SYSTECH®
a solutions division of Markem-Imaje

Brazil

Regulatory Update

August 2020

Regulatory Agency	Brazil National Agency of Sanitary Surveillance (ANVISA)
Regulation Name or System Name	Brazil law 13,410 updates law 11,903.
Compliance Dates	April 28, 2017: ANVISA to publish proposed regulations that meet the requirements of the new law. This date is allowed to be extended, which would push out all of the dates below by a comparable amount. ANVISA published RDC-157/2017 that will regulate the 3-lot pilot on May 11, 2017 and additional "normative instructions" were necessary so the April 28 date was extended to August 28, 2017 and again to April 1, 2019. On November 22, 2017 ANVISA published the initial implementation guide for use in the 3-lot pilot. The implementation dates, at the current moment, are expected to change again. In May 2020 Anvisa published a draft Normative Instruction that proposes a new approach to the deadlines. If approved without modification, those dates would be: **August 8, 2020:** The SNCM system will be operational and ready to receive data from members of the supply chain **December 1, 2020:** Manufacturers and importers should begin serializing and reporting the movements of all medicine packages that they are capable of doing so. For any non-exempt medicines that they are unable to serialize and report the movements of, these companies must submit a detailed plan to Anvisa by this date that shows when each product and packaging line will be ready. **February 28, 2021:** Manufacturers and importers who were unable to serialize and report the movements of all products by the December 1, 2020, all implementation steps documented in the plan they submitted on that date must now be completed. **April 28, 2022:** All drugs must be serialized and their movements in the supply chain reported to Anvisa. The latest version of the ANVISA communications manual was published on May 1, 2020 (in Portuguese)
Applies to	All prescription drug registration-holders (manufacturers, repackagers and importers), wholesale distributors and pharmacies.

SYSTECH®
a solutions division of Markem-Imaje

Unit-level Packaging ("units of sale")

Barcode Symbology	"DataMatrix, as specified in ISO / IEC 16022: 2006 and its updates"
Barcode Contents	The Unique Medication Identifier (IUM), consisting of: • Presentation GTIN (the GTIN that is drug and packaging); • The ANVISA medication registry number for this presentation; • A unique serial number unique to this presentation; • The expiration date of the drug • The lot/batch number of the product. "IUM: a series of numeric, alphanumeric or special characters, created through identification and coding standards, allowing the individualized, exclusive and unambiguous identification of each commercial packaging of the medicinal product;"
Serial Number Randomization	No
Serial Number Reuse	Not clearly specified but perhaps never
Human Readable Expiry Date Format	YYMMDD
Barcode Data Encoding	GS1 Standard
Free Samples must be marked?	No
Stickering after manufacturing allowed?	Apparently not

Homogeneous Cases

Barcode Symbology	Not specified
Barcode Contents	N/A

Logistics Units

Logistics Units Must be Serialized?	Yes "Every transport package containing at least one medicinal product included in the SNCM pilot phase, from the registration holder's dispatch event instance, must have a unique identifier code that allows the relationship with the IUM of the medicinal products contained therein." Aggregations can be done with SSCC, SGTIN or Ad-hoc aggregator based on the Cadastro Nacional da Pessoa Jurídica (CNPJ, the national company id for Brasil) of the supply chain partners, thus avoiding duplication of aggregators.

Data Capture

Unit-to-Case Aggregation Capture?	See Logistics Units above

Data Exchange

Send Unit Data to Government Repository?	Yes
Send Unit Data to Third-Party Repository?	No
Send Unit Data to Trading Partner?	No
Send Aggregation Data to Government Repository?	Yes
Send Aggregation Data to Third-Party Repository?	No
Send Aggregation Data to Trading Partner?	No

Authentication

Who Offers Data Repository for Authentication?	ANVISA
Manufacturers Must Register Shipments in Repository?	Yes
Downstream Trading Partners Must Authenticate on Receipt?	Yes
Downstream Trading Partners Must Authenticate on Shipment?	No

Government Reporting

Manufacturer Activity Reported?	Yes (registration-holder)
Downstream Trading Partner Activity Reported?	Yes

Challenges

- Companies who serve Brazil should pay close attention to developments from ANVISA as they publish the new normative instructions and regulations.
- In late 2019 Sindusfarma proposed to ANVISA that the deadline for full serialization and tracing be pushed out until August 2023.

Documents/Links

- Anvisa home page: http://portal.anvisa.gov.br/
- 2016, Law Number 13,410 establishing the current pharma serialization and traceability requirements, http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=29/12/2016&jornal=1&pagina=3&totalArquivos=800
- 2017, Public Consultation #311, http://portal.anvisa.gov.br/documents/10181/2724161/CONSULTA+P%C3%9ABLICA+N+311+DIGES.pdf/f7c69614-fa3c-4be5-961d-9f9a850221df
- 2017, RDC #157 Provides for the implementation of the System National Drug Control Board and the mechanisms and procedures for medication tracking and gives other measures,

http://portal.anvisa.gov.br/documents/10181/2724161/RDC_157_2017_.pdf/a91d19ef-937e-432b-97b0-4bf9cb75062e

- 2017, PowerPoint presentation by Ms. Bianca Zimon Giacomini Ribeiro, Deputy Chief Adviser for International Affairs, National Agency of Sanitary Surveillance (Anvisa) delivered to GS1 Healthcare, https://www.gs1.org/docs/healthcare/events/17-10-17/7_-_pharmaceutical_traceability_in_brazil_-_zimon.pdf
- 2019, National Control System Medicines – SNCM Analysis of the results of the experimental phase and validation of the information technology solution (version 1.0), http://portal.anvisa.gov.br/documents/219201/4340788/Relat%C3%B3rio+fase+experimental+e+valida%C3%A7%C3%A3o+do+SNCM+29abril2019+%281%29.pdf/99ee2bd6-93fa-4580-bea3-7dd45f62bc5b
- 2020, Anvisa Connectivity to the SNCM Environment manual, version 1.5, http://portal.anvisa.gov.br/rastreabilidade/grupos-de-trabalho

Disclaimer

This information is being provided 'As Is' with no claims of suitability for a particular purpose. It represents just one possible interpretation of information available in the public domain or through membership organizations, and that interpretation is subject to change. This information does not constitute legal advice. Users must refer to the source material for the complete requirements and form their own interpretation before making business decisions.

About Systech

Systech provides digital product authentication and traceability solutions to combat counterfeiting, prevent diversion and meet regulatory compliance. Built on decades of experience as the leader in pharmaceutical serialization, our comprehensive brand protection suite delivers the real-time insight, actionable product data, digital connectivity and consumer engagement functionality needed to fight supply chain threats.

Global brands across industries rely on us to keep their products authentic, safe and connected—from manufacturing to the consumer's hands. Together we are revolutionizing brand protection!

Regulatory Questions?

Contact us at info@systechone.com or visit us online here.