FOOD AND DRUG REGULATORY AGENCY OF THE

REPUBLIC OF INDONESIA

FOOD AND DRUG ADMINISTRATION REGULATION NUMBER
22 OF 2022
ABOUT
APPLICATION OF *2D BARCODE* IN DRUG AND FOOD SUPERVISION BY THE

GRACE OF GOD ALMIGHTY

HEAD OF THE FOOD AND DRUG ADMINISTRATION,

Considering : a. that the public needs to be protected from drugs and food that do not meet the standards and/or requirements for safety, usefulness/efficacy, and quality;

b. whereas pursuant to the provisions of Article 3 paragraph (1) letter d of Presidential Regulation No. 80/2017 on the Food and Drug Supervisory Agency, the Food and Drug Supervisory Agency has the function of carrying out the tasks of supervision before circulation and supervision during circulation;

c. that the provisions regarding the Application of *2D Barcodes* in Drug and Food Monitoring as stipulated in the Regulation of the Food and Drug Supervisory Agency Number 33 of 2018 regarding the Application of *2D Barcodes* in Drug and Food Monitoring are no longer in accordance with legal needs so that they need to be replaced;

d. that based on the considerations as referred to in letters a, b, and c, it is necessary to stipulate a Regulation of the Food and Drug Supervisory Agency on the Application of *2D Barcodes* in Food and Drug Supervision;

Considering: 1. Presidential Regulation Number 80 of 2017 concerning the Food and Drug Supervisory Agency (State Gazette of the Republic of Indonesia Year 2017 Number 180);

2. Food and Drug Administration Regulation Number 21 of 2020 concerning the Organization and Work Procedures of the Food and Drug Supervisory Agency (State Gazette of the Republic of Indonesia of 2020 Number 1002) as amended by Regulation of the Food and Drug Supervisory Agency Number 13 of 2022

concerning Amendments to Regulation of the Food and Drug Supervisory Agency Number 21 of 2020 concerning the Organization and Work Procedures of the Food and Drug Supervisory Agency.

Food (State Gazette of the Republic of Indonesia Year 2022 Number 629);

3. Regulation of the Food and Drug Supervisory Agency Number 22 of 2020 concerning the Organization and Work Procedures of Technical Implementation Units within the Food and Drug Supervisory Agency (State Gazette of the Republic of Indonesia Year 2020 Number 1003) as amended by Regulation of the Food and Drug Supervisory Agency Number 22 of 2020 concerning the Organization and Work Procedures of Technical Implementation Units within the Food and Drug Supervisory Agency.
   23 of 2021 concerning Amendments to Regulation of the Food and Drug Administration Number 22 of 2020 concerning Organization and Work Procedures of Technical Implementation Units within the Food and Drug Administration (State Gazette of the Republic of Indonesia Year 2021 Number 1151);

DECIDE:

Establish: A REGULATION OF THE FOOD AND DRUG SUPERVISORY AGENCY ON THE APPLICATION OF *2D BARCODES* IN THE SUPERVISION OF DRUGS AND FOOD.

CHAPTER I
GENERAL PROVISIONS

Article 1

In this Agency Regulation what is meant by:

1. *Two-dimensional* (*2D*) *barcodes*, hereafter referred to as *2D Barcodes*, are graphical representations of digital data in a two-dimensional format with high *decoding* capacity that can be read by optical devices used for identification, tracking, and tracing.
2. Authentification is a method to trace and verify the legality, batch number, expiration and/or serial number of a Food and Drug product.
3. Identification is a method to verify the legality of Food and Drugs based on the Circulation Permit.
4. A medicine is a substance or combination of substances, including biological products, used to affect or investigate a physiological system or a state of pathology in order to establish diagnosis, prevention, cure, recovery, health promotion and contraception, for humans.
5. Traditional Medicine is an ingredient or mixture of ingredients in the form of plant materials, animal materials, mineral ingredients, galenic preparations, or a mixture of these materials that have been used for generations for treatment, and can be applied in accordance with the norms prevailing in the community.
6. Quasi-drugs are preparations containing active ingredients with pharmacological effects that are non-systemic or local and to treat minor complaints.
7. Health Supplements are products that are intended to complement nutritional needs, maintain, increase and / or improve health functions, have nutritional value and / or effects.

physiological, containing one or more ingredients in the form of vitamins, minerals, amino acids and/or other non-plant ingredients that can be combined with plants.

8. Cosmetics are materials or preparations intended for use on the external parts of the human body such as the epidermis, hair, nails, lips and external genital organs or teeth and oral mucous membranes primarily to cleanse, perfume, change appearance and/or improve body odor or protect or maintain the body in good condition.
9. Processed Food is food or beverages processed by certain means or methods with or without additives.
10. Processed Food for Special Diets, hereinafter referred to as Special Diet Food, is Processed Food that is specially processed or formulated to meet certain nutritional needs due to certain physical or physiological conditions.
11. *Track* and *Trace* Application of the Food and Drug Supervisory Agency, hereinafter referred to as the *Track and Trace* Application of the POM Agency, is an application to issue a code containing a series of numbers and letters in *2D Barcode* and/or record every product movement so that product and product location information can be obtained, both the current location and the location history of the unique product movement.
12. The Aggregation System is a coding system that contains detailed product information that is in the primary code listed in the secondary code while the product details in the primary code and secondary code are listed in the tertiary packaging.
13. Business Actors are any individual or business entity, whether in the form of a legal entity or not, established and domiciled or conducting activities within the jurisdiction of the Republic of Indonesia, either alone or jointly organizing business activities in the field of Food and Drugs.
14. The Pharmaceutical Industry is a business entity that has a license in accordance with the provisions of the laws and regulations to carry out activities to manufacture drugs or drug ingredients.
15. Distribution Facilities are facilities used to distribute or dispense Medicines, namely pharmaceutical wholesalers and government pharmaceutical installations.
16. Pharmaceutical Service Facilities are facilities used to organize pharmaceutical services, namely pharmacies, hospital pharmaceutical installations, clinical pharmaceutical installations, community health centers, and drug stores.
17. Circulation Permit is a form of approval for the registration of Medicines, Traditional Medicines, Quasi-Medicines, Health Supplements and Health Supplements.

Processed food or notification that cosmetics have been notified, notification that processed food commitments have been fulfilled, and approval for processed food to be distributed in Indonesia.

18. Primary Packaging is packaging that is in direct contact with drugs and food.
19. Secondary Packaging is packaging that protects Primary Packaging.
20. Tertiary Packaging is packaging used to combine all Secondary Packaging to facilitate the transportation process and prevent product damage.
21. Single Packaging is packaging in which there is only one pharmaceutical preparation including pharmaceutical preparations equipped with administration aids or solvents which are administered together. Each Single Pack must be labeled with an etiquette that states the identity, strength, manufacturer's name, batch number and expiration date.
22. The Food and Drug Supervisory Agency, hereinafter referred to as the POM Agency, is a non-ministerial government agency that organizes government affairs in the field of drug and food control.
23. Head of Agency means the Head of the Food and Drug Administration.
24. Day is a working day.

Article 2

(1) The application of *2D Barcode* by Business Actors as regulated in this Agency Regulation covers Drugs and foods that are produced and distributed domestically and/or imported for distribution in the territory of Indonesia.

(2) Drugs and food as referred to in paragraph (1) consists of:
   a. Medicine;
   b. Traditional Medicine;
   c. Quasi Medicine;
   d. Health Supplements;
   e. Cosmetics; and
   f. Processed Food.

(3) Exempted from the provisions as referred to in paragraph (1), Drugs and foods distributed in Indonesia using *emergency use authorization* mechanisms and/or *special access schemes* are not required to apply *2D Barcodes.*

CHAPTER II
2D Barcode

General Part
One

Article 3

(1) *2D Barcode* as referred to in Article 2 using the method:
   a. Authentification; and
   b. Identification.
(2) *2D Barcode* with Authentification method as referred to in paragraph (1) letter a applies to Drugs included in the class:
   a. Prescription Drugs, including biological products;
   b. narcotics; and
   c. psychotropic substances.
(3) *2D Barcode* with Identification method as referred to in paragraph (1) letter b applies to:
   a. Drugs that fall under the class of over-the-counter drugs and restricted over-the-counter drugs;
   b. Traditional Medicine;
   c. Quasi Medicine;
   d. Health Supplements;
   e. Cosmetics; and
   f. Processed Food.
(4) Exempted from the provisions of Authentification as referred to in paragraph (2), for Prescription Drugs including radiopharmaceuticals and contrast media must apply *2D Barcode* with Identification method.

Article 4

The application of *2D Barcode* with Authentification method as referred to in Article 3 paragraph (1) letter a refers to the Technical Guidelines for the Application of *2D Barcode* listed in the Appendix which is an integral part of this Agency Regulation.

Second Section
Product
Authentification

Paragraph 1
General

Article 5

(1) *2D Barcode* with Authentification method as referred to in Article 3 paragraph (1) letter a is made by using a code in the form of a series of numbers and letters.
(2) The code as referred to in paragraph (1) is issued by:
   a. POM; or
   b. Business Actors independently.

(3) The conversion of the code as referred to in paragraph (2) into a *2D Barcode* is carried out by Business Actors.

Article 6

The Pharmaceutical Industry that implements *2D Barcode* with Authentification method is required to implement an Aggregation System.

Paragraph 2
Requirements

Article 7

(1) *2D Barcode* for Medicine as referred to in Article 3 paragraph (2) must at least contain information:
   a. Marketing Authorization and/or internationally valid product identity number;
   b. batch number or production code;
   c. expiration date; and
   d. serialization number.

(2) In addition to the information as referred to in paragraph (1), *2D Barcodes* for Medicines may also contain other information as long as they fulfill the aspects of safety, efficacy, and quality in accordance with the provisions of laws and regulations.

Paragraph 3
Application

Article 8

(1) *2D Barcode* as referred to in Article 5 paragraph (1) letter a is issued based on the application of Business Actors submitted online through the *Track and Trace* Application of the POM Agency.

(2) Application for the issuance of *2D Barcode* as referred to in paragraph (1) shall be submitted by the Business Actor holding the Circulation Permit.

(3) To be able to apply for the issuance of *2D Barcode* as referred to in paragraph (1), Business Actors must have access rights registered in the *Track and Trace* Application of the POM Agency.

(4) To obtain the registered access rights as referred to in paragraph (3), Business Actors must fill out the registration form on the *Track and Trace* Application of the POM Agency to obtain a username and password.

Article 9

(1) Application for the issuance of *2D Barcode* as referred to in Article 8 paragraph (2) is carried out by entering data through the *Track and Trace* Application of the POM Agency.

(2) The data as referred to in paragraph (1) includes:
   a. Circulation Permit number;
   b. batch number or production code;
   c. expiration date;

d. number of primary codes requested;
e. the maximum number of primary codes on Secondary Packaging; and
f. maximum number of secondary codes on Tertiary Packaging.

(3) In the event that a business actor already has an international product identity, it may include the product identity in the application data.

Article 10

Application for the issuance of *2D Barcode* as referred to in Article 8 and Article 9 shall be made at the latest 10 (ten) Days before production starts.

Article 11

(1) *2D Barcode* as referred to in Article 8 paragraph (1) issued electronically no later than 5 (five) Days as of the submission of the application.
(2) *2D Barcode* as referred to in paragraph (1) shall only apply to the batch or production code submitted.

Paragraph 4
Reporting

Article 12

(1) Business Actors with distribution permits who manage drugs with *2D Barcodes* and have implemented the Authentification method are required to submit *2D Barcode* reports to the POM Agency.
(2) Distribution Facilities and Pharmaceutical Service Facilities that manage Medicines with the *2D Barcode* Authentication method must submit *2D Barcode* reports to the POM Agency.
(3) Reporting by Distribution Facilities and Pharmaceutical Service Facilities as referred to in paragraph (2) shall be implemented in stages.
(4) The staging of the implementation of reporting by Distribution Facilities and Pharmaceutical Service Facilities as referred to in paragraph (3) shall be stipulated by the Head of the Agency.

Article 13

(1) The report as referred to in Article 12 submitted by the Business Actor holding the Circulation Permit in the form of a report on the use of *2D Barcode*.
(2) The report on the use of *2D Barcode* as referred to in paragraph (1) is carried out on activities:
a. *2D Barcode* activation that is delivered before the product is distributed;
b. distribution that is delivered no later than 3 (three) Days after Medicine with *2D Barcode* distributed;
c. withdrawal back or return which

submitted no later than 3 (three) Days after the Medicine with *2D Barcode* is received; and

d. which is submitted no later than 3 (three) days after the Drug with *2D Barcode* is destroyed.

(3) In addition to the report as referred to in paragraph (2), Business Actors who are Pharmaceutical Industries are required to submit aggregation code information.

(4) The aggregation code as referred to in paragraph (3) includes:

a. primary code;

b. secondary code; and

c. tertiary code.

(5) Report as referred to in paragraph (2) and paragraph (3) submitted via *Track and Trace* Application Food and Drug Administration.

Article 14

(1) Submission of *2D Barcode* reports by Drug Distribution Facilities and Pharmaceutical Service Facilities as referred to in Article 12 paragraph (2) must be submitted through the *Track* and *Trace* Application of the POM Agency.

(2) The report on the use of *2D Barcode* as referred to in paragraph (1) is carried out on activities:

a. acceptance of *2D Barcode* submitted no later than 3 (three) Days after all Medicines with *2D Barcode* are received;

b. distribution that is delivered no later than 3 (three) Days after Medicine with *2D Barcode* distributed;

c. recall or return submitted no later than 3 (three) Days after the Medicine with *2D Barcode* is received or delivered; and

d. which is submitted no later than 3 (three) days after the Drug with *2D Barcode* is destroyed.

(3) Submission of reports as referred to in paragraph (2) shall be submitted through the *Track* and *Trace* Application of the POM Agency.

Third Section
Product Identification

Article 15

(1) *2D Barcode* with Identification method as referred to in Article 3 paragraph (1) letter b must match the *2D Barcode* listed in the electronic Circulation Permit.

(2) The electronic Circulation Permit as referred to in paragraph (1) is issued by the POM Agency.

Article 16

2D Barcode contained in the electronic Circular Permit as referred to in Article 15 contains information regarding the Circular Permit.

CHAPTER III
INCLUSION OF *2D BARCODE* ON PACKAGING

Article 17

(1) *2D Barcode* as referred to in Article 3 is printed on the packaging with an ink color that is different from the base color.
(2) *2D Barcode* as referred to in paragraph (1) must be easily scanned and capable of being read by the BPOM *Mobile* application.
(3) Exempted from the provisions as referred to in paragraph (1), for Traditional Medicine, Quasi Medicine, Health Supplements, Cosmetics, and Processed Food *2D Barcodes* may be printed in the form of a *sticker* whose inclusion is glued to the packaging with a different ink color and contrasts with the base color.
(4) The inclusion of *2D Barcode* as referred to in paragraph (1) and paragraph (3) is carried out in such a way that it is not easily separated or separated from the packaging and is not easily faded or damaged.

Article 18

(1) The Pharmaceutical Industry holding a Drug Distribution Permit as referred to in Article 3 paragraph (2) must include a *2D Barcode* with the Authentification method on the distribution packaging as stated in the approval of the Drug Distribution Permit.
(2) In the case of distribution packaging as referred to in paragraph (1) in the form of Secondary Packaging or Tertiary Packaging, it must be secured to ensure the authenticity of the contents of the Medicine.
(3) The Pharmaceutical Industry holding a Drug Circulation Permit as referred to in Article 3 paragraph (3) letter a must include a *2D Barcode* with the Identification method on the Primary Packaging.
(4) The obligation to include *2D Barcode* on Primary Packaging as referred to in paragraph (3) is exempted for Drugs with the following provisions:
    a. Single Packaging;
    b. volume at under or equal with 10 mL (ten milliliters);
    c. Primary blister packaging;
    d. Primary Packaging strips; or
    e. *tube* packaging.
(5) The *2D Barcode* as referred to in paragraph (4) may be included on Secondary Packaging with safeguards to ensure the authenticity of the contents of the Medicine.

(6) The safeguards referred to in paragraph (2) and paragraph (5) if tampered with will result in damage to the Packaging.

Article 19

(1) Business Actors of Traditional Medicines, Quasi Medicines, and Health Supplements who have a Circulation Permit are required to include a *2D Barcode* on the Primary Packaging.

(2) The obligation to include *2D Barcode* on Primary Packaging as referred to in paragraph (1) is exempted for Traditional Medicines, Quasi Medicines and Health Supplements by including it on Secondary Packaging with the following provisions:
   a. Single Packaging;
   b. Primary blister packaging;
   c. Primary Packaging strip;
   d. *tube* packaging;
   e. *stick pack*;
   f. Primary packaging of suppositories;
   g. has a label surface area less than or equal to 10 cm^2 (ten square centimeters); or
   h. *plastic clip*.

Article 20

(1) Cosmetics Business Actors with Circulation Permit are required to include *2D Barcode* on the packaging.

(2) The provisions as referred to in paragraph (1) shall be implemented in accordance with the provisions of laws and regulations regarding marking of cosmetics.

Article 21

(1) Processed Food Business Actors with Circulation Permit are obliged to include a *2D Barcode* on the retail packaging in accordance with the Processed Food being registered.

(2) *2D Barcode* as referred to in paragraph (1) shall be included in the Primary Packaging.

(3) The obligation to include *2D Barcode* on Primary Packaging as referred to in paragraph (1) shall be exempted for Processed Food which has a label surface area of less than or equal to 10 cm^2 (ten square centimeters).

(4) *2D Barcode* as referred to in paragraph (3) shall be included in the Secondary Packaging.

Article 22

Business Actors are required to include a *2D Barcode* with a rectangular shape with a size of at least 0.6 x 0.6 cm (zero point six by zero point six centimeters).

Article 23

(1) In the event that there are two *2D Barcodes* included in the packaging of Drug and food products, Business Actors are required to include the words "BPOM RI" on one of the *2D Barcodes*.

(2) The inclusion of the words "BPOM RI" as referred to in paragraph (1) is only for *2D Barcodes* with the Identification method.

CHAPTER IV
COMMUNITY PARTICIPATION

Article 24

The public can participate in the supervision of drugs and food through scanning and reporting the results of *2D Barcode* scanning using the BPOM *Mobile* application.

Article 25

BPOM *Mobile* application as referred to in Article 24 shall contain at least the following information:

a. product name;
b. Circulation Permit number;
c. the name and address of the Business Actor; and
d. Packaging.

CHAPTER V
SANCTIONS

Article 26

(1) Business Actors who violate the provisions of Article 3 paragraph (4), Article 6, Article 12 paragraph (1), Article 12 paragraph (2), Article 13 paragraph (3), Article 14 paragraph (1), Article 15 paragraph (1), Article 18 paragraph (1), Article 18 paragraph (2), Article 18 paragraph (3), Article 19 paragraph (1), Article 20 paragraph (1), Article 21 paragraph (1), Article 21 paragraph (2), Article 21 paragraph (4), Article 22, and/or Article 23 paragraph (1) shall be subject to administrative sanctions in accordance with the provisions of laws and regulations in the field of labels or markings.
(2) Administrative sanctions as referred to in paragraph (1) imposed by the Head of the Agency.

CHAPTER VI
TRANSITIONAL PROVISIONS

Article 27

(1) The Pharmaceutical Industry that has implemented the *2D Barcode* with Authentification method shall implement the Aggregation System no later than 1 (one) year as of the promulgation of this Agency Regulation.
(2) *2D Barcode* with Identification method that has been issued prior to the enactment of this Agency Regulation may still be used as long as the Circulation Permit number is still valid.

CHAPTER VII
CLOSING PROVISIONS

Article 28

(1) The Pharmaceutical Industry holding a Drug Circulation Permit issued before December 7, 2023 must implement *2D Barcode* Authentification no later than 4 (four) years after the electronic Circulation Permit is first issued.
(2) The Pharmaceutical Industry holding a Circulation Permit is obliged to implement *2D Barcode* Authentication for all Drugs as referred to in Article 3 paragraph (2) letter a no later than December 7, 2027.
(3) The Pharmaceutical Industry holding a Circulation Permit is obliged to implement *2D Barcode* Authentication for all Drugs as referred to in Article 3 paragraph (2) letter b and letter c no later than December 7, 2025.

Article 29

(1) Business Actors holding Circulation Permit for over-the-counter Drugs, limited over-the-counter Drugs, Traditional Drugs, Quasi Drugs, Health Supplements, Cosmetics, and Processed Food in circulation are required to apply *2D Barcode* in the form of Identification no later than 12 (twelve) months as of the issuance of Electronic Circulation Permit after this Agency Regulation is promulgated.
(2) Business Actors holding Circulation Permits for over-the-counter drugs, limited over-the-counter drugs, Traditional Medicines, Quasi-Medicines, Health Supplements, Cosmetics, and Processed Food in circulation are required to apply *2D Barcodes* in the form of Identification for all drugs and food as referred to in Article 3 paragraph (3) no later than December 7, 2023.

Article 30

When this Agency Regulation comes into force, Regulation of the Food and Drug Supervisory Agency Number 33 of 2018 concerning the Application of *2D Barcodes* in Food and Drug Supervision (State Gazette of the Republic of Indonesia Year 2018 Number 1599), is revoked and declared invalid.

Article 31

This Agency Regulation shall come into force on the date of promulgation.

In order that every person may know it, this Agency Regulation shall be promulgated by placing it in the State Gazette of the Republic of Indonesia.

Established in Jakarta
on October 5, 2022

HEAD OF THE FOOD AND DRUG ADMINISTRATION,

PENNY K. LUKITO

Promulgated in Jakarta on
October 5, 2022

MINISTER OF LAW AND HUMAN RIGHTS OF THE
REPUBLIC OF INDONESIA,

ttd.

YASONNA H. LAOLY

STATE NEWS OF THE REPUBLIC OF INDONESIA YEAR 2022 NUMBER 1021

APPENDIX
FOOD AND DRUG ADMINISTRATION REGULATION
NUMBER 22 OF 2022
ABOUT
APPLICATION *2D BARCODE* IN FOOD AND DRUG CONTROL

TECHNICAL GUIDELINES FOR THE APPLICATION OF *2D BARCODE*

A. GENERAL EXPLANATION

The Track and Trace Application of the POM Agency (www.ttac.pom.go.id) serves to facilitate the following activities for Business Actors who hold Edar Licenses, Distribution Facilities, and Pharmaceutical Service Facilities:

1) Access rights request;
2) *Barcode* Issuance; and
3) Reporting which consists of:
   a. Reporting of product receipts and disbursements;
   b. Product distribution (sales) reporting;
   c. *Return* reporting; and
   d. *Recall* reporting.

The POM Agency *Track and Trace* application is also available in the form of a *mobile* application called BPOM *Mobile*. The BPOM *Mobile* application facilitates activities for Business Actors who hold Circulation Permits, Distribution Facilities, Pharmaceutical Service Facilities, and the public as follows:

1) Reporting in accordance with Article 12 and Article 13 of this Agency Regulation, includes:
   a) Receiving and dispensing of products;
   b) Product distribution (sales) reporting;
   c) Reporting of returned products; and
   d) Reporting of *recalled* products.
2) On Society, including:
   a) Displays the latest news related to Food and Drug Control;
   b) Verification of registered products through *2D Barcode* scanning;
   c) Verify registered products by checking the registration number, product name or manufacturer name;
   d) Display the POM application *link*; and
   e) Complaint.

Business Actors who have Circulation Permits that apply *2D Barcode* Identification do not need to request access rights and reporting through the *Track and Trace* application of the POM Agency.

B. ACCESS RIGHTS REQUEST

Business Actors who hold Circulation Permits, Distribution Facilities, and Pharmaceutical Service Facilities submit applications for access rights to the POM Agency. In the application, the facility must attach official documents from the facility that include appropriate information.

with data in the Electronically Integrated Business Licensing Service (*Online Single Submission/OSS*), as follows:

1) The name of the facility is based on the Trading Business License (SIUP) or Importer Identification Number (API) or Business Identification Number (NIB);
2) Facility address based on SIUP or API or NIB;
3) TIN number;
4) The name of the person in charge of the account;
5) Phone number of the person in charge of the account;
6) *Email* address; and
7) Supporting documents (for example: SIUP, API, and NIB documents). Requests for access rights are addressed to the Directorate of Product Supervision at the POM or through the POM *Track and Trace* Application (www.ttac.pom.go.id/register).

C. *2D BARCODE*

1) *2D Barcode* Identification

In the electronic Circulation Permit, a *2D Barcode* will be issued which consists of information:
(90)XXXXXXXXXXXX
Description:

Code	Information	Total character	Data format
(90)XXXXXXXXXXXX	(90) followed Product Circulation Permit Number	Maximum 16 (alphanumeric)	As per product NIE
2D Barcodes that are put on the packaging must be in accordance with *2D Barcode* contained in the Edar Permit electronically and can be scanned by the BPOM *Mobile* application.			

2) *2D Barcode* Authentification

a. *2D Barcode* Authentication generated by the *Track and Trace* Application of the POM Agency according to the request of Business Actors is in the form of information which can then be converted into a *2D Barcode*.

b. The minimum information on a *2D Barcode* is as follows. (90)XXXXXXXXXXXX(10)WWWWWW(17)VVVVVV(21)YYYYYYYY YYYYY; or
(01)XXXXXXXXXXXXXX(10)WWWWWW(17)VVVVVV(21)YYYYYYY.

Code	Information	Number of characters	Data format
(90)XXXXXXXXXXXX	(90) followed by License Number Product Circulation.	Maximum 16 (alphanumeric) .	As per product NIE.
(10)WWWWWW	(10) followed batch numbers or *lots*.	1-20 (alphanumeric)	As per product no.bets/lots

(17)VVVVVVV	(17) followed by the end of the expiration period products	Maximum 6 (numeric)	YYMMDD (Year-Month-Date)
(21)YYYYYYYYYYYYYY	(21) followed by the product serialization number.	1-20 (alphanumeric)	1) If *2D Barcode* application generated *Track and Trace application* Badan POM: serialization will be generated by the Badan POM application. 2) If *2D Barcodes* are generated by Business Actors Business Actors independently independently then serialization follows the policy that the Business Actor Business Actors set.
01)XXXXXXXXXXXXXX	(01) followed by an international product identity, namely *Global Trade Item Number* (GTIN).	14 (numeric)	Generated by a 3rd party through membership.

c. The information as referred to in letter b can be sorted according to the needs of the business owner of the distribution permit.
d. *2D Barcodes* that are put on the packaging must be in accordance with *2D Barcode* reported to the Food and Drug Administration.
e. *2D Barcodes* generated by the POM *Track and Trace Application* include primary, secondary and tertiary codes.
   - Code primary is code level first level code which is printed on the packaging.
   - Secondary codes are second-level codes that contain information from several primary codes.
   - Tertiary codes are third-level codes that contain information from several secondary codes.
f. Furthermore, primary, secondary and tertiary codes can be used to

generate an aggregation system. An aggregation system is a coding system that contains detailed product information that is in the primary code listed in the secondary code while

product details on the primary code and secondary code are listed in the Tertiary Packaging.

3) In the event that there are two *2D Barcodes* included in the packaging of Medicine and Food products, the inclusion of the *2D Barcode* must be accompanied by the words "BPOM RI" placed adjacent to the *2D Barcode* (below, on the side or above). This inclusion is only for *2D Barcodes* with the Identification method, as shown in the example below:

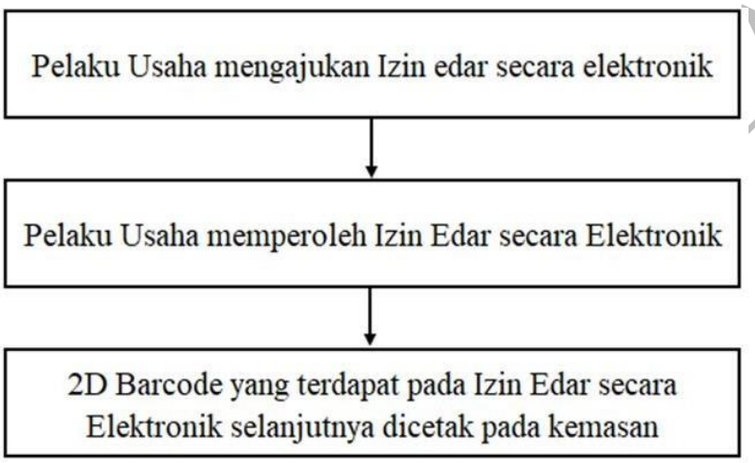
BPOM RI

or

BPOM RI

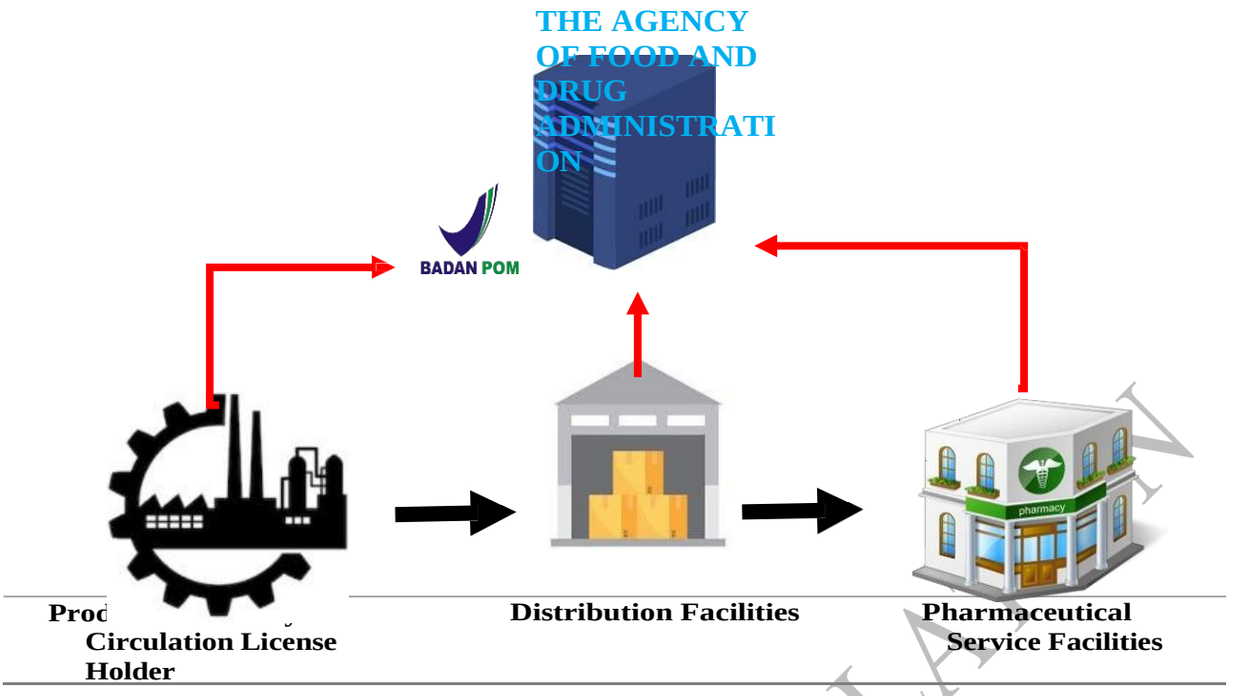
Figure 1. *2D Barcode* on packaging
(example of placement on top of *2D Barcode*)

D. *2D BARCODE* IMPLEMENTATION FLOW - IDENTIFICATION



2D Barcode Implementation Flow - Identification

E. *2D BARCODE* IMPLEMENTATION FLOW - AUTHENTICATION



2D Barcode Implementation Flow - Authentification

2D Barcode Implementation Flow - Authentification

→	Product distribution flow
→	Reporting flow of each facility, reporting details according to the table below
API	*Application Program Interface*

Activities at each facility are as follows:

Production Facility or Circulation License Holder	**Distribution Facilities**	**Pharmaceutical Service Facilities**
1. Publishing *Barcode* via a. Application for issuance to Agency POM through the *Track and Trace* Application POM Agency, or; b. Self-publishing by Performers Business actors follow the provisions regulations	1. Receiving Reporting Products from product facilities (Media reporting media: BPOM *Mobile* application, API and Document *Upload* reporting through POM Agency Application).	1. Receiving Reporting Products from product facilities (Media reporting media: application BPOM *Mobile application*, API and *Upload* Reporting document through the Application *Track and Trace Application* of POM Agency).

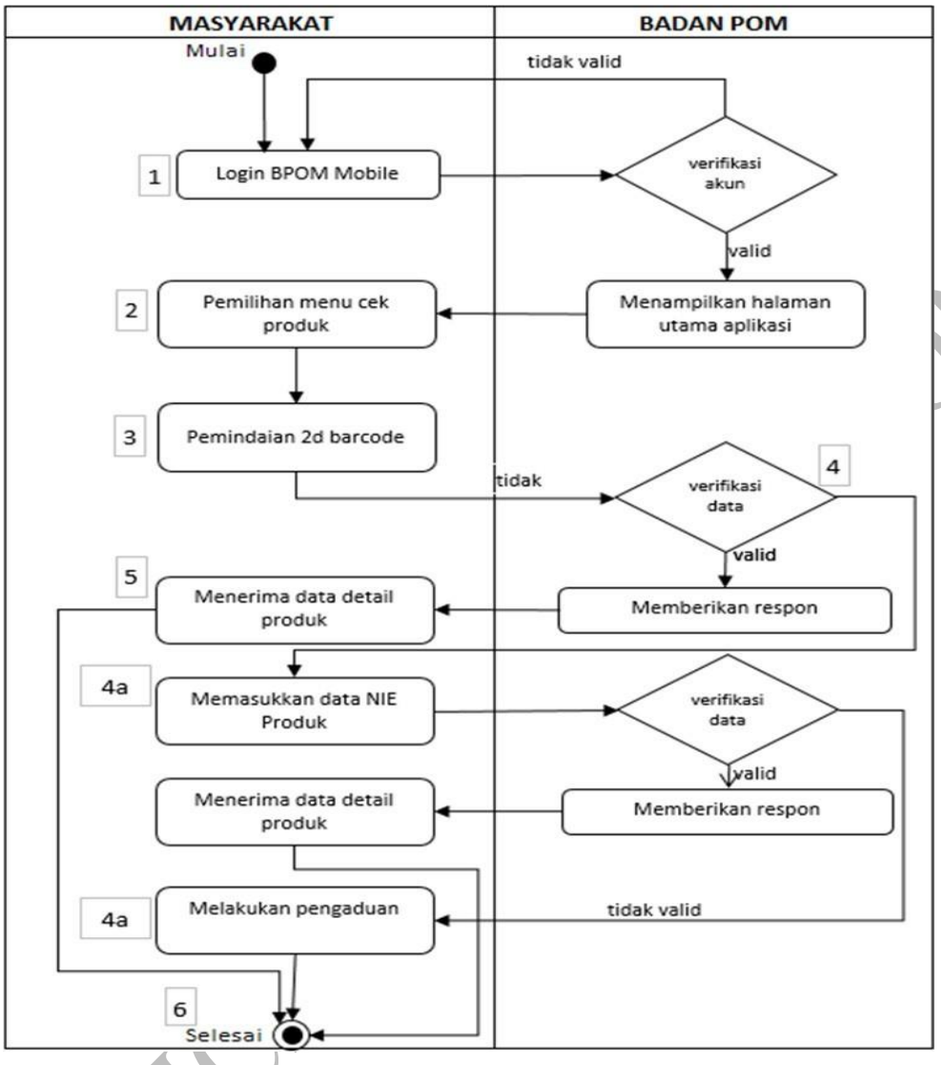
Production Facility or Owner of distribution license	**Distribution Facilities**	**Service Facilities Pharmacy**
legislation-Invitation.		
2. Usage Reporting *Barcode* (Reporting media: API and *Upload* reporting documents through the POM *Track and Trace* Application).	2. Product Expenditure Reporting (Media Reporting: application BPOM *Mobile*, API and *Upload* reporting documents through the POM Agency *Track and Trace* Application).	2. Product Sales Reporting (Reporting media: application BPOM *Mobile*, API and *Upload* reporting documents through the *Track and Trace* Application of the POM Agency).
3. Product Expenditure Reporting (Media reporting media: application BPOM *Mobile application*, API and *Upload* Reporting document through the Application *Track and Trace* Badan POM).		

1) *The Application Program Interface* (API) data *type* format is JSON.
2) The format of the reporting document can be obtained on the *dashboard user* application.
3) The BPOM *Mobile* application can be downloaded on the *play store* or apps *store*, *login* using the *username* and *password* obtained from BPOM.
4) The reporting manual or guideline will be a separate document from the technical instructions *and* can then be obtained at the POM *Track and Trace* Application (www.ttac.pom.go.id).

F. COMMUNITY

1. *2D Barcode* Verification by the Community

Figure 4. 2D *Barcode* Scanning by the Community



***2D Barcode* Scanning by the Community**

1) The public *logs* in to the BPOM *Mobile* application.
2) People choose the Product Check menu.
3) The public *scans* the *2D Barcode*.
4) POM *Track and Trace* application verifies data *2D Barcode*.
   a) If the *2D Barcode* data is invalid, the community inputs the product NIE data. If the NIE data is invalid, the public makes a complaint, according to the technical instructions for complaints by the public.
   b) If the *2D Barcode* data is valid, then proceed to number 5 (five).

5) People receive informationat least at least contains the following information:
   a) product name;
   b) Circulation Permit number;
   c) the name and address of the Business Actor; and
   d) Packaging.
6) Process completed.

2. Complaints through BPOM *Mobile* Application

This flow illustrates the process of public complaints about products received by the public.

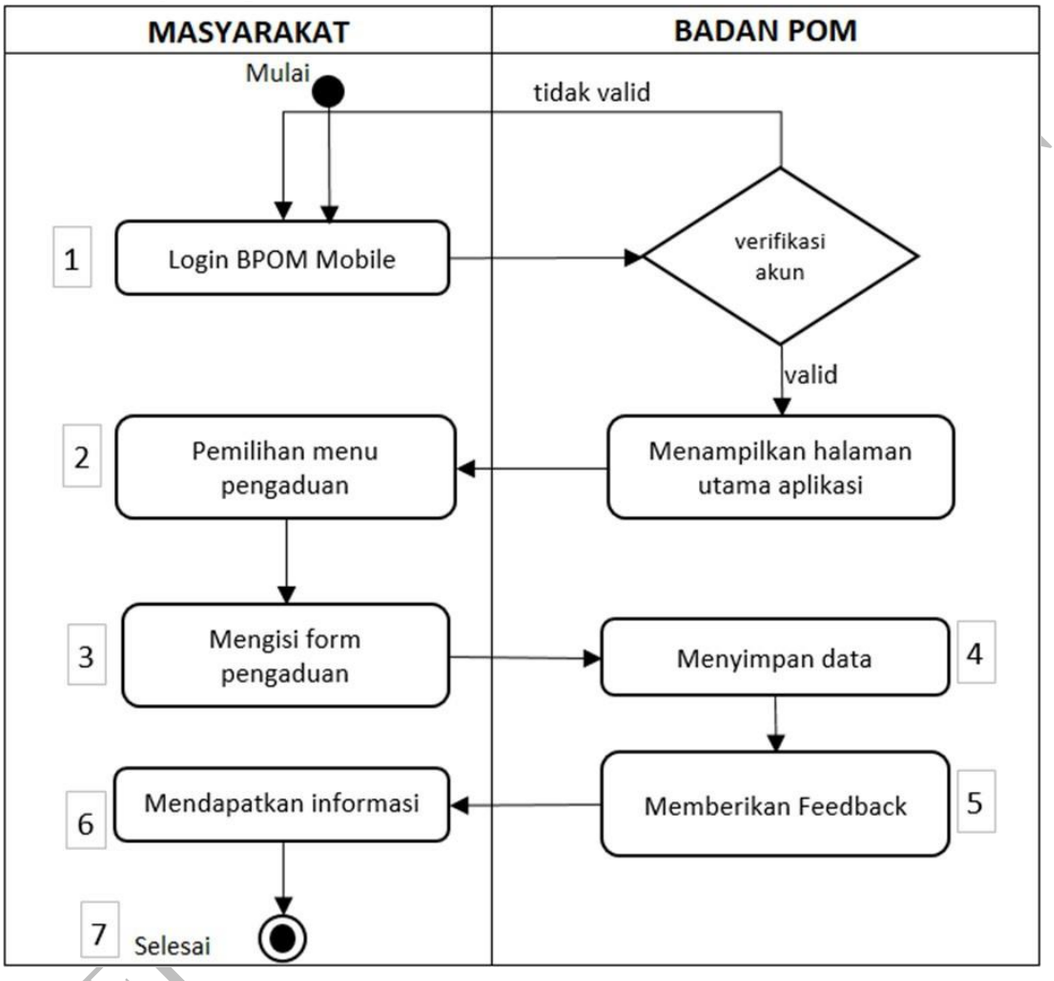


Figure 5: Complaints by the Public

Description of Figure 5. Complaints by the Public:

1) The public *logs* in to the BPOM *Mobile* application.
2) People select the Complaints menu.
3) People do complaint by filling out *form* complaints in the *Mobile* application. The data filled in is in the form of:
   a) Question;
   b) product name;
   c) batch number;

d) the product's Edar License number;
e) supporting photos;
f) purchase location; and
g) purchase address.

4) The submitted complaint data will be stored in the database.
5) *The Mobile* App will provide *feedback*.
6) The public will get information that can be viewed through the *Mobile* application.
7) Process completed.

HEAD OF THE FOOD AND DRUG ADMINISTRATION,

ttd.

PENNY K. LUKITO.