external/pubs/ft/wp/2006/wp06272.pdf; www.adb.org/sites/default/files/economics-wp281.pdf.

⁷ For an overview of globalization and the pharmaceutical industry, see Claudio Casadio Tarabusi and Graham Vickery, *Globalization in the Pharmaceutical Industry*, Parts I

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1.2 Aging Asia: healthcare needs

In a list of ten “mega-trends” in global healthcare identified by the *Harvard Business Review*, aging populations have been named as one of the phenomena which are set to overwhelm healthcare systems.⁸

Asia’s populations, as part of this global phenomenon, face healthcare challenges in light of aging, increased life expectancies and expectations of healthcare (see Table 1.1). These have a significant impact on adequacy of healthcare infrastructures and on healthcare costs. In China alone, the number of persons expected to be 60 years or older by 2050 is 437 million.⁹ In Southeast Asia’s largest country, Indonesia, the figure is 70 million.

As of 2000, an estimated 53% of the world’s oldest persons live in Asia, with this percentage expected to increase further by 2050. Table 1.2 elaborates on this increase.

In terms of absolute numbers, by 2050, the number of persons 60 years or older in China will be 437 million, and in India 324 million. Even in tiny Singapore – with one of the most rapidly aging populations in Asia – it would be about 1.7 million.¹⁰ China reportedly has 185 million elderly (those over 60), with an estimated 34% of the population being elderly by 2050.¹¹ The percentage growth of persons aged 65 and above between 2000 and 2050 is estimated to be a staggering 314%.¹² With *more than half* of the world’s aging population already living in Asia, healthcare

and II, *Int. J. Health Serv.*, Vol. 28, No. 1 (1998), 67–105; and *Int. J. Health Serv.*, Vol. 28, No. 2 (1998), 281–303.

⁸ Karen Dillon and Steve Prokesch, Megatrends in Global Healthcare, *Harvard Business Review*, available at: <http://hbr.org/web/extras/insight-center/health-care/globaltrends/1-slide> (accessed 16 June 2014).

⁹ United Nations, *World Population Aging 2000–2050*, Chapter 2, *Magnitude and Speed of Population Aging* p. 11. See also, generally, *Asian Governments Must Find Strategies to Deal with Aging Populations*, *South China Morning Post* editorial, 13 October 2015, available at: www.un.org/esa/population/publications/worldageing19502050/pdf/119japan.pdf (accessed 13 October 2015).

¹⁰ United Nations, *World Population Aging 2000–2050*, Annex III, *Profiles of Aging*, available at: www.un.org/esa/population/publications/worldageing19502050/countriesorareas.htm (accessed 13 October 2015). For Japan, those aged 60 and above in 2050 are expected to make up 42.3% of the population; see www.un.org/esa/population/publications/worldageing19502050/pdf/119japan.pdf (accessed 13 October 2015).

¹¹ See China Health and Retirement Longitudinal Study, available at: <http://charls.ccer.edu.cn/zh-CN>, and Charles Riley, *New Portrait of China’s 185 Million Seniors*, CNN, 31 May 2013 (accessed 28 June 2014); see <http://money.cnn.com/2013/05/31/news/economy/china-elderly/>.

¹² See *The Future of Population in Asia*, East West Center, Table 1 at p. 83, available at: www.eastwestcenter.org/fileadmin/stored/misc/FuturePop08Ageing.pdf (accessed 24 March 2014).

Table 1.1. *Asian life expectancy*

Country	Life expectancy ^a	Population (2010) ^b
Brunei Darussalam	78	401,000
Cambodia	63	14 m
Indonesia	69	240 m
Lao PDR	67	6.3 m
Malaysia	74	28 m
Myanmar	65	51 m
Philippines	69	93 m
Singapore	81	5 m
Thailand	74	66 m
Vietnam	75	89 m
China	73	1.3bn
India	65	1.2bn
Japan	83	127 m
Korea	81	48 m

Source: Compiled from United Nations data.
^a At birth, data for 2011, collated from <https://data.un.org/Data.aspx?d=SOWC&f=inID%3A97>.
^b Figures from UN, available at: <http://esa.un.org/wpp/Excel-Data/population.htm> (accessed 3 April 2015).

Table 1.2. *Estimated and projected population aged 60 years or over in Asia for 1970, 2000 and 2050, by percentage of world population*

Region	1970	2000	2050
Asia	45	53	63

Source: Excerpted by this author from Table 2 in Barry Mirkin and Mary Beth Weinberger, *The Demography of Aging* available at: www.un.org/esa/population/publications/bulletin42_43/weinbergermirkin.pdf (accessed 24 March 2014), who drew from the United Nations, *The Sex and Age Distribution of the World Populations; the 1998 Revision, Volume II: Sex and Age*. For a breakdown of figures within Asian countries, see Table 2A in Jayant Menon, *Aging in Asia: Trends, Impacts and Responses*, Asia Development Bank, Working Paper Series on Regional Economic Integration No. 25, February 2009.

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costs there – including pharmaceutical costs – can be expected to increase significantly in the coming years. As medical experts have observed:

The elderly are the main consumers of most types of medicines because they are affected by illness much more often than are young and middle-aged adults, and by a much wider range of illnesses, most notably those that reflect degeneration of central nervous, cardiovascular and musculoskeletal systems.¹³

The link between the cost of medicines and aging is therefore of great relevance in Asia, with its vast greying populations.

1.3 Diseases in Asia and the Pacific region

1.3.1 Communicable diseases

Communicable diseases in Asia include HIV/AIDS, tuberculosis and malaria.¹⁴ About 95% of HIV-positive people live in developing countries,¹⁵ while 90% of HIV-positive people in the Asia-Pacific region live in China, India, Indonesia, Thailand, Vietnam, Malaysia and Myanmar.¹⁶ New HIV infections in Indonesia alone increased 48% between 2005 and 2013.¹⁷ India accounts for 51% of AIDS-related deaths in the Asia-Pacific region.¹⁸ While AIDS-related mortality has declined in Cambodia, Thailand, India and Myanmar between 2005 and 2013, it has increased in the same period in Indonesia, Pakistan, Malaysia and Nepal.¹⁹ In Indonesia, the increase is particularly egregious – 427%.

¹³ See John P. Griffin, John Posner and Geoffrey R. Barker, eds., *The Textbook of Pharmaceutical Medicine*, 7th ed. (Wiley-Blackwell, 2013), at p. 151.

¹⁴ See WHO website information, available at: www.who.int/bulletin/volumes/88/3/09-065540/en/ (accessed 30 April 2014).

¹⁵ Para. 116, United Nations, Report of the Secretary-General, *Roadmap to towards the Implementation of the Millennium Development Goals*, A/56/3266 September 2001, available at: www.unmillenniumproject.org/goals/core_mdgs.htm and *AIDS Global Fact Sheet*, 20th International AIDS Conference, 20–25 July 2014, Melbourne, Australia, available at: www.aids2014.org/Default.aspx?pageId=712 (accessed 21 July 2014).

¹⁶ *Fact Sheet, HIV and AIDS in Asia and the Pacific*, 20th International AIDS Conference, 20–25 July 2014, Melbourne, Australia, available at: www.aids2014.org/Default.aspx?pageId=712 (accessed 21 July 2014).

¹⁷ UNAIDS, *Fact Sheet 2014*. See also John McBeth, Health Needs to Become Priority, *The Straits Times*, 23 August 2014, p. A41.

¹⁸ *Ibid.* ¹⁹ UNAIDS, *The Gap Report* (2014), pp. 60–62.

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As for treatment, only Cambodia and Thailand have 50% of all those with HIV on antiretroviral treatment.²⁰ In Indonesia, only about 8% of those affected have access to treatment.²¹ Notably, in 2013 the leading cause of death for HIV-positive people was tuberculosis.²²

Certain infectious diseases affecting particularly poor countries – including those in Asia – such as tuberculosis and malaria, have not, until relatively recently, been the target of pharmaceutical companies due to a lack of financial incentives. This has led to this group of diseases becoming known as “neglected tropical diseases”.²³ This lack of attention to such diseases has led to calls for more urgent research and development on drugs for such diseases.

Hepatitis C, a blood-borne viral disease that can lead to acute and chronic infection, is prevalent in Central and East Asia.²⁴ To compound the problem, there is often co-infection of this disease with HIV (e.g. through the sharing of needles in injected drug use) in parts of Asia.²⁵

1.3.2 Chronic diseases

Non-communicable, chronic diseases such as cardiovascular diseases, chronic respiratory diseases, diabetes and cancer are the main causes of death in the Southeast Asian region, causing as much as 55% of deaths, with 34% of such deaths being those of persons below the age of 60.²⁶

²⁰ Note 17 above. In Vietnam, changes are being made to the availability of ARV medicines; see Circular No. 32/2013/TT-BYT, available at: www.aseconnectvietnam.gov.vn/Law.aspx?ZID1=10&ID1=2&MaVB_id=2346 (accessed 11 October 2015) and generally, *HIV Aid to be Cut in 2017*, 22 August 2015, <http://vietnamnews.vn/society/274824/hiv-aid-to-be-cut-in-2017.html> (accessed 11 October 2015).

²¹ Note 19 above, p. 60. ²² Note 17 above.

²³ See *The Textbook of Pharmaceutical Medicine*, note 13 above, at p. 21.

²⁴ *WHO Fact Sheet*, available at: www.who.int/mediacentre/factsheets/fs164/en/ (accessed 23 August 2014). See also Chapter 8, in relation to Egypt and the use of differential and negotiated pricing.

²⁵ See International Harm Reduction Association and Eurasian Harm Reduction Network, available at: www.ihra.net/files/2013/05/11/HRI_ERHN_HCV.pdf (accessed 23 August 2014), citing N. Walsh, P. Higgs and N. Crofts, Recognition of Hepatitis C Virus Coinfection in HIV-positive Injecting Drug Users in Asia, *J. Acquir. Immune Defic. Syndr.*, Vol. 45 (2007), 363–365. For a discussion on the costs and issues of availability of a new Hepatitis C drug in Asia, see Chapter 7.

²⁶ See World Health Organization information, available at: www.searo.who.int/entity/noncommunicable_diseases/en/ and *Action Plan for the Prevention and Control of Noncommunicable Diseases in South-East Asia, 2013–2020*, p. 2. In 2013, health experts

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In China, the most prevalent non-communicable diseases include cardiovascular disease, chronic obstructive pulmonary disease, diabetes and lung cancer.²⁷ India, too, faces the challenge of dealing with chronic cardiopulmonary and respiratory diseases and diabetes.²⁸

A further dimension is the high incidence of certain cancers in Asia – lung and bronchus cancers are the most common.²⁹ Further, according to Cancer Research UK, the highest rates of stomach cancer in the world occur in Eastern Asia (China, Japan, Republic of Korea, Democratic Republic of Korea and Mongolia).³⁰

1.4 Poverty in Asia

According to the 2011 report of the International Fund for Agricultural Development (IFAD), a specialized agency of the United Nations, despite progress in reducing poverty, 1.4 billion people remain very poor, that is, living on less than US\$1.25 a day.³¹

In the East Asian and Pacific region, it has been reported that while less than 10% of the region live on US\$1.25 a day, close to half a billion people still live on US\$2 a day.³² In Southeast Asia, it has been estimated that in 2010, 76 million live on *less than* US\$1.25 a day,³³ while 208 million live on less than US\$2 a day.³⁴ In China alone, for 2010, the number of people

formed the ASEAN Non-Communicable Diseases Network to deal with these diseases; see *Straits Times* report, 8 April 2013.

²⁷ China's Health Challenge: Control of Chronic Diseases, *The Lancet*, Vol. 378, No. 9790 (2011), p. 456.

²⁸ Vikram Patel, Somnath Chatterji, Dan Chisholm, Shah Ebrahim, Gururaj Gopalakrishna, Colin Mathers, Viswanathan Mohan, Dorairaj Prabhakaran, Ravilla D. Ravindran and K. Srinath Reddy, Chronic Diseases and Injuries in India, *The Lancet*, Vol. 377 (2011), pp. 413–428.

²⁹ American Cancer Society, *Global Cancer Facts & Figures*, 2nd ed. (2008), at p. 5.

³⁰ See Cancer Research UK, available at: www.cancerresearchuk.org/cancer-info/cancerstats/types/stomach/incidence/uk-stomach-cancer-incidence-statistics#geog (accessed 1 May 2014).

³¹ IFAD, *Rural Poverty Report 2011*, p. 3. See also the ASEAN Framework Plan of Action on Rural Development and Poverty Eradication for 2011–2015 (FAP), p. 5.

³² World Bank, available at: www.worldbank.org/en/region/eap/overview (accessed 27 June 2014).

³³ Asian Development Bank, *Poverty in Asia and the Pacific: An Update*, August 2011, at p. 6; figure excludes Brunei Darussalam, Myanmar and Singapore, and is computed from figures from the source. See also generally, UNESCAP, available at: www.unescap.org/stat/data/syb2011/I-People/Income-poverty-and-inequality.asp (accessed 27 June 2014).

³⁴ *Ibid.*, p. 10; computed from figures from the source.

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living on less than US\$2 a day is estimated to be 243 million, while the number in India is 812 million.

In addition, many of the poor in Asia live in rural areas. In Lao PDR, for example, classified as a least developed country, more than three quarters of the population live in rural areas, with the poverty rate in upland areas being as high as 43%.³⁵ Poverty, coupled with poor health infrastructure and other problems, can contribute to issues in access to healthcare and to medicines.

Out-of-pocket healthcare spending by patients can also form an obstacle to access to treatment. According to the Organisation for Economic Co-operation and Development (OECD), out-of-pocket payments represent *more than 50%* of the total expenditure on health in countries such as the Philippines, Singapore and Vietnam, while they reach 71% in Myanmar³⁶ and 86.4% in India.³⁷

1.5 The growth of National Health Expenditure

According to the United Nations:

Per capita health expenditure, both public and private, tends to increase with population aging³⁸ (Italics emphasis added)

(Original footnote omitted)

Given the aging profile in Asia, described earlier, it is not surprising that health expenses are on the rise. In addition, developing countries are becoming increasingly important markets in pharmaceuticals; it has been estimated that in 2009, Brazil, China, India, Mexico, Russia, South Korea and Turkey contributed 51% of global pharmaceutical growth.³⁹

The annual growth rate of pharmaceutical expenditures in major Asian countries is shown in Table 1.3.

³⁵ IFAD rural poverty portal, available at: www.ruralpovertyportal.org/country/home/tags/laos (accessed 27 June 2014).

³⁶ OECD, *Health at a Glance, Asia/Pacific 2014*, p. 82.

³⁷ India Department of Pharmaceuticals, *Annual Report 2011–2012*, <http://pharmaceuticals.gov.in/annualreport2012.pdf>, at p. 23 (accessed 11 August 2014). For out-of-pocket expenditures on private healthcare worldwide, see World Bank, available at: <http://data.worldbank.org/indicator/SH.XPD.OOPC.ZS> (accessed 28 August 2014).

³⁸ UN, *World Population Aging Report 2013*, p. 48.

³⁹ Brian Tempest, *The Structural Changes in the Global Pharmaceutical Marketplace and Their Possible Implications for Intellectual Property*, Policy Brief No. 10, July 2011, UNCTAD-ICTSD Project on IPRs and Sustainable Development, at p. 2.

Table 1.3. *Growth in pharmaceutical expenses in Asia (2000–2010)*

Country	Income group	Average annual growth rate in real pharmaceutical spending per capita in %
Brunei Darussalam	High	0.82
Cambodia	Low	0.0
Indonesia	Low–mid	6.61
Lao PDR	Low–mid	8.93
Malaysia	Up–mid	7.16
Myanmar ^a	Low	15.14
Philippines	Low–mid	8.76
Singapore	High	11.66
Thailand	Up–mid	9.58
Vietnam	Low–mid	10.16
China	Up–mid	9.64
India	Low–mid	2.99
Japan	High	2.32
Korea	High	7.48

Source: Compiled by author from OECD, *Health at a Glance: Asia/Pacific 2014*.^b
^a For a discussion of Myanmar’s healthcare system in recent times, see Benjamin Shobert, *Healthcare in Myanmar*, 19 August 2013, Forbes, www.forbes.com/sites/benjaminshobert/2013/08/19/healthcare-in-myanmar/.
^b OECD, *Health at a Glance: Asia/Pacific 2014 – Measuring Progress towards Universal Health Coverage*. For information on pharmaceutical expenditure as a percentage of countries’ GDP, see *World Medicines Situation 2011, Medicine Prices*.

The data and profiles in Table 1.3 suggest that demand for pharmaceutical products in Asia is expected to continue growing for many countries in the coming years. In China, public expenditure on pharmaceuticals was, as at 2007, a significant 42.7% of the country’s total health expenditure.⁴⁰ In 2009, the Chinese government announced a blueprint for reforming the healthcare system in order to make medicines and healthcare safe, available and affordable, under universal healthcare

⁴⁰ WHO, *World Medicines Situation 2011, Annex – Medicine Expenditures*, pp. 12–13. See also, Qiang Sun, Michael A. Santoro, Qingyue Meng, Caitlin Liu and Karen Eggleston, *Pharmaceutical Policy in China*, *Health Affairs*, Vol. 27, No. 4 (July/August 2008), 1042–1050, at 1043, and generally.