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India Regulatory Updates

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

2023

- **August 14:** The government announced an extension of the iVEDA compliance deadline for track-and-trace exports, shifting the date from August 1, 2023, to February 1, 2024.
- **April 24:** The government has reasserted that there will be no further delays to the implementation of iVEDA. The deadline for iVEDA is August 1, 2023.
- **April 17:** The deadline for iVEDA (track-and-trace for exports) has been extended until August 1, 2023. It was previously March 31, 2023. The other upcoming deadline to track in 2023 is top 300 brands barcoding, which is also on August 1, 2023.

2022

- **September 5:** The MoH published draft rules governing the barcoding of the country's top 300 pharma brands. A public consultation on the rules concluded July 14, 2022, but no formal feedback has been received.
- **June 27:** India's Ministry of Health (MoH) published draft rules governing the barcoding of the country's top 300 pharma brands. A public consultation on the rules is underway until July 14, 2022. The rule is scheduled to go into effect on May, 1 2023.
- **May 1:** GS1 India published a research-based report on "Building Resilience in India's Post-COVID Healthcare Supply Chain."
- **April 3:** There are three compliance initiatives related to active pharmaceutical ingredient (API) or medicines serialization/traceability currently under discussion:
    - Export Reporting (iVEDA portal): On April 4, 2022, the Directorate General of Foreign Trade (DGFT) announced in Public Notice 01/2015-20 an extension to the deadline for export reporting to iVEDA until March 31, 2023.
    - API QR Code Labeling (January 1 2023 deadline): The Confederation of Indian Industry (CII) has requested the Government to establish clear technical guidelines for the law's implementation.
    - Barcoding/QR Code for Top 300 Brands (Domestic barcoding): The Federation of Indian Chambers of Commerce and Industry (FICCI) has

requested the Government to hold a consultation with stakeholders regarding the proposed requirements and their practical implementation.

- **March 27:** As of April 1, there is no update on either the iVEDA portal or in DGFT notifications on a deadline extension for export serialization requirements. In March 2022, ASSOCHAM requested that the Ministry of Commerce and Industry extend the implementation of the iVEDA track-and-trace portal beyond the April 1, 2022 extension granted last year.
- **March 20:** ASSOCHAM has requested the Ministry of Commerce and Industry to extend the implementation of the iVEDA track-and-trace portal for medicines exports beyond the April 1, 2022 extension granted last year.
- **March 20:** The requirement for QR Coding for pharmaceutical APIs is scheduled to go into effect January 1, 2023.
- **January 23:** The Ministry of Health and Family Welfare published a requirement for applying QR Codes to pharmaceutical APIs manufactured or imported into India The requirement goes into effect on January 1, 2023. There does not appear to be reporting linked specifically to data in the QR code. This requirement reflects almost precisely the proposal from 2019.
- **January 23:** Industry is seeking further information on the establishment of a “traceability committee” that will purportedly address both domestic and export serialization.

- **January 16:** Industry discussions indicate that India has formed a traceability committee to address both domestic and export serialization. Multiple industry stakeholders have called for proactive engagement with this committee to ensure adherence to international standards.

2021

- **April 4:** The Director General of Foreign Trade (DGFT) announced an extension of the IVEDA reporting deadline from April 1, 2021 to April 1, 2022. No reason for the delay was stated in the notice, although customer and industry sources cite issues in uploading reports to the portal. The IVEDA website has not been updated with this announcement. It was issued as Public Notice No. 46/2015-20 on March 30, 2021 by the Ministry of Commerce and Industry.

2020

- **September 27:** India’s government is postponing the implementation of reporting capabilities for its Integrated Validation of Export of Drugs and its Authentication (iVEDA) portal until 2021.
- **September 20:** India's government last week released version 1.6 of its technical schemas and implementation guidelines. India's regulations continue to evolve as the October 1, 2020 compliance deadline approaches.
- **September 13:** India’s government published version 1.5 of its technical schemas and implementation guidelines.

- **August 30:** India's Centre for Development of Advanced Computing (C-DAC) published version 1.3 of India’s technical schemas and implementation guidelines on the iVEDA portal.
- **April 5:** India’s government announced a six-month delay before updated requirements for compliance and reporting to the iVEDA system go into effect. The requirements will now go into effect on October 1, 2020.

2019

- **August 11:** The Ministry of Electronics and Information Technology has drafted and circulated a new technical design for an export track and trace system, which has been proposed to replace the existing Drugs Authentication and Verification Application (DAVA) portal. The proposed design uses a proprietary product coding and reporting scheme that does not align with global interoperability standards such as those developed by GS1.
- **July 21:** A public notice was released stating that aggregation and reporting have been further postponed until April 1, 2020.
- **July 14:** A public notice has circulated announcing that aggregation and reporting have been postponed until April 1, 20
- **June 16:** The government has appointed a new expert committee to improve the existing serialization and traceability efforts for exported medicines and to accelerate the adoption of similar requirements for domestic medicines.

- **February 3:** The government has published a new circular that postpones the implementation of primary-level pack barcoding for government procurement until April 2020.
- **January 27:** The government published new barcoding requirements for primary pack-level identification (no serialization) to go into effect April 1, 2019. These requirements will affect government-tendered products in the domestic market. The industry has pushed back on the timelines.

2018

- **November 4:** The implementation of aggregation and reporting requirements to the DAVA portal has been postponed until July 1, 2019. The scope of the requirements remains the same, but there is expected to be modifications to the overall data model and potentially some of the reporting requirements.
- **October 7:** A government sponsored workshop was held on October 5 to discuss export requirements and the patient scanning initiative.
- **September 2:** DAVA is still planning to bring their portal back online in November, but they haven't provided insights as to the technical/data changes for the update. At the same time, there's no word on when the industry will be apprised of the changes to allow serialization/reporting systems to be updated.
- **July 15:** The relaunch of the DAVA portal has an 11/15 deadline. A meeting was held in New Delhi on 6/26 to discuss domestic medicine identification. At this meeting, verification was just the starting point as the government was openly

asking for other options besides the on-pack identifier.

- **June 22:** DTAB is holding a meeting on 6/25 to discuss the proposed government approach to apply human readable serialization codes on the top 300 brands for domestic circulation.
- **May 26:** The official DGFT notice of the six-month hiatus for DAVA reporting was published.
- **May 13:** An official notification was published that put a six-month pause on India DAVA compliance reporting as DGFT works with the DAVA team to update and fix issues that are causing shipments to be held up at customs.
- **April 29:** An update was issued to last week's India note on DGFT publication of a letter outlining India's intention to enforce current serialization and reporting requirements.
- **April 21:** DGFT published a letter outlining India's intention to enforce current serialization and reporting requirements. This letter came about after several reports came in from the field of pharmaceutical company product being stopped in Customs due to product not being serialized or not having the correct DAVA system data.

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