RESOURCES

Egypt Regulatory Updates



This is a compilation of the recent regulatory updates for Egypt. Every week, we post an update of what's new, which you can **view here**.

2022

- **March 27:** The Egyptian Ministry of Procurement (UAP) issued a circular to mandate product barcoding (not serialization) on pharmaceuticals, which would be mandatory starting June 2022.
- **March 27:** GS1 Egypt acknowledged the fast-approaching deadline and lack of specifics, so will be speaking to the UAP for additional context and clarification on requirements.
- **March 6:** The Egyptian Ministry of Health issued a circular to mandate product barcoding (not serialization) on pharmaceuticals.

2021

- **November 7:** GS1 Egypt and the Egyptian Drug Authority (EDA) continue to collaborate on the draft v3 implementation guidelines.
- **August 29:** GS1 Egypt is expected to provide its comments and suggestions to the Egyptian Drug Authority (EDA) on version 3 of the draft implementation guidelines.
- **August 1:** The Egyptian Drug Authority and GS1 Egypt are continuing work on updating the draft guidelines.
- **July 11:** The Egyptian Drug Authority (EDA) and GS1 Egypt are continuing to

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work on updating draft guidelines.

2020

- **August 16:** The Egyptian Drug Authority is moving forward with plans to publish final compliance regulations and deadlines, despite the fact that several reporting issues were discovered during the pilot test of the country's EMVS. Companies may need to manually upload compliance reports when the regulations are first rolled out.
- **January 12:** Egypt's regulatory pilot has concluded, and participants have submitted feedback to the Ministry of Health. The Ministry is now expected to publish an updated technical guideline and announce final implementation deadlines, which could be as short as six months.

2019

- **November 3:** Egypt's Ministry of Health and Population later this month will announce a new pilot phase for the country's track and trace program. As part of the announcement, which is planned for November 15, the Ministry will publish the next version of technical guidelines. The pilot is planned to run for two weeks, with a December analysis period and a potential announcement by the end of the year about new timelines for compliance.
- **June 2:** On May 27, a meeting was held with the CEO of GS1 Egypt to discuss current regulations and the architecture of a government traceability system. Updates to v2 of the technical guidelines are to be finalized in late June followed by a new announcement.
- **April 7:** The Egyptian Minister stated that the upcoming pharmaceutical barcoding deadline for June will include both serialization *and* compliance reporting, and not just serialization. Final requirements and guidelines for Egyptian barcoding will be published in late April according to current plans.
- **March 10:** The Egyptian Ministry of Health (MOH) has issued a request for comments on their current draft regulations, requiring data elements of labels to be encoded in a specific order, which is not aligned to global standards.

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2018

- **December 2:** The European Commission and Heads of Medicines Agencies held a workshop with stakeholders to agree on common key principles for implementing electronic product information for the European Union (EU). Those principles are being drafted for publication in January of 2019 to gain public commentary.
- **November 25:** The Ministry of Health announced a workshop on November 22 to discuss the upcoming regulations and current implementation plan submission requirements regarding medical traceability by factories, companies, and parties working in the Egyptian pharmaceutical market.
- **November 11:** Egypt published an update to their drug track and trace requirements, which document the data and encoding guidelines for individual packs and cases of medicines throughout the supply chain. Along with these guidelines, it was announced that MAHs/manufacturers must submit an initial report and implementation plan to include barcoding and serialization for all medicines and GTINs/GLNs for each company by the end of 2018.
- **June 29:** The serialization and government reporting requirements for June 2018 have been postponed as long as MAH apply a barcode and identifier to at least one pack and report it to the Ministry of Health by the end of the year. No reset timelines were published.
- **April 1:** The official track and trace implementation guidelines are finished and will be published this coming week (week of 4/2). Serialization and compliance reporting details will be included with a follow-up on technical guidelines for specific integration requirements to Egypt national system. No announcements will be made on deadlines, but the outcome of the upcoming April stakeholder meeting with the Ministry of Health is expected to result in the serialization deadline of June 2018 sticking and aggregation/compliance reporting being delayed until 2019.
- **March 11:** Industry guidance on regulations is ready for publication but a

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circulation date hasn't been set. The XML reporting schema will follow soon after and the June 2018 deadline still stands.

- **February 25:** A cross-industry stakeholder meeting was held, with some discussion of agreement to delay the June 2018 deadline for serialization and reporting to 2019 given slow progress on publishing guidelines and the start up of the government system. Recommendations may be made to start with high-priority drugs as a pilot.
- **January 28:** Ministry of Health is drafting serialization and reporting requirements for February publication. They are still expecting full serialization compliance by June 2018.

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