


Pharma Regulations

overview of global aggregation & serialization regulations

Pharma Regulations Overview

Algeria




Regulatory Authority	Ministry of Health, Population and Hospital Reform (MSPRH)
Link	Guide to Health in Algeria
Serialization	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(21) – Serial Number
Data carrier	GS1 DataMatrix
Deadline	Planned for 2025

Argentina




Regulatory Authority	Ministry of Health of the Argentine Republic (ANMAT) (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica)
Links	Administración Nacional de Medicamentos Argentina-Ministry of Health
Serialization	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(21) – Serial Number
Data carrier	GS1 DataMatrix GS1 128
Deadline	30 August 2015


Australia




Regulatory Authority	Department of Health and Aged Care
Links	Department of Health Medicine labels: Guidance on TGO 91 and TGO 92 Federal Register of Legislation
Serialization	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(21) – Serial Number
Data carrier	GS1 DataMatrix
Deadline	01 January 2023


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Bahrain 			
Regulatory Authority	National Health Regulatory Authority (NHRA)		
Links	National Health Regulatory Authority Medicines Barcoding and Serialization Guideline		
Serialization		Aggregation	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(21) – Serial Number		
Data carrier	GS1 DataMatrix	Data carrier	GS1 128
Deadline	31 December 2019	Deadline	01 September 2021


Brazil 			
Regulatory Authority	Brazilian Health Regulatory Authority (ANVISA) RDC 157 / 2017		
Links	Brazilian Health Regulatory Agency (Anvisa) LAW NO. 14.338, OF MAY 11, 2022		
Serialization		Aggregation	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(713) – NHRN AI(21) – Serial Number	Data elements	AI(00) – SSCC
Data carrier	GS1 DataMatrix	Data carrier	GS1 128
Deadline	01 April 2022	Deadline	01 April 2022

Canada 			
Regulatory Authority	Canadian Institute for Safe Medication Practices (ISMP), Canadian Patient Safety Institute (CPSI)		
Links	Institute for Safe Medication Practices Canadian Pharmaceutical Bar Coding Project		
Batch constant		Serialization	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN	Data elements	optional AI(21) – Serial Number
Data carrier	GS1 DataMatrix GS1 128	Data carrier	GS1 DataMatrix GS1 128
Deadline	31 December 2023	Deadline	31 December 2023

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Chile 	
Regulatory Authority	Ministerio de Salud, Sub Secretaria de Salud Publica - Division Juridica
Links	Ministerio de Salud Decree 57 Exempt
Batch constant	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN
Data carrier	GS1 DataMatrix GS1 128
Deadline	2013

China 			
Regulatory Authority	National Medicinal Products Administration (NMPA) CFDA Decree No. 28 “National e-coding system”		
Links	National Medical Products Administration		
Serialization	Aggregation		
Data elements	Proprietary Chinese eCode or AI(01) – GTIN AI(21) – Serial Number	Data elements	Proprietary Chinese eCode or AI(01) – GTIN AI(21) – Serial Number
Data carrier	GS1 128	Data carrier	GS1 128
Deadline	June 2023	Deadline	June 2023

Columbia 	
Regulatory Authority	INVIMA Ministry of Health and Social Protection
Links	GS1 Colombia
Serialization	
Data elements	AI(01) – GTIN AI(21) – Serial Number
Data carrier	RFID
Deadline	1 April 2018


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Ecuador


Regulatory Authority	National Agency for Health Regulatory Control and Surveillance (ARCSA)
Links	Inter-American Coalition for Regulatory Convergence Medical Device Registration in Ecuador
Serialization	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(21) – Serial Number
Data carrier	GS1 DataMatrix GS1 128
Deadline	26 May 2024


Egypt


Regulatory Authority	Egyptian Ministry of Health
Links	Egyptian Drug Authority
Serialization	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(21) – Serial Number
Data carrier	GS1 DataMatrix GS1 128
Deadline	31 December 2018

Europe



Regulatory Authority	EU Commission Directive 2011/62/EU
Links	European Medicines Verification Organisation Falsified Medicines Directive
Serialization	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN/NTIN AI(713) – NHRN if applicable AI(21) – Serial Number
Data carrier	GS1 DataMatrix DataMatrix
Deadline	09 February 2019


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India 			
Regulatory Authority		Ministry of Health and Family Welfare of India	
Links		Ministry of Health and Family Welfare	
Serialization		Aggregation	
Primary	Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(21) – Serial Number	Data elements AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(00) – SSCC
	Data carrier	GS1 DataMatrix GS1 Databar	Data carrier GS1 128
	Deadline	01 April 2015	Deadline 01 July 2019
Secondary	Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(21) – Serial Number	
	Data carrier	GS1 DataMatrix GS1 128 GS1 Databar	
	Deadline	01 October 2013	
Tertiary	Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(21) – Serial Number AI(00) – SSCC	
	Data carrier	GS1 DataMatrix GS1 128	
	Deadline	01 October 2011	

Indonesia 		
Regulatory Authority		National Agency for Pharmaceuticals and Food Control of the Republic of Indonesia
Links		Regulatory Statistics of Medicinal Commodities
Serialization		
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(21) – Serial Number	
Data carrier	GS1 DataMatrix	
Deadline	01 January 2023	

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Iran 	
Regulatory Authority	Ministry of Health and Medical Education TTAC Executive Guideline no 660/11873
Links	Ministry of Health and Medical Education
Serialization	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN UID
Data carrier	GS1 DataMatrix
Deadline	01 January 2015

Japan 			
Regulatory Authority	Ministry of Health, Labour and Welfare		
Links	Ministry of Health, Labour and Welfare Measures to prevent distribution of counterfeit drugs		
Serialization		Aggregation	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – UCC Japanese Number AI(21) – Serial Number	Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – UCC Japanese Number AI(21) – Serial Number AI(30) – Quantity
Data carrier	GS1 DataBar	Data carrier	GS1 128
Deadline	01 July 2015	Deadline	01 April 2021

Jordan 			
Regulatory Authority	Jordanian Food and Drug Administration (JFDA)		
Links	Food and Drug Administration		
Batch constant		Serialization	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN	Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(21) – Serial Number
Data carrier	GS1 DataMatrix	Data carrier	GS1 DataMatrix
Deadline	01 July 2018	Deadline	01 January 2020

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Kazakhstan

Regulatory Authority	Ministry of Finance / Health		
Links	Ministry of Healthcare		
Serialization		Aggregation	
Data elements	AI(01) – GTIN AI(21) – Serial Number AI(91) – Crypto Key AI(92) – Crypto Code	Data elements	AI(00) – SSCC
Data carrier	GS1 DataMatrix	Data carrier	GS1 128
Deadline	01 October 2022 (20%) 01 January 2023 (60%) 01 April 2023 (80%) 01 July 2023 (all)	Deadline	01 October 2022 (20%) 01 January 2023 (60%) 01 April 2023 (80%) 01 July 2023 (all)


Lebanon


Regulatory Authority	Ministry of Public Health		
Links	Ministry of Public Health-Pharmaceutical Traceability		
Batch constant			
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN		
Data carrier	GS1 DataMatrix		
Deadline	31 December 2019		


Malaysia

Regulatory Authority	Malaysian Ministry of Health		
Links	Malaysia Health Ministry NPRA Notice		
Serialization		Aggregation	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(21) – Serial Number	Data elements	AI(00) – SSCC
Data carrier	GS1 DataMatrix	Data carrier	GS1 128
Deadline	01 January 2023	Deadline	01 January 2023

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Norway 	
Regulatory Authority	The Norwegian Medicines Agency
Links	The Norwegian Medicines Agency Regulatory Affairs
Serialization	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN/NTIN AI(21) – Serial Number
Data carrier	GS1 DataMatrix
Deadline	09 February 2019


Oman 			
Regulatory Authority	Directorate General of Medical Supplies MoH MH/DGMS/DSS/M/7043/Directorate		
Links	Ministry of Health		
Batch constant	Serialization		
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN	Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(21) – Serial Number
Data carrier	GS1 DataMatrix	Data carrier	GS1 DataMatrix
Deadline	31 December 2017	Deadline	01 March 2019

Pakistan 					
Regulatory Authority	Pakistan Drug Regulatory Authority (DRAP)				
Links	Drug Regulatory Authority				
Batch constant	Serialization		Aggregation		
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN	Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(21) – Serial Number	Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(21) – Serial Number AI(240) – Product
Data carrier	GS1 DataMatrix	Data carrier	GS1 DataMatrix	Data carrier	GS1 DataMatrix
Deadline	01 August 2025	Deadline	01 August 2025	Deadline	15 December 2025

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Philippines 	
Regulatory Authority	Food and Drug Administration Philippines
Links	Food and Drug Administration Verification Portal
Batch constant	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN
Data carrier	GS1 DataMatrix GS1 128
Deadline	30 June 2016

Qatar 			
Regulatory Authority	Hamad Medical Corporation (HMC)		
Links	Ministry of Health Hamad Medical Corporation		
Batch constant		Serialization	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN	Data elements	AI(21) – Serial Number, if applicable
Data carrier	GS1 DataMatrix GS1 128	Data carrier	GS1 DataMatrix GS1 128
Deadline	01 January 2018	Deadline	01 January 2018

Russia 			
Regulatory Authority	Ministry of Health of the Russian Federation		
Links	CHETSNY ZNAK National Track & Trace Digital System		
Serialization		Aggregation	
Data elements	AI(01) – GTIN AI(21) – Serial Number AI(91) – Crypto Key AI(92) – Crypto Code	Data elements	AI(00) – SSCC or AI(01) – GTIN AI(21) – Serial Number
Data carrier	GS1 DataMatrix	Data carrier	GS1 DataMatrix GS1 128
Deadline	01 July 2020	Deadline	01 July 2020

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Saudi Arabia



Regulatory Authority Saudi Food and Drug Administration (SFDA)

Links Food and Drug Administration – Track & Trace

Batch constant		Serialization		Aggregation	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN	Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(21) – Serial Number	Data elements	AI(00) – SSCC
Data carrier	GS1 DataMatrix	Data carrier	GS1 DataMatrix	Data carrier	GS1 128
Deadline	21 March 2015	Deadline	12 March 2017	Deadline	31 March 2020

South Africa



Regulatory Authority Ministry of Health of the Republic of South Africa (NDOH)

Links South African Health Products Regulatory Authority

Serialization

Data elements AI(10) – Batch/Lot
AI(17) – Expiration Date
AI(01) – GTIN
AI(21) – Serial Number

Data carrier GS1 DataMatrix
GS1 QR

Deadline 01 June 2022

South Korea




Regulatory Authority Ministry for Food and Drug Safety


Links Ministry of Food and Drug Safety
Food and Drug Safety White Paper 2021

Batch constant		Serialization	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – NTIN KDC	Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – NTIN KDC AI(21) – Serial Number
Data carrier	GS1 DataMatrix GS1 128	Data carrier	GS1 DataMatrix GS1 128 RFID
Deadline	01 January 2013	Deadline	01 January 2016


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Switzerland 	
Regulatory Authority	Swiss Federal Office of Public Health (FOPH)
Links	Swiss Medicines Verification Organisation
Serialization	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN/NTIN AI(21) – Serial Number
Data carrier	GS1 DataMatrix
Deadline	2018


Tunisia 	
Regulatory Authority	Ministry of Public Health Conditions for Marketing Authorization of Drug in Tunisia
Links	GS1 Tunisia Medicinal Products Verification Guide
Batch constant	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN
Data carrier	GS1 DataMatrix
Deadline	01 January 2019

Turkey 			
Regulatory Authority	Republic of Turkey Ministry of Health – Turkish Medicines and Medical Devices Agency (TİTCK)		
Links	Ministry of Health Turkish Medicines and Medical Devices Agency		
Serialization		Aggregation	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(21) – Serial Number	Data elements	AI(00) – SSCC
Data carrier	GS1 DataMatrix	Data carrier	GS1 128
Deadline	01 June 2010	Deadline	01 June 2012

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Ukraine 	
Regulatory Authority	State Service of Ukraine on Medicines and Drug Control
Links	Law of Ukraine of 31.05.2016 No 1396-VIII Creation, development and decline of the system of combating falsification of medicines
Serialization	
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(21) – Serial Number
Data carrier	GS1 DataMatrix
Deadline	2021 (not defined)

Unites Arab Emirates 			
Regulatory Authority	Department of Health – Abu Dhabi		
Links	Dubai Health Authority		
Batch constant	Serialization		
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN	Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(21) – Serial Number
Data carrier	GS1 DataMatrix	Data carrier	GS1 DataMatrix
Deadline	01 January 2017	Deadline	01 January 2020

USA 			
Regulatory Authority	U.S. Food and Drug Administration (FDA) Drug Supply Chain Security Act (DSCSA)		
Links	DSCSA Grandfathering Policy Product Identifier Requirements Product Identifier under DSCSA		
Serialization	Aggregation		
Data elements	AI(10) – Batch/Lot AI(17) – Expiration Date AI(01) – GTIN AI(21) – Serial Number	Data elements	Tbd
Data carrier	GS1 DataMatrix	Data carrier	Tbd
Deadline	27 November 2017	Deadline	01 November 2023

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Uzbekistan 	
Regulatory Authority	The State Tax Committee of the Republic of Uzbekistan, the Ministry of Finance and the Ministry of Health
Links	National System of Digital Labelling of Goods
Serialization	
Data elements	AI(01) – GTIN AI(21) – Serial Number AI(91) – Crypto Key AI(92) – Crypto Code
Data carrier	GS1 DataMatrix
Deadline	01 September 2022

Recent and Upcoming Pharma Regulations

