

Indonesia



(based on a *summary* of BPOM Regulation #33 / 2018 which was released on December 7, 2018, and a translation of the DRAFT regulation from the summer of 2018, and the amendment published on December 20, 2019.)

Regulatory Update August 2020

Regulatory Agency	NATIONAL AGENCY OF DRUG AND FOOD CONTROL (BPOM)
Regulation Name or System Name	BPOM Regulation #33 / 2018. IMPLEMENTATION OF 2D BARCODE IN ORDER TO IMPROVE EFFECTIVENESS OF MEDICINES AND PROCESSED FOOD SUPERVISION, and, the Amendment to Regulation #33 / 2018 published on December 20, 2019
Compliance Dates	<p>The summary breaks the requirements down into two different categories: Identification and Authentication. Identification is for a product set that does not need serialization, where Authentication is a different product set that does.</p> <p>Identification products are: OTC, traditional medicine, supplements, cosmetics and processed foods. Authentication products are: Ethical drugs, narcotics and psychotropic drugs, plus certain high-risk products from the Identification category that BPOM will name.</p> <p>Identification products deadline:</p> <ul style="list-style-type: none"> • At the latest 6 (six) month since the issuance of electronic Marketing Authorization (MA) that stipulated after the 2D Barcode regulation became effective. • At the latest 5 (five) year since the 2D Barcode Regulation became effective for all product (effective since 7 Dec 2018) <p>Authentication products deadline:</p> <ul style="list-style-type: none"> • At the latest 2 (two) years since the issuance of electronic MA after the 2D Barcode regulation became effective • At the latest 6 (six) years after the 2D Barcode Regulation became effective for all product (effective date is apparently 7 Dec 2018) <p>As of June 24, 2020, BPOM indicated that it is in the process of revising their requirements but does not know yet when they will be published. At that time, the deadlines above will be set by that date. That is, the “effective date” of the regulation would be the date the revised requirements are published.</p>

Applies to	Pharmaceutical and processed food manufacturers, wholesale distributors and pharmacies
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Pharmaceutical Packaging

Barcode Symbology	<p>Identification:</p> <ul style="list-style-type: none"> Issued through electronic MA Approval, in the form of QR Code <p>Authentication:</p> <ul style="list-style-type: none"> 2D Barcode that is issued by BPOM within 5 working days based on MA Holder Application, 10 working days before production, or 2D Barcode that is issued independently by Industry <p>Some believe that this implies that companies can pick either a QR Code or a Datamatrix barcode for the Authentication products.</p>
Barcode Contents	<p>Identification:</p> <ul style="list-style-type: none"> Registration Number / MA Number (NIE) The validity of MA number (NIE) <p>Authentication:</p> <ul style="list-style-type: none"> MA Number and / or identity product number that is valid internationally Batch No or Production code Expiry date and Serialization Number <p>For barcodes issued by BPOM:</p> <ul style="list-style-type: none"> Application is done by input the data through BPOM Track and Trace Application Data that include on the Application of drug serialization are contain : MA No, batch No, Exp Date, Amount of Primary Code that requested, amount of maximum primary code on the secondary packaging, and amount of maximum secondary code on the tertiary packaging, international product identity (If any)
Serial Number Randomization	Not specified
Serial Number Reuse	Not specified
Human Readable Expiry Date Format	Not specified
Barcode Data Encoding	Not specified
Product Code notes	<ul style="list-style-type: none"> Printed on the packaging with the black ink and base is white color or other color 2D Barcode that printed on the packaging must be easy to be scanned and can be read by BPOM track and trace application. The barcode must be put proportionally on the packaging with minimum size 0,6 x 0,6 cm In case there are two 2D Barcode that included on the packaging of drug and food product, therefore one of the 2D Barcode must contain wording "BPOM RI". 2D Barcode required on the primary packaging

	<ul style="list-style-type: none"> • Exception for above bullet can be applied to products that come in SECONDARY PACKAGING with safety feature (i.e. Tamper evidence) for products with the following conditions: <ul style="list-style-type: none"> – Drug: <ul style="list-style-type: none"> • Volume below 10 mL • Blister primary pack • Strip primary pack • Ampoule • Prefilled syringe • Tube with net below 10g • Individual pack • Stick pack, suppositories and catch cover – Traditional Medicine, Health Supplement, Cosmetic <ul style="list-style-type: none"> • Volume below 5mL • Blister primary pack • Strip primary pack • Ampoule • Tube with net below 5g • Stick pack, suppositories • And or having the surface area of a label is less than or equal to 10 cm² – Processed Food (Article 21 point 3) <ul style="list-style-type: none"> • Processed food that having surface area of a label is less than or equal to 10 cm²
Free Samples must be marked?	Not specified
Stickering after manufacturing allowed?	Not specified

Case Packaging

Barcode Symbology	QR Code or 2D Datamatrix (manufacturer chooses)
Barcode Contents	Same as units
Notes	It is unclear in the translated text whether or not the barcode itself must include the parent-child relationships or if this data must be captured and transmitted to BPOM.

Aggregation Data Capture

Parent-Child Mapping Aggregation Capture?	Yes
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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?	Probably, but unclear

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

Authentication

Who Offers Data Repository for Authentication?	Government (BPOM)
Manufacturers Must Register Shipments in Repository?	Yes
Downstream Trading Partners Must Authenticate on Receipt?	Yes
Downstream Trading Partners Must Authenticate on Shipment?	Yes

Government Reporting

Master Data Upload	No, except minimal info included when serial numbers and/or barcodes are requested from BPOM
Manufacturer Activity Reported?	Yes, but only for Authentication products: <ul style="list-style-type: none"> • MA holder, report 2D Barcode for the product: <ul style="list-style-type: none"> – Product on the Retained Sample – Product that activated – Product that distributed – Product Recall or Returned – Also, information of aggregation code (if any)
Downstream Trading Partner Activity Reported?	Yes, but only for Authentication products: <ul style="list-style-type: none"> • Distribution facility and Pharmaceutical Service Facility, reporting 2D Barcode in form of: <ul style="list-style-type: none"> – Product that received – Product that distributed and Product that recalled or returned

Challenges

- Information based on a draft regulation rather than an official regulation and someone's summary notes of the final regulation. It is for informational purposes only, not for compliance.
- Information is based on an unofficial third-party translation which may be inaccurate, and our interpretation may be inaccurate.
- There is confusion over the meaning of the deadlines. This is probably due to translation difficulties.

Disclaimer

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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](#).