World Health Organization

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Pharmaceutical Sector Country Profile Questionnaire

INDONESIA

Section 0 General Info

0.01 Contact Info

0.01.01	Country (precoded)	Indonesia
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0.01.07	Institution	Gadjah Mada University, Yogyakarta, Indonesia

Section 1 Health and Demographic data

1.00 Respondent Information Section 1

1.00.01	Name of person responsible for filling out Survey section 1	Drs. Purwadi. Secretary, Directorate General of Pharmaceutics and Medical Devices, Ministry of Health, Jl. HR Rasuna Said, Kuningan, Jakarta
1.00.02	Phone number	+62-81510380594
1.00.03	Email address	pwdpwd57@yahoo.com
1.00.04	Other respondents for filling out this section	Drs. Refiandes (+62-811145806), Secretariat of Directorate General of Pharmaceutics and Medical Devices, Ministry of Health, Jakarta Prasidayani Nurita (pnurita@gmail.com), Centre for Clinical Pharmacology and Medicine Policy Studies. Gadjah Mada University. Bulaksumur F/12, Yogyakarta 55281, Indonesia

1.01 Demographic and Socioeconomic Indicators

Core questions (click here for help)

			Year	Source
1.01.01	Population, total (,000)	237,641	2010	Ref 1)
1.01.02	Population growth rate (Annual %)	1.49	2010	Ref 1)
1.01.03	Total Gross Domestic Product (GDP) (millions US$)	540,000.00	2010	Ref 2)
1.01.04	GDP growth (Annual %)	6.90	2010	Ref 2)
1.01.05C	GDP per capita (US$ current exchange rate)	4,150.81 3,004.9	2010	Figure in red-box should be deleted Sourse: Ref 2)
1.01.06	Comments and References	Ref 1) official website: www.bps.go.id Ref 2) www.tradingeconomics.com		

Supplementary questions (click here for help)

			Year	Source
1.01.07S	Population < 15 years (% of total population)	28.1	2010	Ref 3)
1.01.08S	Population > 60 years (% of total population)	6	2010	Ref 3)
1.01.09S	Urban population (% of total population)	52	2010	Ref 3)
1.01.10S	Fertility rate, total (Births per woman)	2.28	2010	Ref 3)
1.01.11S	Population living with less than $1.25/day (international PPP) (%)	18.7	2009	Ref 4)
1.01.12S	Population living below nationally defined poverty line (%)	13.33	2010	Ref 5)
1.01.13S	Income share held by lowest 20% of the population (% of national income)	7.6	2009	Ref 6)
1.01.14S	Adult literacy rate, 15+ years (% of relevant population)	92.58	2009	Ref 7)
1.01.15S	Comments and References	Ref 3) www.theodora.com/wfbcurrent/indonesia Ref 4) http://data.worldbank.org/indicator/SI.POV.DDAY, accessed on 11 May 2011 Ref 5) https://www.cia.gov/library/publications/the-world-factbook/geos/id.html, accessed on 10 May 2011 Ref 6) http://data.worldbank.org/indicator/SI.DST.FRST.20/countries?display=default, accessed 11 May 2010 Ref 7) Indonesia Health Profile, Ministry of Health, Jakarta, 2010		

1.02 Mortality and Causes of Death

Core questions (click here for help)

			Year	Source
1.02.01	Life expectancy at birth for men	68.8	2011	Ref 8)

	(Years)			
1.02.02	Life expectancy at birth for women (Years)	73.99	2011	Ref 8)
1.02.03	Infant mortality rate, between birth and age 1 (/1,000 live births)	34	2010	Ref 9)
1.02.04	Under 5 mortality rate (/1,000 live births)	39	2009	Ref 10)
1.02.05	Maternal mortality ratio (/100,000 live births)	228	2010	Ref 9)
1.02.06	Please provide a list of top 10 diseases causing mortality		2009	Ref 11) *hospitalized patients
1.02.06.01	Disease 1	Blood circulation system		
1.02.06.02	Disease 2	Infections and parasitic diseases		
1.02.06.03	Disease 3	Specific conditions initiated in perinatal states		
1.02.06.04	Disease 4	Respiratory diseases		
1.02.06.05	Disease 5	Gastrointestinal diseases		
1.02.06.06	Disease 6	Trauma, poisoning and other external causes		
1.02.06.07	Disease 7	Endocrine, nutritional, and metabolic diseases		
1.02.06.08	Disease 8	Urinary tract system		
1.02.06.09	Disease 9	Neoplasm		
1.02.06.10	Disease 10	Others (unspecific signs, symptoms, or laboratory results)		
1.02.07	Please provide a list of top 10 diseases causing morbidity		2009	Ref 11) *hospital outpatients
1.02.07.01	Disease 1	Acute upper respiratory tract infections		
1.02.07.02	Disease 2	Unspecified fever		

1.02.07.03	Disease 3	Skin and other subcutaneous diseases
1.02.07.04	Disease 4	Diarrhea and gastroenteritis
1.02.07.05	Disease 5	Refraction and accommodation (eye) disorders
1.02.07.06	Disease 6	Dyspepsia
1.02.07.07	Disease 7	Primary essential hypertension
1.02.07.08	Disease 8	Pulp and periapical diseases
1.02.07.09	Disease 9	Ear and mastoid processus diseases
1.02.07.10	Disease 10	Conjunctivitis and other conjunctival disorders
1.02.08	Comments and References	Top ten morbidity among hospital inpatients include, respectively: 1) diarrhea and gastroenteritis, 2) dengue hemorrhagic fever, 3) typhoid and paratyphoid fever, 4) fever of unknown origin, 5) dispepsia, 6) essential (primary) hypertension, 7) acute upper respiratory tract infections, 8) pneumonia, 9) appendix, 10) gastritis and duodenitis

Supplementary questions **(click here for help)**

			Year	Source
1.02.09S	Adult mortality rate for both sexes between 15 and 60 years (/1,000 population)	206	2008	Ref 12)
1.02.10S	Neonatal mortality rate (/1,000 live births)	19	2010	Ref 13)
1.02.11S	Age-standardized mortality rate by non-communicable diseases (/100,000 population)	690	2004	Ref 12)
1.02.12S	Age-standardized mortality rate by cardiovascular diseases (/100,000 population)	361	2002	Ref 14)
1.02.13S	Age-standardized mortality rate by cancer (/100,000 population)	23.01	2010	Ref 15)
1.02.14S	Mortality rate for HIV/AIDS (/100,000 population)	8.66	2010	Ref 9)

1.02.15S	Mortality rate for tuberculosis (/100,000 population)	68	2010	Ref 16)
1.02.16S	Mortality rate for Malaria (/100,000 population)	11	2004	Ref 16)
1.02.17S	Comments and References	Ref 8) www.cia.gov/library/publications/the-world-factbook/geos/id.html Ref 9) Laporan Riset Kesehatan Dasar (Report of Basic Health Research), Ministry of Health, Jakarta, 2010 Ref 10) http://www.unicef.org/infobycountry/indonesia_statistics.html, accessed on 10 May 2011 Ref 11) Indonesia Health Profile, 2010, Jakarta, Ministry of Health Ref 12) World Health Statistics 2010, WHO Ref 13) http://www.unicef.org/infobycountry/indonesia_statistics.html, (accessed 10 May 2011) Ref 14) http://apps.who.int/whosis/database/core/core_select_process.cfm, accessed on 6 May 2011 Ref 15) Secretariat, Dit.Gen Pharmaceutics and Medical Devices, MOH, communication Ref 16) Survei Kesehatan Rumah Tangga (Household Health Survei), Ministry of Health, 2004		

Section 2 Health Services

2.00 Respondent Information Section 2

2.00.01	Name of person responsible for filling out this section of the instrument	Drs. Purwadi Secretary, Directorate General of Pharmaceutics and Medical Devices, Ministry of Health, Jl. Rasuna Said, Kuningan, Jakarta
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2.00.03	Email address	pwdpwd57@yahoo.com
2.00.04	Other respondents for filling out this section	Drs. Revi, Secretariat, Directorate General of Pharmaceutics and Medical Devices, Ministry of Health Prasidayani Nurita, SE, M.Kes (pnurita@gmail.com), Centre for Clinical Pharmacology and Medicine Policy Studies, Gadjah Mada University

2.01 Health Expenditures

Core questions (click here for help)

			Year	Source
2.01.01.01	Total annual expenditure on health (millions NCU)	153,482,220	2010	Ref 17) Ref 18)
2.01.01.02	Total annual expenditure on health (millions US$ average exchange rate)	16,980	2010	Ref 17) Ref 18)
2.01.02C	Total health expenditure as % of Gross Domestic Product	2.05 2.76		
2.01.03.01C	Total annual expenditure on health per capita (NCU)	445,798.32 640.000		
2.01.03.02C	Total annual expenditure on health per capita (US$ average exchange rate)	45.96 71.45		
2.01.04.01	General government annual expenditure on health (millions NCU)	89,034,150	2010	Ref 17) Ref 18)

2.01.04.02	General government annual expenditure on health (millions US$ average exchange rate)	9,850	2010	Ref 17) Ref 18)
2.01.05	Government annual expenditure on health as percentage of total government budget (% of total government budget)	6.9	2009	Ref 19)
2.01.06C	Government annual expenditure on health as % of total expenditure on health (% of total expenditure on health)	55.31 51.82	2009	Ref 19) Figure in red-box should be deleted
2.01.07.01C	Annual per capita government expenditure on health (NCU)	246,592.95 573,041		
2.01.07.02C	Annual per capita government expenditure on health (US$ average exchange rate)	25.42 41.44		
2.01.08C	Private health expenditure as % of total health expenditure (% of total expenditure on health)	44.69 48.2	2009	Ref 19) Figure in red-box should be deleted
2.01.09	Population covered by a public health service or public health insurance or social health insurance, or other sickness funds of total population)	55.95	2009	Ref 20)
2.01.10	Population covered by private health insurance (% of total population)	3.04	2008	USAID: Private Sector Health Care in Indonesia, 2009
2.01.11.01	Total pharmaceutical expenditure	33,082,740	2010	Ref 17)

	(millions NCU)			Ref 18)
2.01.11.02	Total pharmaceutical expenditure (millions US$ current exchange rate)	3,660	2010	Ref 17) Ref 18)
2.01.12.01C	Total pharmaceutical expenditure per capita (NCU)	PREFILL CALC 138,612		
2.01.12.02C	Total pharmaceutical expenditure per capita (US$ current exchange rate)	PREFILL CALC 15.40		
2.01.13C	Pharmaceutical expenditure as a % of GDP (% of GDP)	PREFILL CALC 0.67		
2.01.14C	Pharmaceutical expenditure as a % of Health Expenditure (% of total health expenditure)	PREFILL CALC 21.55		
2.01.15.01	Total public expenditure on pharmaceuticals (millions NCU)	5,507,372.31	2010	Ref 17) Ref 18)
2.01.15.02	Total public expenditure on pharmaceuticals (millions US$ current exchange rate)	609.29	2010	Ref 17) Ref 18)
2.01.16C	Share of public expenditure on pharmaceuticals as percentage of total expenditure on pharmaceuticals (%)	PREFILL CALC 16.65	2010	Ref 17) Ref 18)
2.01.17.01C	Total public expenditure on pharmaceuticals per capita (NCU)	PREFILL CALC 23,000		
2.01.17.02C	Total public expenditure on pharmaceuticals per capita (US$ current exchange rate)	PREFILL CALC 2.55		
2.01.18.01	Total private expenditure on pharmaceuticals (millions NCU)	27,599,104.96	2010	Ref 17)

				Ref 18)
2.01.18.02	Total private expenditure on pharmaceuticals (millions US$ current exchange rate)	3,053.34	2010	Ref 17) Ref 18)
2.01.19	Comments and References	Note: All figures in red box should be deleted, the author was unable to remove them. Ref 17) (forecast data) Indonesia Pharmaceutical & Health Care Reports Q3 2010, Bussiness Monitor International Ref 18) Average exchange rate 2010: 9,039, Source: Bank Indonesia Ref 19) http://www.who.int/nha/country/idn/en Ref 20) Profil Kesehatan Indonesia (Indonesia Health Profile), 2010, page 141, Ministry of Health, Jakarta		

Supplementary questions (click for help)

			Year	Source
2.01.20S	Social security expenditure as % of government expenditure on health (% of government expenditure on health)	13.7	2009	Ref 19)
2.01.21S	Market share of generic pharmaceuticals [branded and INN] by value (%)	23.2	2010	Ref 17)
2.01.22S	Annual growth rate of total pharmaceuticals market value (%)	12	2010	Ref 19a)
2.01.23S	Annual growth rate of generic pharmaceuticals market value (%)	0.5	2010	2009 to 2010 Ref 17)
2.01.24S	Private out-of-pocket expenditure as % of private health expenditure (% of private expenditure on health)	73.2	2009	Ref 19)
2.01.25S	Premiums for private prepaid health plans as % of total private health expenditure (% of private expenditure	5.09	2008	Ref 19)

	on health)			
2.01.26S	Comments and References	Ref 17) (forecast data) Indonesia Pharmaceutical & Health Care Reports Q3 2010, Bussiness Monitor International Ref 19) http://www.who.int/nha/country/idn/en Ref 19a) IMS Survey		
2.02 Health Personnel and Infrastructure **Core questions** (click for help)				
			Year	Source
2.02.01	Total number of pharmacists licensed/registered to practice in your country	19,953	2009	Ref 20)
2.02.02C	Pharmacists per 10,000 population	0.060 0.86		
2.02.03	Total number of pharmacists working in the public sector	19,953	2009	Ref 20)
2.02.04	Total number of pharmaceutical technicians and assistants	21,312	2009	Ref 20)
2.02.05	A strategic plan for pharmaceutical human resource development is in place in your country?	Yes ☒ No ☐	2010	Govt Regulation No 51, 2010
2.02.06	Total number of physicians	28,332	2009	Ref 20)
2.02.07C	Physicians per 10,000 pop	1.30 1.225		
2.02.08	Total number of nursing and midwifery personnel	278,221	2009	midwife: 93,889, nurse: 184,332 Ref 20)
2.02.09C	Nurses and midwives per 10,000 pop	7.92		

		12.03		
2.02.10	Total number of hospitals	1,523	2009	Ref 20)
2.02.11	Number of hospital beds per 10,000 pop	7.074	2009	Ref 20)
2.02.12	Total number of primary health care units and centers	8737	2009	Ref 20)
2.02.13	Total number of licensed pharmacies	19,953	2009	Ref 20)
2.02.14	Comments and References	Ref 20) Ref 20) Profil Kesehatan Indonesia (Indonesia Health Profile), 2010, Ministry of Health, Jakarta		

Supplementary questions (click here for help)

			Year	Source
2.02.15S	Starting annual salary for a newly registered pharmacist in the public sector (NCU)	800,000	2010	Ref 21)
2.02.16S	Total number of pharmacists who graduated (first degree) in the past 2 years in your country	12,000	2010	Ref 21)
2.02.17S	Are there accreditation requirements for pharmacy schools?	Yes ☒ No☐	2010	Ref 22)
2.02.18S	Is the Pharmacy Curriculum regularly reviewed?	Yes ☒ No ☐	2010	Ref 22)
2.02.19S	Comments and References	Ref 21) Indonesian Pharmacist Association Ref 22) Association of Pharmacy Higher Education Institutions		

Section 3 Policy issues

3.00 Respondent Information Section 4

3.00.01	Name of person responsible for filling out this section of the instrument	Yuli Ekowati, S.Si. Apt. MPPM, Bureau of Planning and Finance. National Agency for Drug and Food Control, Jl. Percetakan Negara 23, Jakarta Drs. Purwadi Apt (pwdpwd57@yahoo.com), Secretary of Directorate General of Pharmaceutics and Medical Devices, Ministry of Health		
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3.00.03	Email address			
3.00.04	Other respondents for filling out this section	Dra. Nurma Hidayati, M.Biomed (nurma.hidayati@ymail.com), National Agency for Drug and Food Control, Jl. Percetakan Negara 23, Jakarta		

3.01 Policy Framework

Core questions (click here for help)

			Year	Source
3.01.01	National Health Policy exists. If yes, please write year of the most recent document in the "year" field.	Yes ☒ No ☐	2009	Ref 23)
3.01.02	National Health Policy Implementation plan exists. If yes, please write the year of the most recent document in the "year"	Yes ☒ No ☐	2009	Ref 24) Ref 24a)
3.01.03	Please provide comments on the Health policy and its implementation plan	National Health Policy is presented in the Health Act of Republic of Indonesia No 36/2009. The National Health Policy Implementation Plan is presented in the Strategic Plan of Ministry of Health 2010-2014 and other government regulations and decrees related to health sector.		
3.01.04	National Medicines Policy	Yes ☒ No ☐	2006	Ref 25)

	official document exists. If yes, please write the year of the most recent document in the "year" field.			Ref 25a) Ref 26)
3.01.05	Group of policies addressing pharmaceuticals exist.	Yes ☒ No ☐	2010	Ref 27)
3.01.06	National Medicines Policy covers the following components:	—		
3.01.06.01	Selection of Essential Medicines	☒Yes		
3.01.06.02	Medicines Financing	☒Yes		
3.01.06.03	Medicines Pricing	☒Yes		
3.01.06.04	Medicines Procurement	☒Yes		
3.01.06.05	Medicines Distribution	☒Yes		
3.01.06.06	Medicines Regulation	☒Yes		
3.01.06.07	Pharmacovigilance	☒Yes		
3.01.06.08	Rational Use of Medicines	☒Yes		
3.01.06.09	Human Resource Development	☒Yes		
3.01.06.10	Research	☒Yes		
3.01.06.11	Monitoring and Evaluation	☒Yes		
3.01.06.12	Traditional Medicine	☒Yes		
3.01.07	National medicines policy implementation plan exists. If yes, please write year of the most recent document.	Yes ☒ No ☐	2009	Ref 24)
3.01.08	Policy or group of policies on clinical laboratories exist. If yes, please write year of the most recent document in the "year" field	Yes ☒ No ☐	2000	Ref 28)

3.01.09	National clinical laboratory policy implementation plan exists. If yes, please write year of the most recent document in the "year" field	Yes ☒ No ☐	2000	Ref 28)
3.01.10	Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or national legislation?	Yes ☒ No ☐	2011	Ref 29) 2011 edition is in progress
3.01.11	There are official written guidelines on medicines donations.	Yes ☒ No ☐	2002	Ref 30) Ref 30a) Ref 30b)
3.01.12	Is pharmaceutical policy implementation being regularly monitored/assessed?	Yes ☒ No ☐	2011	Ref 31)
3.01.12.01	Who is responsible for pharmaceutical policy monitoring?	National Agency for Drug and Food Control and its 33 provincial branches Dit.General of Pharmaceutical Care and Medical Devices, MOH		
3.01.13	Is there a national good governance policy?	Yes ☒ No ☐	1999	Ref 32) Ref 32a)
3.01.13.01	Multisectoral	☒Yes	1999	Ref 32) Ref 32a)
3.01.13.02	For the pharmaceutical sector	☒Yes	1999	Ref 32) Ref 32a)
3.01.13.03	Which agencies are responsible?	Ministry of States and Bureaucratic Reform		
3.01.14	A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs.	Yes ☒ No ☐	2010	Ref 32) Ref 32a)
3.01.15	There is a formal code of conduct for public officials.	Yes ☒ No ☐	1999	Ref 32) Ref 32a)

3.01.16	Is there a whistle-blowing mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of your country (ombudsperson)?	Yes ☒ No ☐	2008	Ref 32) Ref 32a)
3.01.16.01	Please describe:	The National Agency for Drug and Food Control has a specific unit in charge of receiving complaints and information regarding wrong-doing occuring in the pharmaceutical sector. Act of Republic Indonesia no 37/2008 regulates mechanism that allowing individuals or organization to report mal-administration in public service perform by government agencies. The organization responsible for this task is OMBUDSMAN of Republic of Indonesia		
3.01.17	Comments and References	Ref 23) Health Law No 36/2009, revision of Health Law No 23/1992. Ref 24) Decree of Ministry of Health No 374/Menkes/SK/V/2009 on National Health System Ref 24a) Strategic plan 2010-2014, Ministry of Health, Jakarta Ref 25) Decree of MOH No 189/Menkes/SK/III/2006 on National Medicine Policy Ref 25a) Kebijakan Obat Nasional (National Medicine Policy), 2007 Ministry of Health, Jakarta Ref 26) Kebijakan Obat Tradisional Nasional (National Traditional Medicine Policy), 2007, Ministry of Health, Jakarta Ref 27) Peraturan Menteri Kesehatan RI No 1010/Menkes/Per/XI/2008 tentang Registrasi Obat Ref 28) Cara Uji Klinik Obat yang Baik (Good Clinical Research Practices), 2000, National Agency fro Drug and Food Control, Jakarta Ref 29) National Essential Medicine List, 2008, Ministry of Health, Jakarta Ref 30) Pedoman Pengelolaan Obat dan Perbekalan Kesehatan di Saat Bencana (Management Guideline for Donation in Emergency), 2002, Directorate General of Pharmaceutics and Medical Devices, Ministry of Health, Jakarta Ref 30a) Keputusan Kepala Badan Pengawasan Obat dan Makanan No. HK.00.05.3.00914 tentang Pemasukan Obat Jalur		

		Khusus (Special Access Scheme), 2002 Ref 31) Self-assessment document, 2011, National Agency for Drug and Food Control, Jakarta Ref 32) Undang-Undang Republik Indonesia No 31 th 1999 tentang Pemberantasan Tindak Pidana Korupsi Ref 32a) Undang-Undang Republik Indonesia No 20 th 2001 tentang Perubahan atas UU No 31 th 1999 tentang Pemberantasan Tindak Pidana Korupsi

Section 4 Medicines Trade and Production

4.00 Respondent Information Section 4

4.00.01	Name of person responsible for filling out this section of the instrument	Dra. Agustine Zairi, Director of Standard of Therapeutic Products, National Agency for Drug and Food Control, Jl. Percetakan Negara 23, Jakarta
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4.00.04	Other respondents for filling out this section	Prasidayani Nurita, SE (pnurita@gmail.com), Centre for Clinical Pharmacology and Medicine Policy Studies, Gadjah Mada University Dra. Nurma Hidayati, M.Biomed (nurma.hidayati@ymail.com), National Agency for Drug and Food Control, Jl. Percetakan Negara 23, Jakarta, mobile +62-857-19587163

4.01 Intellectual Property Laws and Medicines

Core questions (click here for help)

			Year	Source
4.01.01	Country is a member of the World Trade Organization	Yes ☒ No☐	1994	Ref 33)
4.01.02	Legal provisions provide for granting of Patents on:		2010	Ref 34)
4.01.02.01	Pharmaceuticals	Yes ☒ No☐		
4.01.02.02	Laboratory supplies	Yes ☒ No ☐		
4.01.02.03	Medical supplies	Yes ☒ No ☐		
4.01.02.04	Medical equipment	Yes ☒ No ☐		
4.01.03.01	Please provide name and address of the institution responsible for managing and enforcing intellectual property rights	Ministry of Law and Human Rights Directorate General of Intelectual Property Rights Jl. Daan Mogot Km 24, Tangerang 15119		
4.01.03.02	Please provide URL	http://www.dgip.go.id/ebhtml/hki		

4.01.04	National Legislation has been modified to implement the TRIPS Agreement	Yes ☒ No ☐	1994	Ref 33)
4.01.05	Current laws contain (TRIPS) flexibilities and safeguards	Yes ☒ No☐	2002	Ref 34) Ref 35)
4.01.06	Country is eligible for the transitional period to 2016	Yes ☐ No☒		
4.01.07	Which of the following (TRIPS) flexibilities and safeguards are present in the national law?		2001	Ref 34)
4.01.07.01	Compulsory licensing provisions that can be applied for reasons of public health	Yes ☒ No ☐		
4.01.07.02	Bolar exception	Yes ☒ No ☐		
4.01.08	Are parallel importing provisions present in the national law?	Yes ☐ No ☒	2001	Ref 34)
4.01.09	The country is engaged in initiatives to strengthen capacity to manage and apply intellectual property rights to contribute to innovation and promote public health	Yes ☒ No ☐	2001	Ref 34)
4.01.10	Are there legal provisions for data exclusivity for pharmaceuticals	Yes ☐ No ☒	2001	Ref 34)
4.01.11	Legal provisions exist for patent extension	Yes ☐ No ☒	2001	Ref 34)
4.01.12	Legal provisions exist for linkage between patent status and Marketing Authorization	Yes ☒ No ☐	2008	Ref 36)
4.01.13	Comments and References	Ref 33) Undang-Undang Republik Indonesia No. 7 tahun 1994 tentang Pengesahan Agreement Establishing The World Trade Organization (Persetujuan Pembentukan Organisasi Perdagangan Dunia) Ref 34) Undang-Undang Republik Indonesia No. 14 Tahun 2001 Tentang Paten (Patent Law)		

		Ref 35) Undang-Undang Republik Indonesia No. 19 Tahun 2002, tentang Hak Cipta (Copyright Law) Ref 36) Permenkes RI No 1010/Menkes/XI/2008 tentang Registrasi Obat (Drug Registration), revision of Regulation no 949/2000 on Drug Registration		

4.02 Manufacturing

Core questions (click here for help)

			Year	Source
4.02.01	Number of licensed pharmaceutical manufacturers in the country	200	2010	Ref 37)
4.02.02	Country has manufacturing capacity		2010	Ref 37)
4.02.02.01	R&D to discover new active substances	Yes ☐ No ☒ Unknown ☐		
4.02.02.02	Production of pharmaceutical starting materials (APIs)	Yes ☒ No ☐ Unknown ☐		
4.02.02.03	Production of formulations from pharmaceutical starting material	Yes ☒ No ☐ Unknown ☐		
4.02.02.04	Repackaging of finished dosage forms	Yes ☒ No ☐ Unknown ☐		
4.02.03	Percentage of market share by value produced by domestic manufacturers (%)	80	2010	70-80% source: NADFC
4.02.04	Comments and References	Ref 37) Annual Report, National Agency for Drug and Food Control, 2011, NADFC, Jakarta		

Supplementary questions (click here for help)

			Year	Source
4.02.05S	Percentage of market share by volume produced by domestic manufacturers (%)	90	2010	NADFC
4.02.06S	Number of multinational pharmaceutical companies	27	2010	NADFC

	manufacturing medicines locally			
4.02.07S	Number of manufacturers that are Good Manufacturing Practice (GMP) certified	200	2010	NADFC
4.02.08S	Comments and References			

Section 5 Medicines Regulation

5.00 Respondent Information Section 4

5.00.01	Name of person responsible for filling out this section of the instrument	Dra. Retno Tyas Utami, National Agency for Drug and Food ControlJl. Percetakan Negara 23, Jakarta
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5.00.04	Other respondents for filling out this section	Dra. Endang Woro Tedjowati, National Agency for Drug and Food ControlJl. Percetakan Negara 23, Jakarta. Dra. Nurma Hidayati (nurma.hidayati@ymail.com), National Agency for Drug and Food ControlJl. Percetakan Negara 23, Jakarta.

5.01 Regulatory Framework

Core questions (click here for help)

			Year	Source
5.01.01	Are there legal provisions establishing the powers and responsibilities of the Medicines Regulatory Authority (MRA)?	Yes ☒ No ☐	1998	Ref 38) Ref 39) Ref 40)
5.01.02	There is a Medicines Regulatory Authority	Yes ☒ No ☐	2000	Ref 41)
5.01.03	If yes, please provide name and address of the Medicines regulatory authority	National Agency of Drug and Food Control of Republic of Indonesia (NADFC RI), Jl. Percetakan Negara No. 23 Jakarta Pusat – Indonesia 10560		
5.01.04	The Medicines Regulatory Authority is:		2000	Ref 41)
5.01.04.01	Part of MoH	☐Yes		
5.01.04.02	Semi autonomous agency	☒Yes		
5.01.04.03	Other (please specify)	Before 2000: Part of MoH; From 2001: autonomous agency in coordination with MoH (Non-		

		Departmental Government Agency)		
5.01.05	What are the functions of the National Medicines Regulatory Authority?		2000	Ref 41)
5.01.05.01	Marketing authorization / registration	Yes ☒ No ☐		
5.01.05.02	Inspection	Yes ☒ No ☐		
5.01.05.03	Import control	Yes ☒ No ☐		
5.01.05.04	Licensing	Yes ☒ No ☐		
5.01.05.05	Market control	Yes ☒ No ☐		
5.01.05.06	Quality control	Yes ☒ No ☐		
5.01.05.07	Medicines advertising and promotion	Yes ☒ No ☐		
5.01.05.08	Clinical trials control	Yes ☒ No ☐		
5.01.05.09	Pharmacovigilance	Yes ☒ No ☐		
5.01.05.10	Other: (please explain)			
5.01.06	Number of the MRA permanent staff	3,807	2010	Ref 42)
5.01.06.01	Date of response	May 20th, 2011		
5.01.07	The MRA has its own website	Yes ☒ No ☐	2009	Ref 42)
5.01.07.01	- If yes, please provide MRA Web site address (URL)	http://www.pom.go.id		
5.01.08	The MRA receives external technical assistance	Yes ☒ No ☐	2010	Ref 42)
5.01.08.01	If yes, please describe:	e.g.: External drug evaluators; National Committee on Drug Evaluation; GMP consultants; Consultants / Experts for BA/BE evaluation; National Advisory Team on Clinical Trial		
5.01.09	The MRA is involved in harmonization/ collaboration initiatives	Yes ☒ No ☐	2010	Ref 42)

5.01.09.01	- If yes, please specify	ASEAN Harmonization on Pharmaceutical Regulations; Developing Countries Vaccine Regulators Network; WHO Global Training Network; WHO NRA Joint Inspection		
5.01.10	An assessment of the medicines regulatory system has been conducted in the last five years.	Yes ☒ No ☐	2011	Ref 43)
5.01.11	Medicines Regulatory Authority gets funds from regular budget of the government.	Yes ☒ No ☐	2010	Ref 42)
5.01.12	Medicines Regulatory Authority is funded from fees for services provided.	Yes ☒ No ☐	2010	Ref 42) Ref 44)
5.01.13	Medicines Regulatory Authority receives funds/support from other sources	Yes ☒ No ☐	2010	Ref 42)
5.01.13.01	- If yes, please specify	From WHO, e.g. fund support for trainings		
5.01.14	Revenues derived from regulatory activities are kept with the Regulatory Authority	Yes ☐ No ☒		Ref 44)
5.01.15	The Regulatory Authority is using a computerized information management system to store and retrieve information on registration, inspections, etc.	Yes ☒ No ☐	2010	Ref 42)
5.01.16	Comments and References	Ref 38) Government Regulation No.72/1998 on Pharmaceuticals and Medical Devices Control Ref 39) Health Law No.36/2009 (revision of Health Law No.23/1992) Ref 40) Regulation of Ministry of Health No.1010/2008 (revision of Regulation No. 949/2000) on Drug Registration Ref 41) Before 2000, the institution's name is Directorate General of Drug and Food Control, Ministry of Health Ref 42) Annual Report of the National Agency for Drug and Food		

		Control, 2011 Ref 43) Self Assessment Document (internal document) Ref 44) Indirect funding, the service fees are paid to Ministry of Finance, and the operational expenses of the MRA are provided through Government budget.		
5.02 Marketing Authorization (Registration) **Core questions (click here for help)**				
			Year	Source
5.02.01	Legal provisions require a Marketing Authorization (registration) for all pharmaceutical products on the market	Yes ☒ No ☐	2008	Ref 45)
5.02.02	Are there any mechanism for exception/waiver of registration?	Yes ☒ No ☐	2008	Ref 45) Ref 46)
5.02.03	Are there mechanisms for recognition of registration done by other countries	Yes ☐ No ☒		
5.02.03.01	If yes, please explain:	-		
5.02.04	Explicit and publicly available criteria exist for assessing applications for Marketing Authorization of pharmaceutical products	Yes ☒ No ☐	2003	Ref 47)
5.02.05	Information from the prequalification programme managed by WHO is used for product registration	Yes ☒ No ☐	2003	Ref 47)
5.02.06	Number of pharmaceutical products registered in your country	15,072	2010	Ref 48)
5.02.07	Legal provisions require the MRA to make the list of registered pharmaceuticals with defined periodicity publicly available	Yes ☐ No ☒	2003	Ref 47)
5.02.07.01	If yes, how frequently	every week		

	updated			
5.02.07.02	If yes, please provide updated list or URL *	http://www.pom.go.id		
5.02.08	Medicines registration always includes the INN (International Non-proprietary Names)	Yes ☐ No ☒	2003	Ref 47)
5.02.09	Legal provisions require the payment of a fee for Medicines Marketing Authorization (registration) applications	Yes ☒ No ☐	2010	Ref 49)
5.02.10	Comments and References	Ref 45) Regulation of Ministry of Health No.1010/2008 (revision of Regulation No. 949/2000) on Drug Registration Ref 46) Decree of Ministry of Health No. 1379.A/ Menkes/SK/XI/2002 on Management and Usage of Special Drug, Device and Health Food Ref 47) Head of NADFC Decree No.HK.00.05.3.1950 on Criteria and Procedure of Drug Registration Ref 48) Annual Report of the National Agency for Drug and Food Control, 2011 Ref 49) Government Regulation No. 48 on Type and Tarrif of Non-Tax National Income Applicable for NADFC		

Supplementary questions (click here for help)

			Year	Source
5.02.11S	Legal provisions require Marketing Authorization holders to provide information about variations to the existing Marketing Authorization	Yes ☒ No ☐	2003	Ref 50)
5.02.12S	Legal provisions require publication of a Summary of Product Characteristics (SPCs) of the medicines registered	Yes ☒ No ☐	2003	Ref 50)
5.02.13S	Legal provisions require the establishment of an expert committee involved in the marketing authorization process	Yes ☒ No ☐	2003	Ref 50)

5.02.14S	Certificate for Pharmaceutical Products in accordance with the WHO Certification scheme is required as part of the Marketing Authorization application	Yes ☒ No ☐	2003	Ref 50) Ref 51)
5.02.15S	Legal provisions require declaration of potential conflict of interests for the experts involved in the assessment and decision-making for registration	Yes ☒ No ☐	2010	Ref 52)
5.02.16S	Legal provisions allow applicants to appeal against MRAs decisions	Yes ☒ No ☐	2003	Ref 50)
5.02.17S	Registration fee - the amount per application for pharmaceutical product containing New Chemical Entity (NCE) (US$)	3,318.95	2010	Ref 53) Ref 54)
5.02.18S	Registration fee - the Amount per application for a generic pharmaceutical product (US$)	829.74	2010	Ref 53) Ref 54) Ref 55) Ref 56)
5.02.19S	Time limit for the assessment of a Marketing Authorization application (months)	80	2003	Ref 50) Ref 57) Ref 58) Ref 59) Ref 60)
5.02.20S	Comments & References	Ref 50) Head of NADFC Decree No.HK.00.05.3.1950 on Criteria and Procedure of Drug Registration Ref 51) No written regulation that CPP should be in accordance with the WHO Certification scheme Ref 52) Head of NADFC Decree on National Committee on Drug Evaluation, Committee on Evaluation of Efficacy and Safety, and Committee on Evaluation of Quality, Technology, Labeling and		

		Rationality of Drug, No. HK.00.05.1.31.0183 Ref 53) Government Regulation No. 48 on Type and Tarrif of Non-Tax National Income Applicable for NADFC Ref 54) US$1 = Rp 9,039.- (average 2010, Bank Indonesia) Ref 55) Generic products marketed under a brand (propietary) name: US$ 829.74; Generic products marketed under a brand (propietary) name and supported by clinical studies (incl. BA/BE study): US$ 1,382.90; Ref 56) Generic products marketed under the approved nonpropietary name: US$ 221,26; Generic products marketed under the approved nonpropietary name and supported by clinical studies (incl. BA/BE study): US$ 774.42 Ref 57) Max. within: 80 WD: Copy drug with STINEL and drug for export Ref 58) Max. within: 100 WD: New Drug (NCE) - Serious diseases and life saving drug, Essential generic for program Ref 59) Max. within: 150 WD: Drugs approved in countries with harmonized system of drug evaluation plus 1 country with well recognized evaluation system, Drug approved in 3 countries with well recognized evaluation system, Copy drugs without STINEL, Blood Prod; Ref 60) Max. within: 300 WD: Other NCE Drug

5.03 Regulatory Inspection

Core Questions(click here for help)

			Year	Source
5.03.01	Legal provisions exist allowing for appointment of government pharmaceutical inspectors	Yes ☒ No ☐	2010	Ref 61)
5.03.02	Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed	Yes ☒ No ☐	1998	Ref 61) Ref 62)
5.03.02.01	If yes, legal provisions exist requiring inspections to be performed	Yes ☒ No ☐		

5.03.03	Inspection is a pre-requisite for licensing of:		2010	Ref 61)
5.03.03.01	Public facilities	Yes ☒ No ☐		
5.03.03.02	Private facilities	Yes ☒ No ☐		
5.03.04	Inspection requirements are the same for public and private facilities	Yes ☒ No ☐	2010	Ref 61)
5.03.05.01	Local manufactures are inspected for GMP compliance	Yes ☒ No ☐	2010	Ref 61)
5.03.05.02	Private wholesalers are inspected	Yes ☒ No ☐		
5.03.05.03	Retail distributors are inspected	Yes ☒ No ☐		
5.03.05.04	Public pharmacies and stores are inspected	Yes ☒ No ☐		
5.03.05.05	Pharmacies and dispensing points of health facilities are inspected	Yes ☒ No ☐		
5.03.05.06	Please provide details on frequency of inspections for the different categories of facilities	Wholesaler is inspected once in 3 years, retail distributor is inspected once in 5 years, pharmacy is inspected once in 3 years, and health facility is inspected once in 4 years		
5.03.06	Comments and References	Ref 61) Ministerial Decree No. 1799 regarding Pharmaceutical Industry, 2010 Ref 62) Government Regulation No.72, 1998		

5.04 Import Control

Core Questions (click here for help)

			Year	Source
5.04.01	Legal provisions exist requiring authorization to import medicines	Yes ☒ No ☐	1998	Ref 63) Ref 64)
5.04.02	Legal provisions exist allowing the sampling of imported products for	Yes ☒ No ☐	1998	Ref 63) 64) 65) 66) 67)

	testing			68)
5.04.03	Legal provisions exist requiring importation of medicines through authorized ports of entry	Yes ☒ No ☐	2005	Ref 64) Ref 65)
5.04.04	Legal provisions exist allowing inspection of imported pharmaceutical products at the authorized ports of entry	Yes ☐ No ☒		
5.04.05	Comments and References	Ref 63) Government Regulation No.72, 1998 Ref 64) Decree of the Head of NADFC No. HK.00.05.1.3459 on Monitoring of Importation Medicine, 2005 Ref 65) Decree of the Head of NADFC No. HK.00.05.1.3460 on Monitoring of Importation Drug Substance, 2005 Ref 66) Decree of the Head of NADFC No. HK.00.05.1.4415 on Implementation of National Single Window in NADFC, 2008 Ref 69) Decree of the Head of NADFC No. HK.00.05.1.4416, 2008 Service Level Arrangement of NSW in NADFC, 2008 Ref 70) 2003: Decree of the Head of NADFC No. HK.00.05.3.2522 on Implementation of Good Distribution Practices mentions that Wholesalers and all parties involved in distribution of medicines have the obligation to comply with Good Distribution Practices in all aspects		

5.05 Licensing

			Year	Source
5.05.01	Legal provisions exist requiring manufacturers to be licensed	Yes ☒ No ☐	2009	Ref 71) 72) 73) 74) 75) 76)
5.05.02	Legal provisions exist requiring both domestic and international manufacturers to comply with Good manufacturing Practices (GMP)	Yes ☒ No ☐	2008	Ref 73) Ref 76)
5.05.02.01	If no, please explain			
5.05.03	GMP requirements are published by	Yes ☒ No ☐	2006	Ref 77)

	the government.			
5.05.04	Legal provisions exist requiring importers to be licensed	Yes ☒ No ☐	1998	Ref 72 78) 79) 80)
5.05.05	Legal provisions exist requiring wholesalers and distributors to be licensed	Yes ☒ No ☐	2003	Ref 80)
5.05.06	Legal provisions exist requiring wholesalers and distributors to comply with Good Distributing Practices **When filling in this part, please also fill in the relevant questions in the procurement and distribution section (Section 7)**	Yes ☒ No ☐	2003	Ref 80)
5.05.07	National Good Distribution Practice requirements are published by the government	Yes ☒ No ☐	2003	Ref 80)
5.05.08	Legal provisions exist requiring pharmacists to be registered	Yes ☒ No ☐	1998	Ref 72) Ref 73) Ref 75)
5.05.09	Legal provisions exists requiring private pharmacies to be licensed	Yes ☒ No ☐	1998	Ref 72) Ref 81)
5.05.10	Legal provision exist requiring public pharmacies to be licensed	Yes ☒ No ☐	1998	Ref 72) Ref 81)
5.05.11	National Good Pharmacy Practice Guidelines are published by the government	Yes ☒ No ☐	2003	Ref 80) Ref 81)
5.05.12	Legal provisions require the publication of a list of all licensed pharmaceutical facilities	Yes ☐ No ☒		
5.05.13	Comments and References	Ref 71) 2009: Health Law No.36/2009 (revision of Health Law No.23/1992) Ref 72) 1998: Government Regulation No.72/1998 on		

		Pharmaceuticals and Medical Devices Control Ref 73) 2008: Regulation of Ministry of Health No.1010/2008 (revision of Regulation No. 949/2000) on Drug Registration Ref 74) 2003: Joint Decree between MoH and Min. of Gov. Officer Empowerment No.264A/Menkes/SKB/ VII/2003 Ref 75) 2003: Head of NADFC Decree No.HK.00.05.3.1950, on Criteria and Procedure of Drug Registration Ref 76) 2003: Regulation of Ministry of Health No.1799/2010 (Revision of regulation No.245/1990) Ref 77) Decree of the Head of NADFC No. HK.00.053.0027 Ref 78)2005: Decree of the Head of NADFC No. HK.00.05.1.3459 on Monitoring of Importation Medicine Ref 79) 2005: Decree of the Head of NADFC No. HK.00.05.1.3460 on Monitoring of Importation Drug Substance Ref 80) 2003: Decree of the Head of NADFC No. HK.00.05.3.2522 on Implementation of Good Distribution Practices mentions that Wholesalers and all parties involved in distribution of medicines have the obligation to comply with Good Distribution Practices in all aspects Ref 81) 2002: Decree of Ministry of Health No. 1332/MENKES/SK/X/ 2002 regarding changes in the Regulation of Ministry of Health No. 922/MENKES/PER/X/1993 regardiing Conditions and Procedures for Pharmacies Licensing

5.06 Market Control and Quality Control

Core Questions (click here for help)

			Year	Source
5.06.01	Legal Provisions for regulating the pharmaceutical market exist	Yes ☒ No ☐	1998	Ref 82) Ref 83)
5.06.02	Does a laboratory exist in the country for Quality Control testing?	Yes ☒ No ☐		
5.06.02.01	If yes, is the laboratory part of the	Yes ☒ No ☐		

	MRA?			
5.06.02.02	Does the regulatory authority contract services elsewhere?	Yes ☐ No ☒		
5.06.02.03	If yes, please describe	The National Agency Laboratories locate in 32 provinces, and the Central Lab locates in Jakarta		
5.06.03	Is there any national laboratory accepted for collaboration with WHO prequalification Programme? Please describe.	Yes, for the WHO prequalification of vaccines, testing is provided by Biofarma		
5.06.04	Medicines are tested:		2010	Vaccines tested are listed in Ref 84)
5.06.04.01	For quality monitoring in the public sector (routine sampling in pharmacy stores and health facilities)	Yes ☒ No ☐		
5.06.04.02	For quality monitoring in private sector (routine sampling in retail outlets)	Yes ☒ No ☐		
5.06.04.03	When there are complaints or problem reports	Yes ☒ No ☐		
5.06.04.04	For product registration	Yes ☐ No ☒		
5.06.04.05	For public procurement prequalification	Yes ☒ No ☐		
5.06.04.06	For public program products prior to acceptance and/or distribution	Yes ☒ No ☐		
5.06.05	Samples are collected by government inspectors for undertaking post-marketing surveillance testing	Yes ☒ No ☐	2009	Ref 83a)
5.06.06	How many Quality Control samples were taken for testing in the last two years?	37025	2009	Ref 83b) 2008-2009

5.06.07	Total number of samples tested in the last two years that failed to meet quality standards	259	2009	Ref 83b) 2008-2009
5.06.08	Results of quality testing in past two years are publicly available	Yes ☒ No ☐	2009	Ref 83a) Ref 83c)
5.06.09	Comments and References	Ref 82) 1998: Government Regulation No.72/1998 on Pharmaceuticals and Medical Devices Control Ref 83) 2003: Decree of the Head of NADFC No. HK.00.05.3.2522 on Implementation of Good Distribution Practices mentions that Wholesalers and all parties involved in distribution of medicines have the obligation to comply with Good Distribution Practices in all aspects Ref 83a) Annual Report of the National Agency for Drug and Food Control, 2009, NADFC, Jakarta Ref 83b) Annual Report of Deputy of Therapeutic Products and Controlled Drug, National Agency of Drugs and Food Control, 2009 Ref 83c) Result is published in the Annual Report of NADFC without specifying the products of concern Ref 84) List of vaccines tested: Diphteria-Tetanus Vaccine Diphteria-Tetanus-Pertussis (whole cell) Vaccine Diphteria-Tetanus-Pertussis (whole cell)-Hepatitis B Vaccine Hepatitis B Vaccine Measles Vaccine Polio Vaccine - Oral (OPV) Bivalent Types 1 and 3 Polio Vaccine - Oral (OPV) Monovalent Type 1 PolioVaccine - Oral (OPV) Trivalent Tetanus Toxoid Vaccine		

5.07 Medicines Advertising and Promotion

Core Questions (click here for help)

			Year	Source
5.07.01	Legal provisions exist to control the promotion and/or advertising of prescription medicines	Yes ☒ No ☐	1998	Ref 85) 86) 87) 88) 89)
5.07.02	Who is responsible for regulating, promotion and/or advertising of medicines? Please describe:	Deputy of Therapeutic Products and Controlled Substances, National Agency for Drug and Food Control		
5.07.03	Legal provisions prohibit direct advertising of prescription medicines to the public	Yes ☒ No ☐	1993	Ref 89)
5.07.04	Legal provisions require a pre-approval for medicines advertisements and promotional materials	Yes ☒ No ☐	2002	Ref 88)
5.07.05	Guidelines/Regulations exist for advertising and promotion of non-prescription medicines	Yes ☒ No ☐	2002	Ref 88)
5.07.06	A national code of conduct exists concerning advertising and promotion of medicines by marketing authorization holders and is publicly available	Yes ☒ No ☐	2002	Ref 88)
5.07.06.01	If yes, the code of conduct applies to domestic manufacturers only, multinational manufacturers only, or both			
	Domestic only	☐Yes		
	Multinational only	☐Yes		
	Both	☒Yes		
5.07.06.02	If yes, adherence to the code is voluntary	Yes ☒ No ☐		
5.07.06.03	If yes, the code contains a formal	Yes ☒ No ☐		

	process for complaints and sanctions			
5.07.06.04	If yes, list of complaints and sanctions for the last two years is publicly available	Yes ☐ No ☒		
5.07.07	Comments and References	Ref 85) 1998: Government Regulation No.72/1998 on Pharmaceuticals and Medical Devices Control Ref 86) 2008: Regulation of Ministry of Health No.1010/2008 (revision of Regulation No. 949/2000) on Drug Registration Ref 87) 2009: Health Law No.36/2009 (revision of Health Law No.23/1992) Ref 88) 2002: Decree of the Head of NADFC No. HK.00.05.3.02706 regarding Medicines Promotion 89) 1993: Permenkes 386 tentang Periklanan Obat Bebas dan Bebas Terbatas, Obat Tradisional dan Alat Kesehatan		

5.08 Clinical trials

Core Questions (click here for help)

			Year	Source
5.08.01	Legal provisions exist requiring authorization for conducting Clinical Trials by the MRA	Yes ☒ No ☐	2001	Ref 90)
5.08.02	Legal provisions exist requiring the agreement by an ethics committee/ institutional review board of the Clinical Trials to be performed	Yes ☒ No ☐	2001	Ref 90) Ref 91)
5.08.03	Legal provisions exist requiring registration of the clinical trials into international/national/regional registry	Yes ☒ No ☐	2001	Ref 90) Ref 91a)
5.08.04	Comments and References	Ref 90) Decree of the Head of the National Agency of Drug and Food Control Republic of Indonesia No. 02002/SK/KBPOM Regarding Clinical Trial Procedures Ref 91) All protocols must get approval from Ethics Committee prior to Clinical Trial Authorization; Ref 91a) National Institute of Health Research and Development		

		(Part of MoH)		
Supplementary questions (click here for help)				
			Year	Source
5.08.05S	Legal provisions exist for GMP compliance of investigational products	Yes ☒ No ☐	2001	Ref 92)
5.08.06S	Legal provisions require sponsor, investigator to comply with Good Clinical Practices (GCP)	Yes ☒ No ☐	2003	Ref 93)
5.08.07S	National GCP regulations are published by the Government.	Yes ☒ No ☐	2001	Ref 92)
5.08.08S	Legal provisions permit inspection of facilities where clinical trials are performed	Yes ☒ No ☐	2001	Ref 93)
5.08.09S	Comments and References	Ref 92) Decree of the Head of the National Agency of Drug and Food Control Republic of Indonesia No. 02002/SK/KBPOM Regarding Clinical Trial Procedures Ref 93) Head of NADFC Decree No.HK.00.05.3.1950 on Criteria and Procedure of Drug Registration		

5.09 Controlled Medicines **Core Questions (click here for help)**				
			Date	Source
5.09.01	The country has adopted the following conventions:			
5.09.01.01	Single Convention on Narcotic Drugs, 1961	Yes ☒ No ☐	1976	Ref 94)
5.09.01.02	The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes ☒ No ☐	1976	Ref 94)
5.09.01.03	Convention on Psychotropic Substances 1971	Yes ☒ No ☐	1996	Ref 94)
5.09.01.04	United Nations Convention against the Illicit Traffic in Narcotic Drugs and	Yes ☒ No ☐	1999	Ref 94)

	Psychotropic Substances, 1988			
5.09.02	Laws for the control of narcotic and psychotropic substances, and precursors exist	Yes ☒ No ☐	2010	Ref 95) 96) 97)
5.09.03	Annual consumption of Morphine (mg/capita)	0.050000	2009	Ref 98)
5.09.04	Comments and References	Ref 94) International Narcotics Control Board, 2010, www.incb.org Ref 95) Undang-Undang Narkotika Ref 96) Undang-Undang Psikotropika Ref 97) Undang-Undang Prekursor (draft?) Ref 98) INCB Statistics of Narcotics, 2010: the annual consumption of morphine is 12 kg, which has gradually increased from 5 kg (2005), 6 kg (2006), to 10 kg in 2007 and 2008). The 2009 consumption equals to (12millgram/237mill inhabitant) 0.05mg/capita, or 9 S-DDD per million inhabitants.		
Supplementary questions (click here for help)				
			Year	Source
5.09.05S	The legal provisions and regulations for the control of narcotic and psychotropic substances, and precursors have been reviewed by a WHO International Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need	Yes ☐ No ☒ Unknown ☐		No evidence of assessment
5.09.05.01S	If yes, year of review			
5.09.06S	Annual consumption of Fentanyl (mg/capita)	0.002	2009	Ref 98)
5.09.07S	Annual consumption of Pethidine (mg/capita)	0.27	2009	Ref 98)
5.09.08S	Annual consumption of Oxycodone (mg/capita)	0	2009	Ref 98)
5.09.09S	Annual consumption of Hydrocodone	0	2009	Ref 98)

	(mg/capita)			
5.09.10S	Annual consumption of Phenobarbital (mg/capita)		2008	Ref 99) Ref 100)
5.09.11S	Annual consumption of Methadone (mg/capita)	0.113220	2009	Ref 98)
5.09.12S	Comments and References	Ref 98) INCB Statistics of Narcotics, 2010: fentanyl consumption is 565.048 kg, pethidine consumption is 67 kg, methadone consumption is 87 kg. These quantities were then converted to per capita consumption. Ref 99) Estimates of Psychotropics, International Narcotics Control Board, 2010 Ref 100) Consumption level of phenobarbital is not known, as reporting consumption is not obligatory. However, Indonesia imported 2,105kg in 2008 for manufacturing, which equals to 8.86mg/capita		

5.10 Pharmacovigilance

Core Questions (click here for help)

			Year	Source
5.10.01	There are legal provision in the Medicines Act that provides for pharmacovigilance activities as part of the MRA mandate	Yes ☒ No ☐	2009	Ref 100a)
5.10.02	Legal provisions exist requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA	Yes ☒ No ☐	2009	Ref 100a)
5.10.03	Legal provisions about monitoring Adverse Drug Reactions (ADR) exist in your country	Yes ☒ No ☐	2009	Ref 100a)
5.10.04	A national pharmacovigilance centre linked to the MRA exists in your country	Yes ☒ No ☐	1998	Ref 100a) - 100g)
5.10.04.01	If a national pharmacovigilance centre exists in your country,	8		

	how many staff does it employ full-time			
5.10.04.02	If a national pharmacovigilance center exists in your country, an analysis report has been published in the last two years.	Yes ☒ No ☐		
5.10.04.03	If a national pharmacovigilance center exists in your country, it publishes an ADR bulletin	Yes ☒ No ☐		
5.10.05	An official standardized form for reporting ADRs is used in your country	Yes ☒ No ☐	2010	NADFC
5.10.06	A national Adverse Drug Reactions database exists in your country	Yes ☒ No ☐	2010	NADFC
5.10.07	How many ADR reports are in the database?	953	2010	NADFC
5.10.08	How many reports have been submitted in the last two years?	737	2009	NADFC
5.10.09	Are ADR reports sent to the WHO database in Uppsala?	Yes ☒ No ☐		
5.10.09.01	If yes, number of reports sent in the last two years	259	2010	2009 -2010
5.10.10	Is there a national ADR or pharmacovigilance advisory committee able to provide technical assistance on causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management including crisis communication?	Yes ☒ No ☐	2009	Ref 100a)
5.10.11	Is there a clear communication strategy for routine communication and crises communication?	Yes ☒ No ☐		
5.10.12	In the absence of a national pharmacovigilance system, ADRs are monitored in at least one public	Yes ☒ No ☐		

	health program (for example TB, HIV, AIDS)?			
5.10.13	Please describe how you intend to enhance the Pharmacovigilance system	Developing PV Guideline for MAH, developing Guideline for specific PV of public health concern/program, initiate sentinel for PV, establishment of electronic reporting mechanism, upgrading of electronic ADR Database, encouragement of ADR reporting to HCPs by conducting workshops, training on PV for HCPs and MAHs, regular coordination meeting and/or forum for PV		
5.10.14	Comments and References	Ref 100a) Health Law No. 36, 2009 Ref 100b) Government Regulation No. 72, 1998 on Pharmaceuticals and Medical Devices Safety Ref 100c) MoH Regulation No. 1010/Menkes/Per/XI/2008 on Drug Registration Ref 100d) MoH Regulation No. 1799/Menkes/Per/XII/2010 on Pharmaceutical Industries Ref 100e) Presidential Decree No. 103, 2001 on Position, Mandate, Function, Authority, Organizational Structure and Management of Government Body/Agency, and it has been changed with Presidential Decree No 2, 2002. Ref 100f) Presidential Decree No. 110, 2002 on Organizational Unit and Mandate of Eselon I of Non Department Government Body/Agency Ref 100g) Head of NADFC Decree No. 02110/SK/KBPOM, 26 February 2001 on Organizational and Management of NADFC		
Supplementary questions (click here for help)				
			Year	Source
5.10.15S	Feedback is provided to reporters	Yes ☒ No ☐	2009	Ref 100a)
5.10.16S	The ADR database is computerized	Yes ☒ No ☐	2011	Electronic database is just initiated, its use to be maximized
5.10.17S	Medication errors (MEs) are reported	Yes ☐ No ☒	2010	NADFC

5.10.18S	How many MEs are there in the ADRs database?	0	2010	NADFC
5.10.19S	There is a risk management plan presented as part of product dossier submitted for Marketing Authorization?	Yes ☐ No ☒	2010	Has been prepared
5.10.20S	In the past two years, who has reported ADRs?		2009	2009 only
5.10.20.01S	Doctors	☒Yes		
5.10.20.02S	Nurses	☒Yes		
5.10.20.03S	Pharmacists	☒Yes		
5.10.20.04S	Consumers	☐Yes		
5.10.20.05S	Pharmaceutical Companies	☒Yes		
5.10.20.06S	Others, please specify whom	Ref 100a) Data 2009: 61 reports submitted by hospitals, 0 by healthcentres, 0 by private practitioners, 28 by pharmacists, and 444 by pharmaceutical companies		
5.10.21S	Was there any regulatory decision based on local pharmacovigilance data in the last 2 years?	Yes ☐ No☒	2010	NADFC
5.10.22S	Are there training courses in pharmacovigilance?	Yes ☒ No☐	2009	Ref 100a)
5.10.22.01S	If yes, how many people have been trained in the last two years?	45	2010	Ref 100b)
5.10.23S	Comments and References	Ref 100a) Annual Report of Deputy of Therapeutic Products and Controlled Drug, National Agency of Drugs and Food Control, 2009 Ref 100b) Number of people trained in 2010 is 45. Trainings have been conducted by Provincial offices of the National Agency for Drug and Food Control and in collaboration with Referral Hospitals		

Section 6 Medicines Financing

6.00 Respondent Information Section 5

6.00.01	Name of person responsible for filling out this section of the instrument	Yusi Anggriani, Dra. Apt., M.Kes. (PhD student), Faculty of Pharmacy, University of Pancasila, Jakarta
6.00.02	Phone number	+62-812-2954935
6.00.03	Email address	yusi1777@yahoo.com
6.00.04	Other respondents for this sections	Dra. Sadiah (+62-812-9297717), Directorate of Public Pharmaceutics, Directorate General of Pharmaceutics and Medical Devices, Ministry of Health Dr. Kent. K. Sarosa (kent.k.sarosa@gsk.com), BU Director, GlaxoSmithKline, Jakarta

6.01 Medicines Coverage and Exemptions

Core Questions (click here for help)

			Year	Source
6.01.01	Do the followings receive medicines free of charge:		2010	MOH
6.01.01.01	Patients who cannot afford them	Yes ☒ No ☐		
6.01.01.02	Children under 5	Yes ☒ No ☐		
6.01.01.03	Pregnant women	Yes ☒ No ☐		
6.01.01.04	Elderly persons	Yes ☒ No ☐		
6.01.01.05	Please describe/explain your yes answers for questions above	Government insurance scheme for the poor covers people who are in needs, regardless the age or sex or pregnancy Patient receive medicines free of charge at Primary Health Center, at secondary level (hospital) only poor patient who is covered by government can receive medicine a free of charge		
6.01.02	Is there a public health system or social health insurance scheme or public programme providing medicines free of charge for :		2010	MOH
6.01.02.01	All medicines included in the EML	Yes ☒ No ☐		

6.01.02.02	Any non-communicable diseases	Yes ☒ No ☐		
6.01.02.03	Malaria medicines	Yes ☒ No ☐		
6.01.02.04	Tuberculosis medicines	Yes ☒ No ☐		
6.01.02.05	Sexually transmitted diseases medicines	Yes ☒ No ☐		
6.01.02.06	HIV/AIDS medicines	Yes ☒ No ☐		
6.01.02.07	Expanded Program on Immunization (EPI) vaccines	Yes ☒ No ☐		
6.01.02.08	If others, please specify			
6.01.02.09	Please describe/explain your yes answers for questions above			
6.01.03	Does a national health insurance, social insurance or other sickness fund provide at least partial medicines coverage?	Yes ☒ No ☐	2010	Ref 101)
6.01.03.01	Does it provide coverage for medicines that are on the EML for inpatients	Yes ☒ No ☐		
6.01.03.02	Does it provide coverage for medicines that are on the EML for outpatients	Yes ☒ No ☐		
6.01.03.03	Please describe the medicines benefit of public/social insurance schemes	Medicines listed in the formulary of the insurance scheme are covered. The list is selected and revised annually by an National Expert Committee, where standard WHO procedures in revising EML is implemented		
6.01.04	Do private health insurance schemes provide any medicines coverage?	Yes ☒ No ☐		
6.01.04.01	If yes, is it required to provide coverage for medicines that are on the EML?	Yes ☐ No ☒		
6.01.05	Comments and References	Ref 101) National health insurance schemes include: - Askes: Health insurance for govt officials and their family,		

		premium paid by individuals - Jamsostek: Health insurance for employees and labours, premium paid by employers - Jamkesmas: Health insurance for people below poverty line, premium paid by the government		
6.02 Patients Fees and Copayments **Core Questions (click here for help)**				
			Year	Source
6.02.01	In your health system, at the point of delivery, are there any co-payment/fee requirements for consultations	Yes ☒ No ☐	2010	MOH
6.02.02	In your health system, at the point of delivery, are there any co-payment/fee requirements for medicines	Yes ☐ No ☒	2010	MOH
6.02.03	In practice, (even though this may be contrary to regulations) is revenue from fees or sales of medicines sometimes used to pay the salaries or supplement the income of public health personnel in the same facility?	Yes ☐ No ☒		
6.02.03.01	Please describe the patient fees and copayments system	After decentralization of the pharmaceutical procurement for primary health care, district governments establish a modest retribution fee for patients visiting public health facilities, which varies depending on the capability of district government to subsidy health services		
6.02.04	Comments and References			
6.03 Pricing Regulation for the Private Sector **Core Questions (click here for help)**				
			Year	Source
6.03.01	Are there legal or regulatory provisions affecting pricing of medicines	Yes ☒ No ☐	2010	Ref 102) 103) 104)

				105) 106) 107) 108)
6.03.01.01	If yes, are the provisions aimed at Manufacturers	Yes ☒ No ☐		
6.03.01.02	If yes, are the provisions aimed at Wholesalers	Yes ☒ No ☐		
6.03.01.03	If yes, are the provisions aimed at Retailers	Yes ☒ No ☐		
6.03.01.04	Please explain the positive answers above: (explain scope of provisions i.e generics vs. originator or subsets of medicines, EML etc.)	Medicine pricing policy only regulated Generic Medicines with INN name. Branded generic and originator brand are not regulated by government. MOH regulates generic medicines.		
6.03.02	Government runs an active national medicines price monitoring system for retail prices	Yes ☒ No ☐	2010	Ref 109)
6.03.03	Regulations exists mandating that retail medicine price information should be publicly accessible	Yes ☒ No ☐	2010	Ref 110)
6.03.03.01	-if yes, please explain how the information is made publically available	Generic name and the maximum retail price must be printed on labels. Information is published to the MoH website		
6.03.04	Comments and References	Ref 102) Generic medicine prive policy regulated the selling price of generic medicines from distributors to retailers (eg. pharmacies, hospitals) and the maximum selling price to the patient Ref 103) MOH Decree no: 632/MenKes/SK/III/2011 Ref 104) MOH Decree no 146/MenKes/SK/I/2010 Ref 105) MOH Decree no. 302/MenKes/SK/III/2008 Ref 106) MOH Decree no. 720/MenKes/SK/V/2006 Ref 107) MOH Decree no. 336/MenKes/SK/V/2006 Ref 108) MOH Decree no. 12/MenKes/SK/V/2005 Ref 109) Price Monitoring is the task of the Sub-Directorate of Price Monitoring, Directorate of Public Pharmaceutics, Directorate General of Public Pharmaceutics and Medical Devices, MOH Ref 110) No 069/Menkes/SK/II/2006, Regarding Maximum Price		

		Labelling on the Package and MoH Decree No 314/Menkes/SK/V/2006 In 2008, GlaxoSmithKline revisited their product prices and recalculated the appropriate prices for Asian countries, including Indonesia. The recalculation included the country gross net income, competition with generics, and acceptable price by patients, doctors, and pharmacies. The result of such innitiative is highly apreciated, resulting in significant reduction of their product prices.

6.04 Prices, Availability and Affordability

Core Questions (click here for help)

			Year	Source
6.04.01-04	Please state if a medicines price survey using the WHO/HAI methodology has been conducted in the past 5 years in your country. **If yes**, please indicate the year of the survey and use the results to fill in this table ***If no***, but other surveys on medicines prices and availability have been conducted, please do not use them to fill in this section, but rather use the comment box to write some of the results and attach the report to the questionnaire	Yes ☒ No ☐ Unknown ☐	2010	Ref 111)

	Basket Of key medicines			Public procurement	Public patient	Private patient		
	Availability (one or both of)	**Mean (%)**	**Orig**		6.04.01.01 4.6	6.04.01.03 27.6		
			LPG		6.04.01.02 55.4	6.04.01.04 58.8		
		Median (%)	**Orig**		6.04.02.01	6.04.02.03		
			LPG		6.04.02.02	6.04.02.04		

	Price	**Median Price Ratio**	**Orig**	6.04.03.01	6.04.03.03 18.4	6.04.03.05 32.15	
			LPG	6.04.03.02 1.34	6.04.03.04 2.0	6.04.03.06 2.00	
	Affordability Days' wages of the lowest paid govt worker for standard treatment with co-trimoxazole for a child respiratory infection	**Number of days' wages**	**Orig**		6.04.04.01	6.04.04.03 1.8	
			LPG		6.04.04.02 0.1	6.04.04.04 0.1	
6.04.05	Comments and References			Ref 111) Ongoing Doctoral Thesis 2009-2011 Yusi Anggriani: Evaluation Of The Effectiveness Of Medicine Price Policy By Indonesian Moh And Its Impact On Price, Avalabilty And Affordability.			

6.05 Price Components and Affordability

Core Questions (click here for help)

			Year	Source
6.05.01	Please state if a survey of medicines price components has been conducted in the past 5 years in your country	Yes ☒ No ☐ Unknown ☐	2006	Ref 112)
6.05.02	Median cumulative percentage mark-up between Manufacturer Selling Price (MSP)/ Cost Insurance and Freight (CIF) price and final medicine price for a basket of key medicines in the public sector (Median % contribution)	10		
6.05.03	Median cumulative percentage mark-up between MSP/CIF price and final medicine price for a basket of key medicines in the private sector (Median % contribution)	45.75		

6.05.04	Comment and References	Ref 112) Based on survey conducted by Dra. Selma Siahaan, Kajian tentang Harga Obat yang rasional untuk pelayanan kesehatan. Pusat Penelitian dan Pengembangan Sistem dan Kebijakan. Departemen Kesehatan RI, 2006 For private sector: Information was obtained from a leading multinational company in Indonesia
Supplementary questions (click here for help)		
6.05.05S	Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the public sector (Median % contribution)	10
6.05.06S	Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the private sector (Median % contribution)	45.75
6.05.07S	Median manufacturer selling price (CIF) as percent of final medicine price for a basket of key medicines (%)	73.07
6.05.08S	Median wholesaler selling price as percent of final medicine price for a basket of key medicines (%)	80
6.05.09S	Median pharmacist mark-up or dispensing fee as percent of retail price for a basket of key medicines (%)	0
6.05.10S	Median percentage contribution of the wholesale mark-up to final medicine price for a basket of key medicines (in the public and private sectors) (%)	5
6.05.11S	Median percentage contribution of the retail mark-up to final medicine price for a basket of key medicines (in the public and private sectors) (%)	25
6.05.12S	Comment and References	Survey conducted by Dra. Selma Siahaan, Kajian tentang Harga Obat yang rasional untuk pelayanan kesehatan. Pusat Penelitian dan Pengembangan Sistem dan Kebijakan. Departemen

		Kesehatan RI, 2006 For private sector: Information was obtained from a leading multinational company in Indonesia		
6.06 Duties and Taxes on Pharmaceuticals (Market) **Core Questions (click here for help)**				
			Year	Source
6.06.01	There are duties on imported active pharmaceutical ingredients (APIs)	Yes ☒ No ☐	2011	Ref 113)
6.06.02	There are duties on imported finished products	Yes ☒ No ☐	2011	Ref 113)
6.06.03	VAT (value-added tax) or any other tax is levied on finished pharmaceuticals products	Yes ☒ No ☐	2011	Ref 113)
6.06.04	There are provisions for tax exceptions or waivers for pharmaceuticals and health products	Yes ☒ No ☐	2011	Ref 113)
6.06.05	Please specify categories of pharmaceuticals on which the taxes are applied and describe the exemptions and waivers that exist	Bilateral trading agreement with China exempts taxes for pharmaceutical commodities from China. Exemption for trading with other countries is given upon request		
6.06.06	Comments and References	Ref 113) Ministry of Finance, Macroeconomy framework and fiscal policy 2011		
Supplementary questions (click here for help)				
			Year	Source
6.06.07S	Duty on imported active pharmaceutical ingredients, APIs (%)	5	2010	Ref 113a)
6.06.08S	Duty on imported finished products (%)	5	2010	Ref 113a)
6.06.09S	VAT on pharmaceutical products (%)	10	2010	Ref 113a) Ref 113b)
6.06.10S	Comments and References	Ref 113a) Personal communication with a leading multinational		

		pharmaceutical company in Indonesia Ref 113b) Unpublished report: Price component study in Indonesia. Center for Health Services and Technology Research National Institute of Health Research and Development Ministry of Health Indonesia, In collaboration with: WHO Jakarta Health Action International, 2005 - 2006. The results of the study are the accumulative mark ups of the medicines prices from distributor to consumer were 54% to 88%. The profit margin charged by distributors, retail pharmacies and hospital are varied, from 6 to 15% (for distributor) and 20 to 35% (for retail pharmacies and hospital). The profit margin from dispensing doctors and drugs stores cannot be measured. The total VAT's are imposed on distributors' and retailers' prices are 20%.

Section 7 Pharmaceutical procurement and distribution

7.00 Respondent Information Section 6

7.00.01	Name of person responsible for filling out this section of the instrument	Drs. Syafrizal (sbinfar@yahoo.com), Directorate of Public Pharmaceutics, Directorate General of Pharmaceutics and Medical Devices, Ministry of Health
7.00.02	Phone number	+62-8176000363
7.00.03	Email address	sbinfar@yahoo.com
7.00.04	Other respondents for filling out this section	Drs. Pandu. Procurement Committee, Directorate of Public Pharmaceutics, Directorate General of Pharmaceutics and Medical Devices, Ministry of Health

7.01 Public Sector Procurement

Core Questions (click here for help)

			Date	Source
7.01.01	Public sector procurement is:		2001	Ref 114)
7.01.01.01	Decentralized	☐Yes		
7.01.01.02	Centralized and decentralized	☒Yes		
7.01.01.03	Please describe	Medicines are procured by district/municipal government. Provincial Governments procure buffer stock and emergency medicines, central government procures national buffer stock and medicines for 13 vertical programs		
7.01.02	If public sector procurement is wholly or partially centralized, it is under the responsibility of a procurement agency which is:		2001	Ref 114)
7.01.02.01	Part of MoH	Yes ☒ No ☐		

7.01.02.02	Semi-Autonomous	Yes ☐ No ☒		
7.01.02.03	Autonomous	Yes ☐ No ☒		
7.01.02.04	A government procurement agency which procures all public goods	Yes ☐ No ☒		
7.01.03	Public sector requests for tender documents are publicly available	Yes ☒ No ☐	2003	Ref 115)
7.01.04	Public sector tender awards are publicly available	Yes ☒ No ☐	2003	Ref 115)
7.01.05	Procurement is based on prequalification of suppliers	Yes ☒ No ☐	2003	Ref 115)
7.01.05.01	If yes, please describe how it works	Tender must include all medicines in a packages Suppliers must have established distribution channels throughout Indonesia		
7.01.06	Comments and References	Ref 114) President of Indonesia, 2000. Peraturan Pemerintah No. 84 tahun 2000 tentang Pedoman Organisasi Perangkat Daerah (Government Regulation on the Guidelines of District Authority Organization), President of Indonesia, Jakarta Ref 115) Presidential Decree No 80/2003 on Guidelines of Procurement of Goods and Services for Government		

Supplementary questions (click here for help)

			Year	Source
7.01.07S	Is there a written public sector procurement policy?. If yes, please write the year of approval in the "year" field	Yes ☒ No ☐	2003	Ref 115)
7.01.08S	Are there legal provisions giving priority in public procurement to goods produced by local manufacturers?	Yes ☒ No ☐	2003	Ref 115)
7.01.09S	The key functions of the procurement unit and those of the tender committee are clearly separated	Yes ☒ No ☐	2003	Ref 115)

7.01.10S	A process exists to ensure the quality of products procured	Yes ☒ No ☐	2003	Ref 115)
7.01.10.01S	If yes, the quality assurance process includes pre-qualification of products and suppliers	Yes ☒ No ☐		
7.01.10.02S	If yes, explicit criteria and procedures exist for pre-qualification of suppliers	Yes ☒ No ☐		
7.01.10.03S	If yes, a list of pre-qualified suppliers and products is publicly available	Yes ☒ No ☐		
7.01.11S	List of samples tested during the procurement process and results of quality testing are available	Yes ☒ No ☐		
7.01.12S	Which of the following tender methods are used in public sector procurement:		2003	Ref 115)
7.01.12.01S	National competitive tenders	Yes ☒ No ☐		
7.01.12.02S	International competitive tenders	Yes ☐ No ☒		
7.01.12.03S	Direct purchasing	Yes ☒ No ☐		
7.01.13S	Comments and References	Ref 115) Presidential Decree No 80/2003 on Guidelines of Procurement of Goods and Services for Government		

7.02 Public Sector Distribution

Core Questions (click here for help)

			Year	Source
7.02.01	The government supply system department has a Central Medical Store at National Level	Yes ☒ No ☐	2010	MOH
7.02.02	Number of public warehouses in the secondary tier of public distribution (State/Regional/Provincial)	530	2009	Ref 116)

7.02.03	There are national guidelines on Good Distribution Practices (GDP)	Yes ☒ No ☐	2007	Ref 117)
7.02.04	There is a licensing authority that issues GDP licenses	Yes ☐ No ☒		Not yet implemented
7.02.04.01	If a licensing authority exists, does it accredit public distribution facilities?	Yes ☐ No ☒		
7.02.05	List of GDP certified warehouses in the public sector exists	Yes ☐ No ☒		
7.02.06	List of GDP certified distributors in the public sector exists	Yes ☐ No ☒		
7.02.07	Comments and References	Ref 116) Indonesia Health Profile 2009, Ministry of Health, district 497 + provincial 33 Ref 117) Pedoman Cara Distribusi Obat yang Baik (Good Distribution Practices), Badan Pengawasan Obat dan Makanan, 2007. The guideline has been published in 2007 by the National Agency for Drug and Food Control, but no implementation has yet been in place. Such implementation needs political, administrative, and technical support form the Ministry of Health and all stakeholders in pharmaceuticals as well as district governments		

Supplementary questions (click here for help)

			Year	Source
7.02.08S	Which of the following processes is in place at the Central Medical Store:		2011	onsite observation
7.02.08.01S	Forecasting of order quantities	Yes ☒ No ☐		
7.02.08.02S	Requisition/Stock orders	Yes ☒ No ☐		
7.02.08.03S	Preparation of picking/packing slips	Yes ☒ No ☐		
7.02.08.04S	Reports of stock on hand	Yes ☒ No ☐		
7.02.08.05S	Reports of outstanding order lines	Yes ☒ No ☐		

7.02.08.06S	Expiry dates management	Yes ☒ No ☐		
7.02.08.07S	Batch tracking	Yes ☒ No ☐		
7.02.08.08S	Reports of products out of stock	Yes ☒ No ☐		
7.02.09S	Percentage % availability of key medicines at the Central Medical Store	100	2010	Ref 118)
7.02.10S	Average stock-out duration for a basket of medicines at the Central Medical Store, in days	0		
7.02.11S	Routine Procedure exists to track the expiry dates of medicines at the Central Medical Store	Yes ☒ No ☐	2010	Ref 118)
7.02.12S	The Public Central Medical Store is GDP certified by a licensing authority	Yes ☐ No ☒		
7.02.13S	The Public Central Medical Store is ISO certified	Yes ☐ No ☒		
7.02.14S	The second tier public warehouses are GDP certified by a licensing authority	Yes ☐ No ☒		
7.02.15S	The second tier public warehouses are ISO certified	Yes ☐ No ☒		
7.02.16S	Comments and References	Ref 118) The Central Medical Store stocks only national buffer stock, which is only 0.3% by value of the approximate total pharmaceuticals procurement. Distribution to provincial medical store is made upon request, which is only made by 3-4 provinces on average per year		

7.03 Private Sector Distribution

Core Questions (click here for help)

			Year	Source
7.03.01	Legal provisions exist for licensing wholesalers in the private sector	Yes ☒ No ☐	2010	Ref 119)

7.03.02	Legal provisions exist for licensing distributors in the private sector	Yes ☒ No ☐	2010	Ref 119)
7.03.03	List of GDP certified wholesalers in the private sector exists	Yes ☐ No ☒		Ref 119)
7.03.04	List of GDP certified distributors in the private sector exists	Yes ☐ No ☒		Ref 119)
7.03.05	Comments and References	Ref 119) Pedoman Cara Distribusi Obat yang Baik (Good Distribution Practices), Badan Pengawasan Obat dan Makanan, 2007. The guideline has been published in 2007 by the National Agency for Drug and Food Control, but no implementation has yet been in place.		

Section 8 Selection and rational use

8.00 Respondent Information Section 7

8.00.01	Name of person responsible for filling out this section of the instrument	Dra. Engko Sosialine, Director of Pharmaceutical Services, Directorate Genderal of Pharmaceutics and Medical Devices, Ministry of Health, Jakarta.
8.00.02	Phone number	+62-815-19339736
8.00.03	Email address	engkosm@yahoo.com
8.00.04	Other respondents for filling out this section	Dra. Hidayati Mas'ud, Directorate of Pharmaceutical Services, Directorate Genderal of Pharmaceutics and Medical Devices, Ministry of Health, Jakarta. Dra. Sari Mutiarani, Directorate of Pharmaceutical Services, Directorate Genderal of Pharmaceutics and Medical Devices, Ministry of Health, Jakarta.

8.01 National Structures

Core Questions (click here for help)

			Year	Source
8.01.01	National essential medicines list (EML) exists. If yes, please write year of last update of EML in the "year" field	Yes ☒ No ☐	2008	Ref 120)
8.01.01.01	If yes, number of medicines on the EML (no. of INN)	323		
8.01.01.02	If yes, there is a written process for selecting medicines on the EML	Yes ☒ No ☐		
8.01.01.03	If yes, the EML is publicly available	Yes ☒ No ☐		
8.01.01.04	If yes, is there any mechanism in place to align the EML with the Standard Treatment Guidelines (STG)	Yes ☒ No ☐		
8.01.02	National Standard Treatment Guidelines (STGs) for most common illnesses are produced/endorsed by the MoH. If	Yes ☒ No ☐	2007	Ref 120a)

	yes, please insert year of last update of STGs in the "year" field			
8.01.03	STGs specific to Primary care exist. Please use the "year" field to write the year of last update of primary care guidelines	Yes ☒ No ☐	2007	Ref 120a)
8.01.04	STGs specific to Secondary care (hospitals) exists. Please use the "year" field to write the year of last update of secondary care STGs.	Yes ☒ No ☐	2010	Every hospital has STG
8.01.05	STGs specific to Paediatric conditions exist. Please use the "year" field to write the year of last update of paediatric condition STGs	Yes ☒ No ☐	2004	Ref 120b)
8.01.06	% of public health facilities with copy of EML (mean)- Survey data	93.75	2009	MOH
8.01.07	% of public health facilities with copy of STGs (mean)- Survey data	100	2009	MOH
8.01.08	A public or independently funded national medicines information centre provides information on medicines to prescribers, dispensers and consumers	Yes ☒ No ☐	2010	University-based Drug Information Centre
8.01.09	Public education campaigns on rational medicine use topics have been conducted in the previous two years	Yes ☒ No ☐	2008	As national program since 2008
8.01.10	A survey on rational medicine use has been conducted in the previous two years	Yes ☒ No ☐	2008	As national program since 2008
8.01.11	A national programme or committee (involving government, civil society, and professional bodies) exists to monitor and promote rational use of medicines	Yes ☒ No ☐	2008	Coordinated by Directorate of Pharmaceutical Services,

				MOH
8.01.12	A written National strategy exists to contain antimicrobial resistance. If yes, please write year of last update of the strategy in the "year" field	Yes ☒ No ☐	2011	Antimicrobial Policy, MOH, April 2011
8.01.13	Comments and References	Ref 120) National Essential Medicine List 2008, Ministry of Health Ref 120a) Pedoman Pengobatan Dasar Puskesmas, Ministry of Health, Jakarta, 2007 Ref 120b) Buku saku Pelayanan Kesehatan Anak di Rumah Sakit, translated from WHO: Hospital Care for Children, WHO 2005		
Supplementary questions (click here for help)				
			Year	Source
8.01.14S	The Essential Medicines List (EML) includes formulations specific for children	Yes ☐ No ☐	2008	Ref 120)
8.01.15S	There are explicitly documented criteria for the selection of medicines in the EML	Yes ☒ No ☐	2005	since 2005, Ref 120) preamble of the NEML
8.01.16S	There is a formal committee or other equivalent structure for the selection of products on the National EML	Yes ☒ No ☐	2005	National Committee on Selection and Use of Essential Medicines
8.01.16.01S	If yes, conflict of interest declarations are required from members of national EML committee	Yes ☒ No ☐		
8.01.17S	National medicines formulary exists	Yes ☒ No ☐	2010	MOH
8.01.18S	Is there a funded national inter-sectoral task force to coordinate the promotion of appropriate use of antimicrobials and prevention of	Yes ☒ No ☐	2010	MOH

	spread of infection?			
8.01.19S	A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	Yes ☒ No ☐	2010	MOH
8.01.20S	Comments and References	Ref 120) Indonesian National Essential Medicine List, Ministry of Health 2008. Revision of the 2011 still in progress, will be completed and published by end of year 2011 Antimicrobial Resistance Program in Indonesia (AMRIN) was established in 2002, led by Dr. Sutomo Hospital, Surabaya. The MOH coordinates the intersectoral activities. Recently in April 2011, the National Antimicrobial Policy was launched.		

8.02 Prescribing

Core Questions (click here for help)

			Year	Source
8.02.01	Legal provisions exist to govern the licensing and prescribing practices of prescriber	Yes ☒ No ☐	2010	Indonesia Medical Association
8.02.02	Legal provisions exist to restrict dispensing by prescribers	Yes ☐ No ☒		
8.02.03	Do prescribers in the private sector dispense medicines?	Yes ☒ No ☐		
8.02.04	Regulations require hospitals to organize/develop Drug and Therapeutics Committees (DTCs)	Yes ☒ No ☐		
8.02.05	Do more than half of referral hospitals have a DTC?	Yes ☒ No ☐ Unknown ☐	2009	Ref 121)
8.02.06	Do more than half of general hospitals have a DTC?	Yes ☒ No ☐ Unknown ☐	2009	Ref 121)
8.02.07	Do more than half of regions/provinces have a DTC?	Yes ☒ No ☐ Unknown ☐	2009	Ref 121)

8.02.08	The core medical training curriculum includes components on:		2010	Ref 122)
8.02.08.01	Concept of EML	Yes ☒ No ☐		
8.02.08.02	Use of STGs	Yes ☒ No ☐		
8.02.08.03	Pharmacovigilance	Yes ☒ No ☐		
8.02.08.04	Problem based pharmacotherapy	Yes ☒ No ☐		
8.02.09	Mandatory continuing education that includes pharmaceutical issues is required for doctors (see physician)	Yes ☒ No ☐	2010	Ref 122)
8.02.10	Mandatory continuing education that includes pharmaceutical issues is required for nurses	Yes ☐ No ☒		
8.02.11	Mandatory continuing education that includes pharmaceutical issues is required for paramedical staff	Yes ☐ No ☒		
8.02.12	Prescribing by INN name is obligatory in:		2010	MOH decree
8.02.12.01	Public sector	Yes ☒ No ☐		
8.02.12.02	Private sector	Yes ☐ No ☒		
8.02.13	Average number of medicines prescribed per patient contact in public health facilities (mean)	3.4	2010	Ref 123)
8.02.14	% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)	93	2002	Ref 124)
8.02.15	% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)			updated national data is not available

8.02.16	% of patients in outpatient public health care facilities receiving antibiotics (mean)	57.37	2010	Ref 123)
8.02.17	% of patients in outpatient public health care facilities receiving injections (mean)	2.96	2010	Ref 123)
8.02.18	% of prescribed drugs dispensed to patients (mean)			updated national data is not available, , but availability is no more a problem
8.02.19	% of medicines adequately labeled in public health facilities (mean)	100	2010	Routine monitoring
8.02.20	Comments and References	Ref 121) Annual Report 2009, Directorate General of Pharmaceutics and Medical Devices, Ministry of Health 2010 Ref 122) KIPDI 3, Core Curriculum of Indonesian Medical Undergraduate Training Ref 123) Routine monitoring as part of national program in promoting rational drug use, by Directorate of Pharmaceutical Services, MOH Ref 124) Report, Impact of currency crisis on medicine cost, availability, and use of key essential medicines in Indonesia, 1997-2002, Suryawati et al, Centre for Clinical Pharmacology and Medicine Policy Studies Gadjah Mada University, 2004		

Supplementary questions (click here for help)

			Year	Source
8.02.21S	A professional association code of conduct exists governing professional behaviour of doctors	Yes ☒ No ☐		Indonesian Medical Association
8.02.22S	A professional association code of conduct exists governing professional behaviour of nurses	Yes ☒ No ☐		

8.02.23S	Diarrhoea in children treated with Oral Rehydration Solution (ORS) (%)			Update national data is not available
8.02.24S	Comments and References			
8.03 Dispensing **Core Questions (click here for help)**				
			Year	Source
8.03.01	Legal provisions exist to govern dispensing practices of pharmaceutical personnel	Yes ☒ No ☐	2010	Ref 125)
8.03.02	The basic pharmacist training curriculum includes components on:		2009	Association of Pharmacy Higher Education Institutions
8.03.02.01	Concept of EML	Yes ☒ No ☐		
8.03.02.02	Use of STGs	Yes ☒ No ☐		
8.03.02.03	Drug Information	Yes ☒ No ☐		
8.03.02.04	Clinical pharmacology	Yes ☒ No ☐		
8.03.02.05	Medicines supply management	Yes ☒ No ☐		
8.03.03	Mandatory continuing education that includes rational use of medicines is required for pharmacists	Yes ☐ No ☒		
8.03.04	Generic substitution at the point of dispensing in public sector facilities is allowed	Yes ☒ No ☐		
8.03.05	Generic substitution at the point of dispensing in private sector facilities is allowed	Yes ☒ No ☐		

8.03.06	In practice, (even though this may be contrary to regulations) are antibiotics sometimes sold over-the-counter without any prescription?	Yes ☒ No ☐ Unknown ☐		
8.03.07	In practice, (even though this may be contrary to regulations) are injections sometimes sold over-the-counter without any prescription?	Yes ☐ No ☒ Unknown ☐		
8.03.08	Comments and References	Ref 125) Government Regulation No. 51/2009 on Pharmaceutical Care		
Supplementary questions (click here for help)				
			Year	Source
8.03.09S	A professional association code of conduct exists governing professional behaviour of pharmacists	Yes ☒ No ☐		
8.03.10S	In practice, (even though this may be contrary to regulations) do the following groups of staff *sometimes* prescribe prescription-only medicines at the primary care level in the public sector?			
8.03.10.01S	Nurses	Yes ☐ No ☒ Unknown ☐		
8.03.10.02S	Pharmacists	Yes ☒ No ☐ Unknown ☐		
8.03.10.03S	Paramedics	Yes ☐ No ☒ Unknown ☐		
8.03.10.04S	Personnel with less than one month training	Yes ☐ No ☒ Unknown ☐		
8.03.11S	Comments and References			

Section 9 Household data/access

9.00 Respondent Information section 8

9.00.01	Name of person responsible for filling out this section of the instrument	author
9.00.02	Phone number	
9.00.03	Email address	
9.00.04	Other respondents for filling out this section	

9.01 Data from Household Surveys

Core Questions (click here for help)

			Year	Source
9.01.01	What household surveys have been undertaken in the past 5 years to assess access to medicines?	Survei kesehatan rumah tangga Indonesia (Sakerti): Indonesia Household Health Survey, 2007. However the survey did not provide the information as requested below (questions no 9.01.01 to 9.01.19S), while no other recent national survey is available.		
9.01.02	Adults with acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)			not known
9.01.03	Adults with acute conditions not taking all medicines because they cannot afford them (%)			not known
9.01.04	Adults (from poor households) with an acute health condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)			not known
9.01.05	Adults (from poor households) with an acute condition in two-week recall period who did not take all medicines because they cannot afford them (%)			not known

9.01.06	Adults with chronic conditions taking all medicines prescribed by an authorized prescriber (%)			not known
9.01.07	Adults (from poor households) with chronic conditions not taking all medicines because they cannot afford them (%)			not known
9.01.08	Adults (from poor households) with chronic conditions who usually take all medicines prescribed by an authorized prescriber (%)			not known
9.01.09	Children (from poor households) with an acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)			not known
9.01.10	Percentage of people who obtained the medicines prescribed in the 15 days before the interview (%)			not known
9.01.11	People who obtained prescribed medicines for free in the 15 days before the interview (%)			not known
9.01.12	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
9.01.13S	Adults with acute conditions not taking all medicines because the medicines were not available (%)			not known
9.01.14S	Adults with chronic conditions not taking all medicines because they cannot afford them (%)			not known
9.01.15S	Adults with chronic conditions not taking all medicines because the medicines were not available (%)			not known
9.01.16S	Children with acute conditions taking all medicines prescribed by			not known

	an authorized prescriber (%)			
9.01.17S	Children with acute conditions not taking all medicines because they cannot afford them (%)			not known
9.01.18S	Children with acute conditions not taking all medicines because the medicines were not available (%)			not known
9.01.19S	Children (from poor households) with acute conditions not taking all medicines because they cannot afford them (%)			not known
9.01.20S	Comments and References			

Key Documents to be attached

Document	Exact title	Author	Publisher	Year	File name
National Medicines Policy (NMP)					
NMP implementation plan					
National Medicines Act					
National pharmaceutical human resources report or strategic plan					
Latest report on the national pharmaceutical market (any source)					
National Pharmacovigilance Centre report (including Adverse Drug Reaction, ADR, analysis report in the last two years)					
National pharmaceutical legislation for regulation					
Annual report of quality control laboratories					
Annual report of national regulatory authority					
Legal provisions on medicines price regulations					
Medicines procurement policy					
National Essential Medicines List (EML)					
National Standard Treatment Guidelines (STGs)					
National Strategy for anti-microbial resistance					
Any other medicines					

pricing/availability surveys, household surveys, and rational use surveys than the ones used to prefill in the instrument.					