REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY

NUMBER 33 OF 2018

ON

THE APPLICATION OF 2D BARCODES FOR FOOD AND DRUG CONTROL

BY THE BLESSINGS OF ALMIGHTY GOD

CHAIRPESRON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

Considering : a. that the public needs be protected against food and drugs not meeting established standards and requirements;

b. that to strengthen the effectiveness of comprehensive control of food and drugs before and during their distribution, there is a need for support by means of an information technology system;

c. that the support of an information technology system as referred to in point b is realized among other things through the application of 2D Barcodes in the food and drug control system;

d. that based on the considerations as referred to in point a, point b, and point c, it is necessary to issue a Regulation of the Indonesian Food and Drug Authority on the application of 2D Barcodes for Food and Drug Control;

Observing : 1. Presidential Regulation Number 80 of 2017 on the Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia of 2017 Number180);

2. Regulation of the Indonesian Food and Drug Authority Number 26 of 2017 on Organizational Structures and Work Procedures of the Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2017 Number 1745);
3. Regulation of the Indonesian Food and Drug Authority Number 12 of 2018 on Organizational Structures and Work Procedures of the Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2018 Number 784);

HAS DECIDED:

To issue : REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY ON THE APPLICATION OF 2D BARCODES FOR FOOD AND DRUG CONTROL.

CHAPTER I
GENERAL PROVISIONS

Article 1

In this Authority Regulation:

1. 2D Barcode means a two-dimensional, graphical representation of digital data with high decoding capacity readable by optical devices for the purposes of identification, tracing, and tracking.
2. Authentication means the method of tracing and verifying legalities, batch numbers, expiries, and serial numbers of food and drug products.
3. Identification means the method of marketing authorization-based legality verification of food and drugs.
4. Drug means a finished medicine including Biological Products, which is an ingredient or combination of ingredients used to influence or investigate the physiological system or state of pathology in order to establish diagnosis, prevention, healing, recovery, and improvement of health, and contraception for humans.

5. Traditional Medicine means materials or ingredients in the form of vegetable materials, animal materials, mineral materials, dosage form extracts (galenic), or a mixture of those materials which have been used hereditarily for medication purposes, and which can be administered in accordance with norms prevailing in society.
6. Health Supplement means a product designed to supplement nutrient intake, to maintain, to increase, and/or to improve health functions, to have nutritional value and/or a physiological effect, to contain one or more materials in the form of vitamins, minerals, amino acids and/or other non-plant materials combinable with plants.
7. Cosmetic means a material or dosage form designed for topical use on the human body (epidermis, hair, nails, lips, and external genital organs) or teeth and the oral mucosa mainly to clean, to perfume, to alter the appearance, and/or to improve body odor or to protect or to maintain the body in good condition.
8. Processed Food means food or beverage that is processed in a certain way or method with or without food additives.
9. Processed Food for Special Diets, hereinafter referred to as Special Dietary Food, means processed food that has been processed or formulated specially in order to meet specific nutritional requirements because of a specific physical or physiological condition.
10. Indonesian Food and Drug Authority Track and Trace Application, hereinafter referred to as Indonesian FDA Track and Trace Application, means an application issuing 2D barcodes and recording any product movement to obtain product information and product location, both the product's current location and a unique location history of its movement.
11. Quick Response Code, hereinafter referred to as QR Code, means a two-dimensional code (2D barcode) comprising three square signs placed in the lower left corner, the upper left corner and the upper right corner, featuring a black module (a square of pixels), and capable of storing alphanumeric data, characters, and symbols.

12. Business Actor means an individual or business enterprise, operating either as a legal entity or otherwise, that has been established and is domiciled or performs activities in the jurisdiction of the Republic of Indonesia, either individually or collectively, under an agreement to perform business activities in the Food and Drug sector.
13. Pharmaceutical Industry means a business enterprise holding a license from the Minister of Health to perform Drug or raw material manufacturing activities.
14. Marketing Authorization means a form of agreement to have Food and Drugs registered for marketing in Indonesian territory.
15. Primary Packaging means packaging in direct contact with Food and Drug.
16. Secondary Packaging means packaging protecting the primary packaging.
17. Tertiary Packaging means packaging used to combine all secondary packaging to facilitate the transportation process and to prevent product damage.
18. Indonesian Food and Drug Authority, hereinafter referred to as Indonesian FDA, means a non-ministerial government agency administering government affairs in the Food and Drug control sector.

Article 2

(1) The application of 2D Barcodes as regulated in this Authority Regulation encompasses Food and Drugs produced and distributed domestically and/or imported for being distributed in Indonesia territory.

(2) Food and Drugs as referred to in section (1) consist of:
    a. Drugs;
    b. Traditional Medicines;
    c. Health Supplements;
    d. Cosmetics; and
    e. Processed Foods.

CHAPTER II
2D Barcodes

Part One
General

Article 3

(1) 2D Barcodes as referred to in Article 2 employ the following methods:
   a. Authentication; and
   b. Identification.

(2) 2D Barcodes employing the Authentication method as referred to in section (1) point a apply to Drugs falling under the category of:
   a. Prescription Drugs;
   b. biological products;
   c. narcotics; and
   d. psychotropic drugs.

(3) 2D Barcodes employing the identification method as referred to in section (1) point b apply to:
   a. Drugs falling under the category of Over-The-Counter Drugs and limited Over-The-Counter Drugs;
   b. Traditional Medicines;
   c. Health Supplements;
   d. Cosmetics; and
   e. Processed Foods.

(4) Based on the risk assessment, Drugs falling under the category of specific Over-The-Counter Drugs and limited Over-The-Counter Drugs and Processed Food in the form of Special Dietary Food are required to apply 2D Barcodes applying the Authentication method.

(5) Drugs falling under the category of specific Over-The-Counter Drugs and limited Over-The-Counter Drugs as referred to in section (4) are stipulated by the Chairperson of the Indonesian Food and Drug Authority.

Article 4

The application of 2D Barcodes employing the Authentication method as referred to in Article 3 section (1) point a refers to the technical directive on the application of 2D Barcodes denoted within the Annex as an integral part of this Authority Regulation.

Part Two

Product Authentication

Paragraph 1

General

Article 5

(1) 2D Barcodes employing the Authentication method may be issued by:
   a. the Indonesian FDA; or
   b. Business Actors acting independently.
(2) 2D Barcodes issued by the Indonesian FDA as referred to in section (1) point a take the form of QR codes.
(3) 2D Barcodes issued by Business Actors as referred to in section (1) point b take the form of QR Codes or 2D Barcodes readable by the Indonesian FDA Track and Trace Application.

Paragraph 2

Conditions

Article 6

2D Barcodes for Drugs as referred to in Article 3 section (2) must include the following information:

a. Marketing Authorization number and/or an internationally valid product identification number;
b. batch number or production code;
c. expiration date; and
d. serialization number.

Paragraph 3
Application

Article 7

(1) 2D Barcodes as referred to in Article 5 section (1) point a are application-based.
(2) An application for a 2D Barcode as referred to in section (1) is submitted by the Business Actor holding a Marketing Authorization.

Article 8

(1) The application for a 2D Barcode as referred to in Article 7 section (2) is carried out by inputting data through the Indonesian FDA Track and Trace Application.
(2) The data as referred to in section (1) include:
    a. Marketing Authorization number;
    b. batch number or production code;
    c. expiration date:
    d. amount of primary codes requested;
    e. amount of maximum primary codes on secondary packaging; and
    f. amount of maximum secondary codes on tertiary packaging.
(3) In the event that the business actor already has an internationally recognizable product identity, this can be denoted within the application data.

Article 9

The application for a 2D barcode as referred to in Article 7 and Article 8 is submitted within not more than 10 (ten) work days before production is to start.

Article 10

(1) The 2D barcode as referred to in Article 7 section (1) point a is issued electronically within not more than 5 (five) workdays calculated from when the application was submitted.

(2) The 2D barcode as referred to in section (1) is valid only for the batch or production code submitted for.

Paragraph 4
Reporting

Article 11

A business actor possessing a marketing authorization, a distribution facility, and a pharmaceutical services facility are obligated to submit a 2D barcode report to Chairperson of the IFDA.

Article 12

(1) The report submitted by the business actor possessing a marketing authorization takes the form of a 2D barcode utilization report.
(2) The 2D barcode utilization report as referred to in section (1) includes:
    a. the 2D barcode denoted within the retained sample;
    b. the activated 2D barcode;
    c. the distributed 2D barcode; and
    d. the 2D barcode denoted within recalled or returned products.
(3) In addition to the report as referred to in section (2), an applicant comprising a Pharmaceutical Industry applying an aggregation system is also obligated to submit information on its aggregation code.
(4) The aggregation code as referred to in section (3) encompasses:
    a. primary code;
    b. secondary code; and
    c. tertiary code.
(5) The report as referred to in section (2) and section (3) is submitted through the Indonesian FDA Track and Trace Application not later than 24 (twenty-four) hours for every activity as referred to in section (2).

Article 13

(1) Drug distribution facility and the pharmaceutical service facility are required to submit the report incoming and outgoing Drugs through the Indonesia FDA Track and Trace Application.

(2) The report as referred to in section (1) encompasses:
   a. all products received;
   b. all products distributed; and
   c. all products recalled or returned.

(3) Report submission as referred to in section (2) is carried out through the Indonesian FDA Track and Trace Application not later than 24 (twenty-four) hours for every activity as referred to in section (2).

(4) Provisions regarding report submission as referred to in section (1), section (2), and section (3) are not valid for Drugs that have not yet applied 2D Barcodes in the form of Authentication.

Part Three

Product Identification

Article 14

2D Barcodes employing the identification method are included within the electronic Marketing Authorization in the form of QR Codes issued by the Indonesian FDA.

Article 15

2D Barcodes as referred to in Article 14 must include the following information:

a. Marketing Authorization number; and
b. Marketing Authorization's validity period.

Article 16

Business Actors are obligated to use 2D Barcodes as referred to in Article 15 corresponding to those included within the electronic Marketing Authorization.

CHAPTER III
INCLUSION OF 2D BARCODES ON PACKAGING

Article 17

(1) 2D Barcodes as referred to in Article 3 are printed on packaging in black ink against a white or other color background.

(2) 2D Barcodes as referred to in section (1) must allow for easy scanning and be readable by the Indonesian FDA Track and Trace Application.

Article 18

(1) A Pharmaceutical Industry holding a Marketing Authorization is obligated to include 2D Barcodes on its primary Packaging.

(2) The obligation to include 2D Barcodes on primary packaging as referred to in section (1) is exempted for Drugs meeting the following conditions:
   a. volumes under 10 (ten) millimeters;
   b. primary blister packaging;
   c. primary strip packaging;
   d. ampule packaging;
   e. prefilled syringe;
   f. tube packaging with net weights under 10 (ten) grams;
   g. single packaging;
   h. stick pack;
   i. suppositories; and
   j. catch cover.

(3) 2D Barcodes as referred to in section (2) may be included on secondary packaging with a safety in place to ascertain the contents' originality.

Article 19

(1) Business actors of Traditional Medicines and Health Supplements holding Marketing Authorizations are obligated to include 2D Barcodes on Primary Packaging.

(2) The obligation to include 2D Barcodes on Primary Packaging as referred to in section (1) is exempted for Traditional

Medicines and Health Supplements by including these on the Secondary Packaging, meeting the following conditions:

a. volumes under 5 (five) millimeters;
b. Primary blister packaging;
c. Primary strip packaging;
d. ampule packaging;
e. tube packaging with net weights under 5 (five) grams;
f. stick pack;
g. suppositories; and/or
h. having a label surface of less than or equal to 10 cm2 (ten square centimeters).

Article 20

(1) Business Actors of cosmetics holding Marketing Authorizations are obligated to include 2D Barcodes on packaging.
(2) The conditions as referred to in section (1) are implemented in accordance with provisions of the legislation concerning the marking of Cosmetics.

Article 21

(1) Business Actors of Processed Food holding Marketing Authorizations are obligated to include 2D Barcodes on retail packaging for Processed Food that has been registered.
(2) It is compulsory to include 2D barcodes as referred to in section (1) on primary packaging.
(3) The obligation to include 2D Barcodes on Primary Packaging as referred to in section (1) is exempted for Processed Food with surface labels less than or equal to 10 cm2 (ten square centimeters).
(4) It is compulsory to include 2D Barcodes as referred to in section (3) on Secondary Packaging.

Article 22

Business Actors are obligated to include 2D Barcodes commensurate to the packaging's surface area with the smallest

measurement being 0.6 x 0.6 cm (zero point six times zero point six centimeters).

Article 23

(1) In the event that packaging of Food and Drugs includes two 2D barcodes, the Business Actor is obligated to include the text "BPOM RI" on one of the two 2D Barcodes.
(2) The inclusion of the text "BPOM RI" as referred to in section (1) applies only to 2D Barcodes issued by the Indonesian FDA.

CHAPTER IV
PUBLIC PARTICIPATION

Article 24

The public may participate in the control of Food and Drugs by scanning and reporting 2D barcode scans using the BPOM Mobile application.

Article 25

The BPOM Mobile application as referred to in Article 24 contains at least the following information:

a. product name;
b. Marketing Authorization number;
c. Marketing Authorization's validity period;
d. Business Actor's name and address; and
e. packaging.

CHAPTER V
SANCTIONS

Article 26

Violations against provisions under Article 11, Article 12 section (3), Article 13 section (1), Article 16, Article 18 section (1), Article 19 section (1), Article 20 section (1), Article 21, Article 22, and Article 23 section (1) are subject to administrative sanctions in accordance with provisions of the legislation on the labeling.

CHAPTER VI
CLOSING PROVISIONS

Article 27

At the time this Authority Regulation comes into force:

a. Pharmaceutical Industries holding a Marketing Authorization are obligated to apply 2D Barcodes for Authentication not later than 2 (two) years calculated from the time the Marketing Authorization electronically issued after the promulgation of this Authority Regulation.
b. Pharmaceutical Industries holding a Marketing Authorization as referred to in Article 3 section (2) are obligated to apply 2D Barcodes for Authentication not later than 7 (seven) years after the promulgation of this Authority Regulation.

Article 28

At the time this Authority Regulation comes into force:

a. Pharmaceutical Industries, Business Actors of Traditional Medicines, Business Actors of Health Supplements, Business Actors of Cosmetics or Business Actors of Food holding a Marketing Authorization are obligated to apply 2D Barcodes for identification not later than 6 (six) months calculated from the date the marketing authorization issued electronically after the promulgation of this Authority Regulation.
b. Business Actors holding a Marketing Authorization for Drugs falling under the category of Over-The-Counter Drugs, limited Over-The-Counter Drugs, Traditional Medicines, Health Supplements, Cosmetics, and Processed Food which are on the market are obligated to apply 2D Barcodes for identification not later than 5 (five) years calculated as of the promulgation of this Authority Regulation.

Article 29

This Authority Regulation comes into force on the date of its promulgation.

In order that every person may know hereof, it is ordered to promulgate this Authority Regulation by its placement in the State Bulletin of the Republic of Indonesia.

Issued in Jakarta
on 5 December 2018

CHAIPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

Promulgated in Jakarta
on 7 December 2018

DIRECTOR GENERAL OF LEGISLATION OF MINISTRY OF LAW AND HUMAN RIGHTS OF THE REPUBLIC OF INDONESIA,

signed

WIDODO EKATJAHJANA

STATE BULLETIN OF THE REPUBLIC OF INDONESIA OF 2018 NUMBER1599

Jakarta, 17 October 2022
Has been translated as an Official Translation
on behalf of Minister of Law and Human Rights
of the Republic of Indonesia
DIRECTOR GENERAL OF LEGISLATION AD INTERIM,

DIREKTUR JENDERAL PERATURAN PERUNDANG-UNDANGAN KEMENTERIAN HUKUM DAN HAK ASASI MANUSIA REPUBLIK INDONESIA

DHAHANA PUTRA

ANNEX TO
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 33 OF 2018
ON
THE APPLICATION OF 2D BARCODES FOR FOOD AND DRUG CONTROL

TECHNICAL DIRECTIVES ON THE APPLICATION OF 2D BARCODES

A. GENERAL EXPLANATION

The Indonesian FDA track and trace application (www.ttac.pom.go.id) serves to facilitate business actors as marketing authorization holder, distribution facilities, and service facilities with the following activities:

1) Requests for access rights;
2) Issuance of barcodes; and
3) Reporting consisting of:
    a. Reporting of incoming and outgoing products;
    b. Product sales reporting;
    c. Returned products reporting;
    d. Recalled products reporting.

A mobile version of the Indonesian FDA track and trace application is also available, called BPOM Mobile. The BPOM Mobile application facilitates business actors as Marketing Authorization Holder, distribution facilities, service facilities, and the public with the following activities:

1) Reporting in accordance with Article 12 and Article 13 of this Authority Regulation, consists of:
    a) Incoming and outgoing products;
    b) Product sales reporting;
    c) Returned products reporting; and
    d) Recalled Products reporting.
2) to the public, consists of:
    a) Displaying the latest news on food and drug control;
    b) Verification of 2D Barcodes; and
    c) Complaints.

Business actors as marketing authorization holder who apply 2D Barcodes for identification do not need to request for access rights and

reporting through the track and trace application.

B. REQUEST FOR ACCESS RIGHTS

A business actor as marketing authorization holder, a distribution facility, and a pharmaceutical services facility submits a request for access rights to the Indonesian FDA. When making the submission, the facilities must attach official documents for the facilities including the following information reflecting the data submitted to the Online Single Submission (OSS):

1) The facilities' names as indicated in either the Trade Business License, *Surat Izin Usaha Perdagangan* (SIUP), the Importer's Identification Number, *Angka Pengenal Impor* (API) or the Business Identification Number, *Nomor Induk Berusaha* (NIB);
2) The facilities' addresses as indicated in either the SIUP, the API or the NIB;
3) Tax Identification Number:
4) Name of the account's holder;
5) Telephone number of the account's holder;
6) Email address; and
7) Supporting documents (e.g. SIUP, API, and NIB documents). Requests for access rights should be addressed to the Indonesian FDA Directorate of Control for the relevant products.

C. 2D BARCODE

1) 2D Barcode for Identification

   A 2D barcode will be issued electronically for the marketing authorization, consisting of the following information:
   (90)XXXXXXXXXXXX(91)YYYYYY

Notes:

Code	Information	Character count	Data format
(90)XXXXXXXXXXXX	(90) followed by the product's Marketing Authorization Number	Maximum 16 (alphanumeric al)	Corresponding to product NIE

(91)YYYYYY	(91) followed by the Marketing Authorization Number's validity period	Maximum 6 (numerical)	YY-MM-DD (Year – Month – Date)

Code	Information	Character count	Data format
2D barcodes denoted on packaging must be in accordance with the 2D barcodes indicted electronically on the marketing authorization and must be scanned by BPOM Mobile			

2) 2D Barcode for Authentication

a. 2D Barcodes for authentication produced by the Indonesian FDA track and trace application in accordance with a Business Actor's request are information subsequently changed into 2D Barcodes.

b. The minimum information required for a 2D barcode is as follows.
(90)XXXXXXXXXXXX(10)WWWWWW(17)VVVVVV(21)YYYYYYYYYYYYYYY; or
(01)XXXXXXXXXXXX(10)WWWWWW(17)VVVVVV(21)YYYYYYYYYYYYYYY.

Code	Information	Character count	Data format
(90)XXXXXXXXXX X	(90) followed by the product's Marketing Authorization Number	Maximum 16 (alphanumerical)	Corresponding to product NIE
(10)WWWWWW	(10) followed by the batch or lots number	1-20 (alphanumeric)	Reflecting the product's batch/lots number

(17)VVVVVV	(17) followed by the product's expiration date	Maximum 6 (numerical)	YY-MM-DD (Year – Month Date)
(21)YYYYYYYYYYYYYYYY	(21) followed by the product's serialization number	1-20 (alphanumeric)	1) If a 2D barcode is produced by the Indonesian FDA Track and Trace application: serialization will be produced by the BPOM application 2) If the 2D barcode is produced by the Business Actor independently, the serialization follows the policy stipulated by the Business Actor.

Code	Information	Character count	Data format
(01)XXXXXXXXXXXX	(01) followed third product by way of membership namely *Global Trade International Number* (GTIN)	14 (numerical)	Produced by identity through international

a) 2D Barcodes included on packaging must be in accordance with the 2D Barcodes reported to the Indonesian FDA

b) 2D barcodes produced by the Indonesian FDA Track and Trace application encompass primary, secondary, and tertiary codes.

3) Primary codes are the first level of code printed on packaging.

4) Secondary codes are the second level of code holding information of multiple primary codes.

5) Tertiary codes are the third level of code holding information of multiple secondary codes.

c) Subsequently, primary, secondary, and tertiary codes can be utilized to produce an aggregation system. An aggregation system is a system to assign code holding information on product details stored in the

primary code included on the secondary code while product details on both the primary and secondary codes are included on the tertiary packaging.

d) It's not compulsory to use the aggregation system

3) Inclusion of 2D Barcodes on the packaging of food and drug products with 2D barcodes

In the event that two 2D barcodes are included on the packaging of a food and drug product, the 2D Barcode from the Indonesian FDA must include the text "BPOM RI" as indicated below:

BPOM RI

or

BPOM RI

D. FLOW OF 2D BARCODES' IMPLEMENTATION – IDENTIFICATION

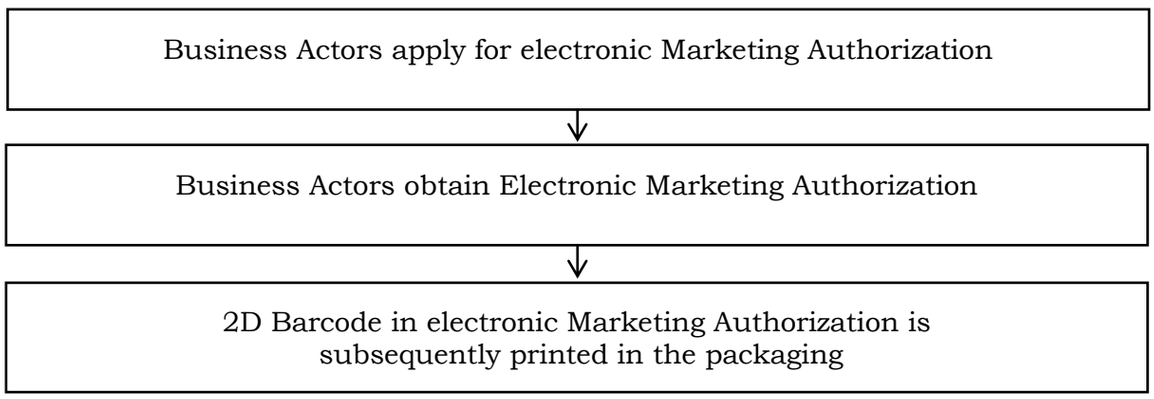

Figure 1. Flow of the Implementation of 2D Barcodes – Identification

E. FLOW OF 2D BARCODES' IMPLEMENTATION – AUTHENTICATION

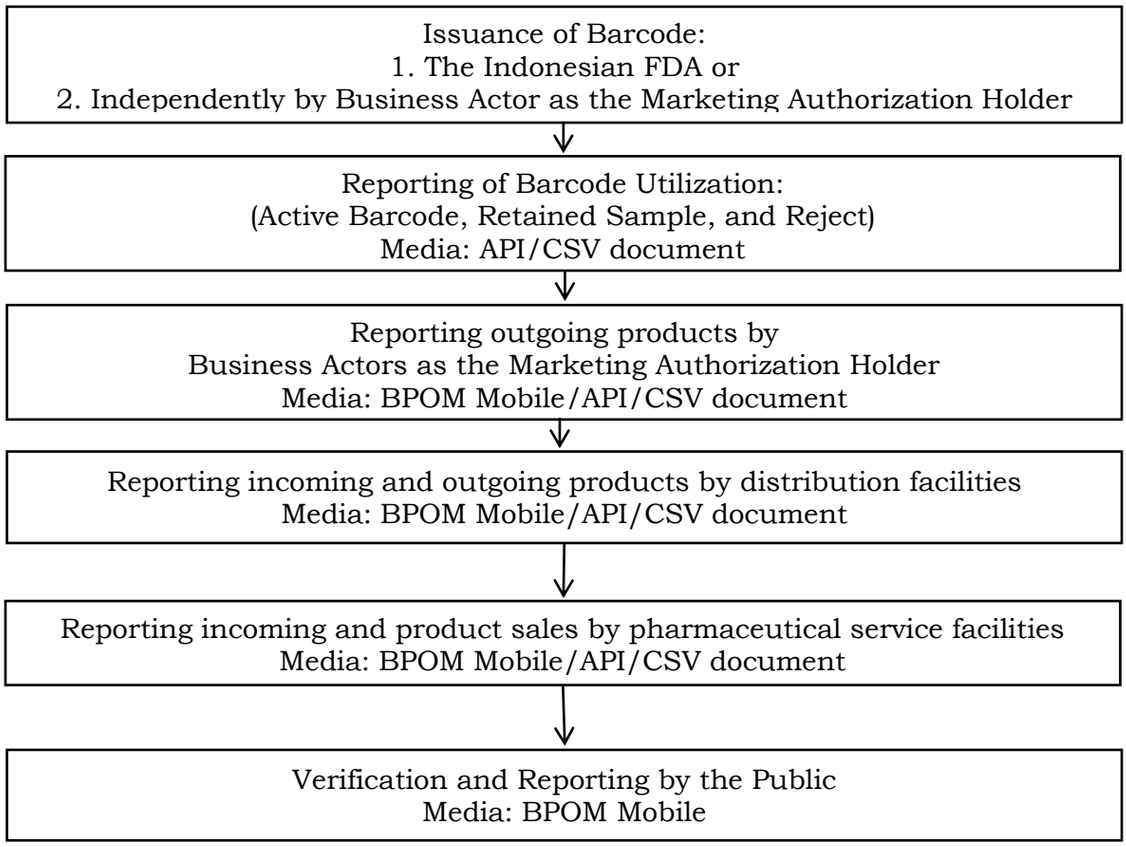

Figure 2. Flow of the Implementation of 2D Barcodes – Authentication

1) The Application Programmer Interface's (API) data type is JSON.
2) A CSV template can be accessed on the dashboard of the user's application
3) BPOM mobile can be downloaded from either play Store or the apps store; login by using the username and password provided by the Indonesian FDA.

F. FLOW OF 2D BARCODES' ISSUANCE FOR AUTHENTICATION BY INDONESIAN FDA

Business actors as marketing authorization holder submit requests for 2D barcodes through the Indonesian FDA track and trace application (ttac.pom.go.id)

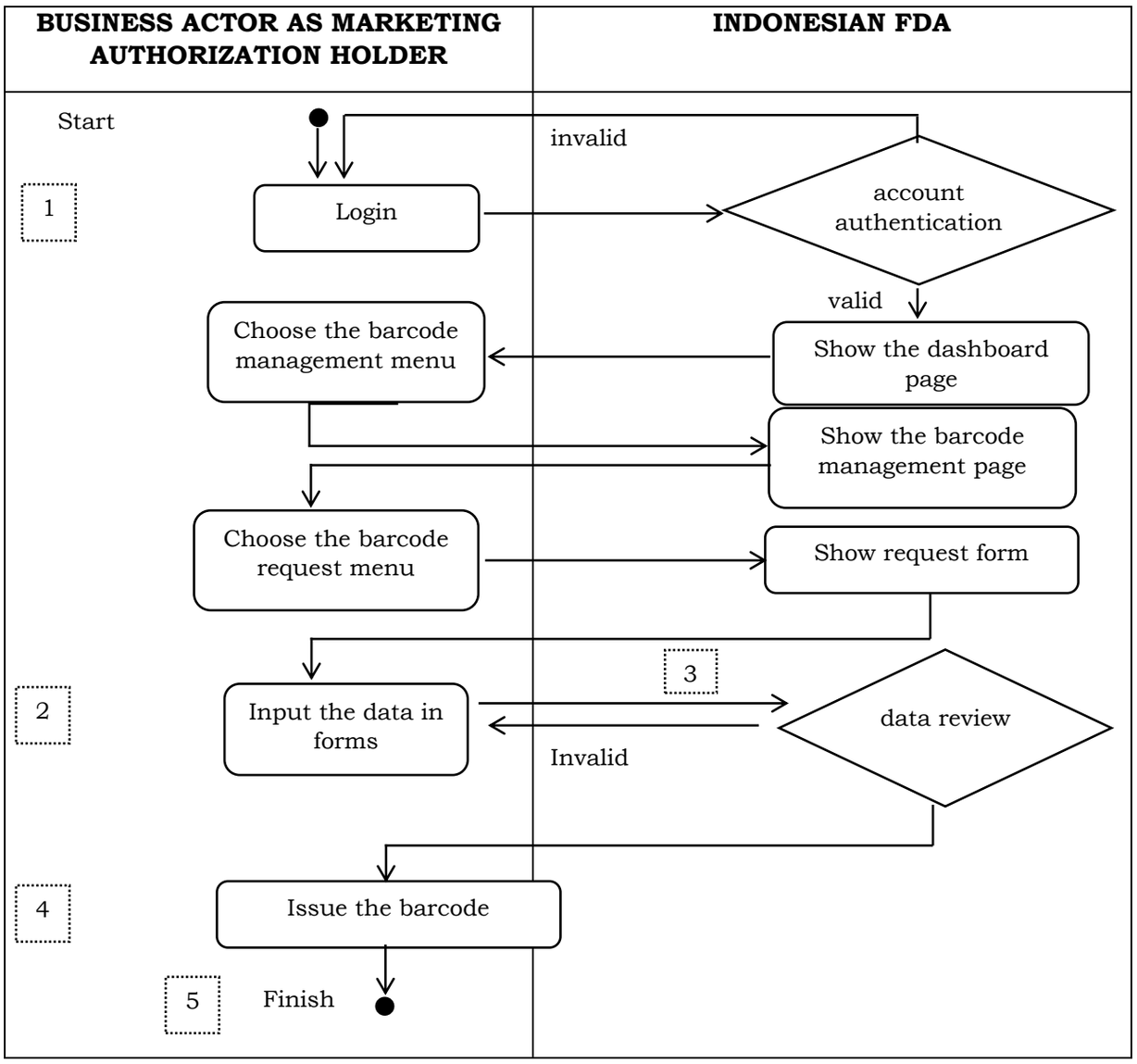

Figure 3. Flow of 2D Barcode's Issuance by Indonesian FDA Notes

Note:

1) A business actor as marketing authorization holder logs into the Indonesian FDA track and trace application.
2) A business actor as marketing authorization holder submits a request for a 2D Barcode by inputting data into the barcode management menu. Namely:
    a) Product name

b) Marketing Authorization number
c) Dosage form
d) Product Packaging
e) Batch number
f) Expiration date
g) Product identity internationally, if any
h) Amount of primary codes requested
i) Amount of maximum primary codes on secondary packaging
j) Amount of maximum secondary codes on tertiary packaging

3) The Indonesian FDA track and trace application reviews the data.
   a) If the product does not have a marketing authorization number yet, the barcode request cannot be processed and the product must be registered first.
   b) If the product already has a marketing authorization and its data are valid, the process proceeds to step number 4 (four).
4) The Indonesian FDA track and trace application responds to the barcode request by issuing an alphanumeric code displayed on the barcode management menu.
5) Finish.

G. REPORT ON THE USE OF 2D BARCODES FOR AUTHENTICATION BY BUSINESS ACTOR AS MARKETING AUTHORIZATIONS HOLDER

Business actors as Marketing Authorization Holder report the use of 2D barcodes by indicating the barcode's status, i.e. Active, Reject, Retained Sample, Aggregation (if any). With regard to aggregation, the Business Actor is required to submit successive reports in a single process, i.e. primary codes associated to secondary codes, and secondary codes associated to tertiary codes

Reporting can be done through API or by uploading CSV documents, by proceeding according to the following flow:

a. Through API

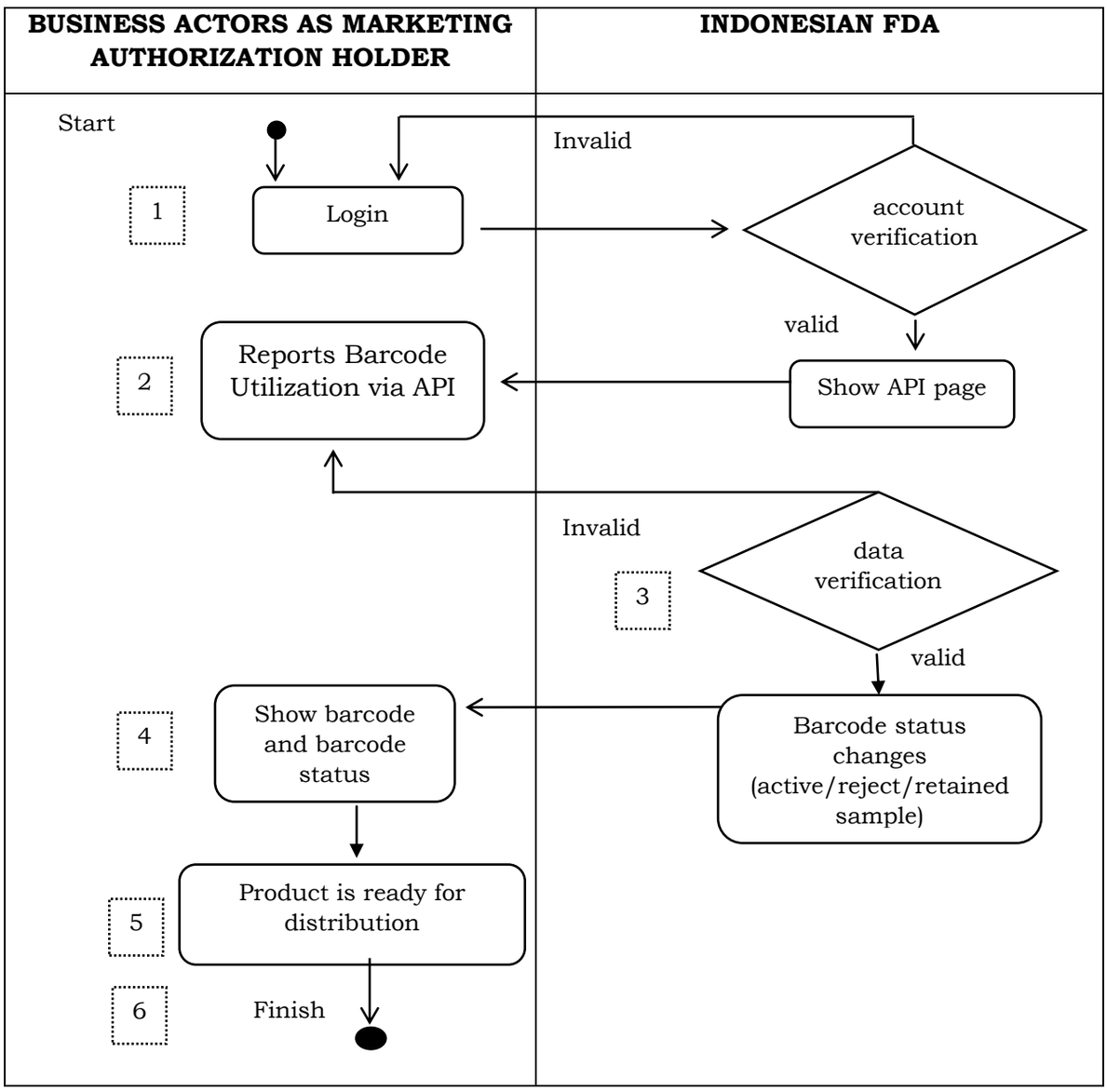

Figure 4. Reporting on the use of 2D barcodes

Note

1) A business actor as marketing authorization holder logs into the API
2) The business actor as marketing authorization holder sends in data regarding the use of primary codes and aggregations (if any)
3) The application will verify the sent in data
   a) If the data are invalid, return to step number 2 (two);
   b) If the data are valid, proceed to step number 4 (four).

4) Changed status of product (active/retained sample/ reject)
5) Product is ready for distribution
6) Finish.

b. By uploading CSV documents

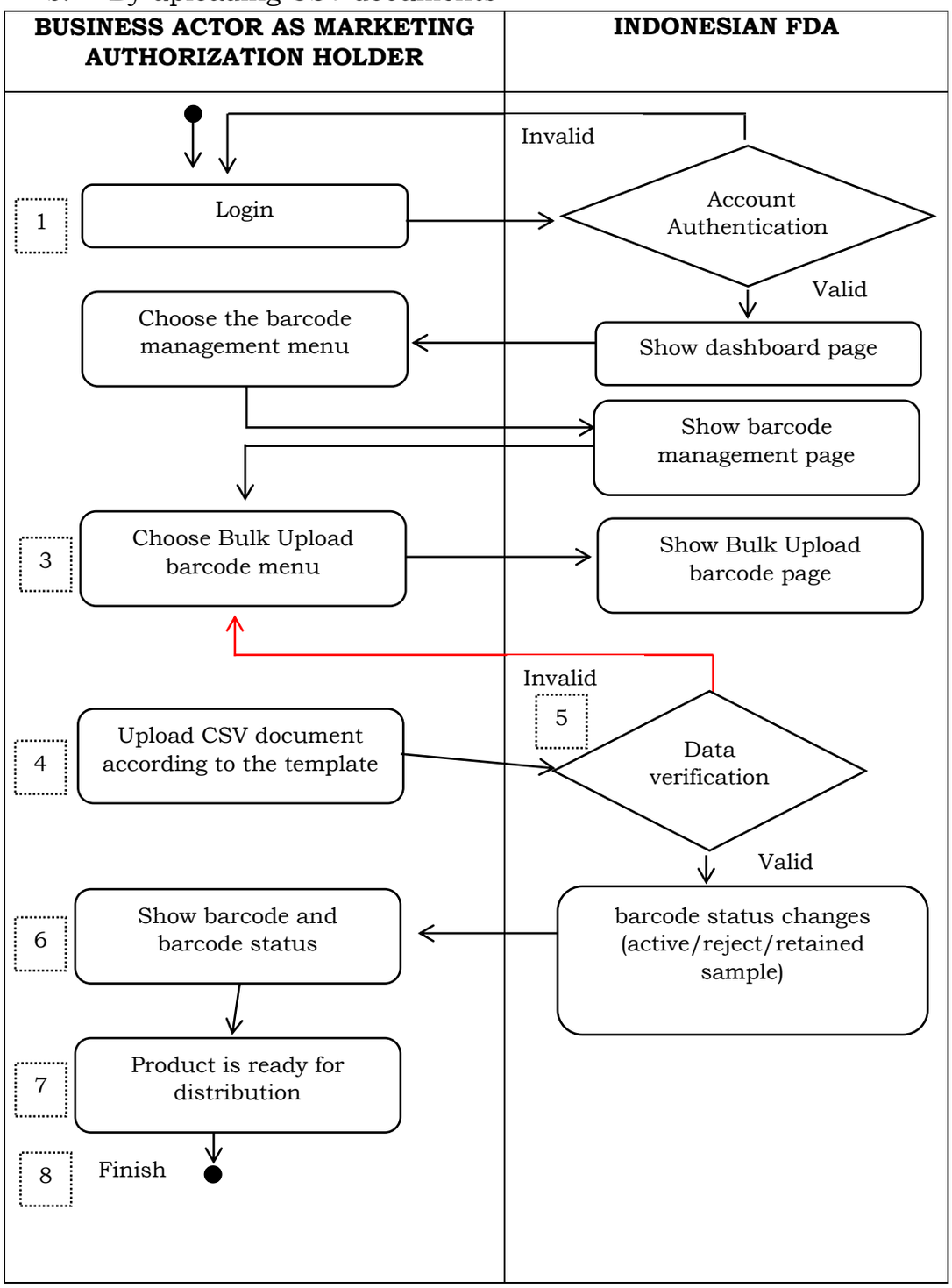

Figure 5. Reporting on the use of 2D barcodes by uploading of CSV documents

Notes:

1) A business actor as marketing authorization holder logs into the Indonesian track and trace application.
2) The business actor as marketing authorization holder selects the

barcode management menu.

3) The business actor as marketing authorization holder selects the Bulk Upload Barcode menu

4) The business actor as marketing authorization holder uploads the CSV documents conforming to the template available on the Indonesian FDA track and trace application.

a) On this menu the production facility reports the barcode and its status (active, reject, and/or retained sample) and aggregations.

b) The information submitted in the CSV documents includes

i. Supplier ID : obtained from the Indonesian FDA track and trace
application

ii. Packaging : product packaging reported corresponds to packaging included on Cekbpom.pom.go.id

iii. Primary Code : information to be filled in regarding the primary 2D barcode

iv. Secondary Code : Information to be filled in regarding the secondary 2D barcode (in case of aggregation) If there are no aggregations, write down 0 (zero)

v. Tertiary code Information to be filled in regarding the tertiary 2D barcode (in case of aggregation). If there are no aggregations, write down 0 (zero)

vi. NIE : The marketing authorization registered with the Indonesian FDA

vii. The product's expiration date (yyyy-mm-dd)

viii. Batch number or production code

ix. Product identity internationally, if any

x. The product's status (for pharmaceuticals only):

- active "*TRUE*", inactive "*FALSE*"
- retained sample "*TRUE*", not retained sample "*FALSE*"
- reject "*TRUE*", non-reject "*FALSE*"

5) The Indonesian FDA track and trace application inspects the CSV documents.

a) If the uploaded CSV documents fail to conform to the template, the process will revert to step number 4 (four).

b) If the uploaded CSV documents are valid, the process proceeds to step number 6 (six).

6) The Indonesian FDA track and trace application responds to the 2D barcode report by displaying a list of reported barcodes on the barcode management menu.
7) The business actor as Marketing Authorization Holder may subsequently distribute the product
8) Finish.

H. REPORT ON OUTGOING PRODUCTS (2D BARCODES FOR AUTHENTICATION) BY FACILITIES

Facilities filing reports on outgoing products encompass business actors as marketing authorization holder, distribution facilities, and pharmaceutical service facilities. The facility files a report on outgoing products in the form of 2D barcodes with the receiving facility. These 2D barcodes are as follows:

1. Primary codes, or
2. Secondary/tertiary codes (largest packaging) only if the facility utilizes the aggregation process.

a. Through API

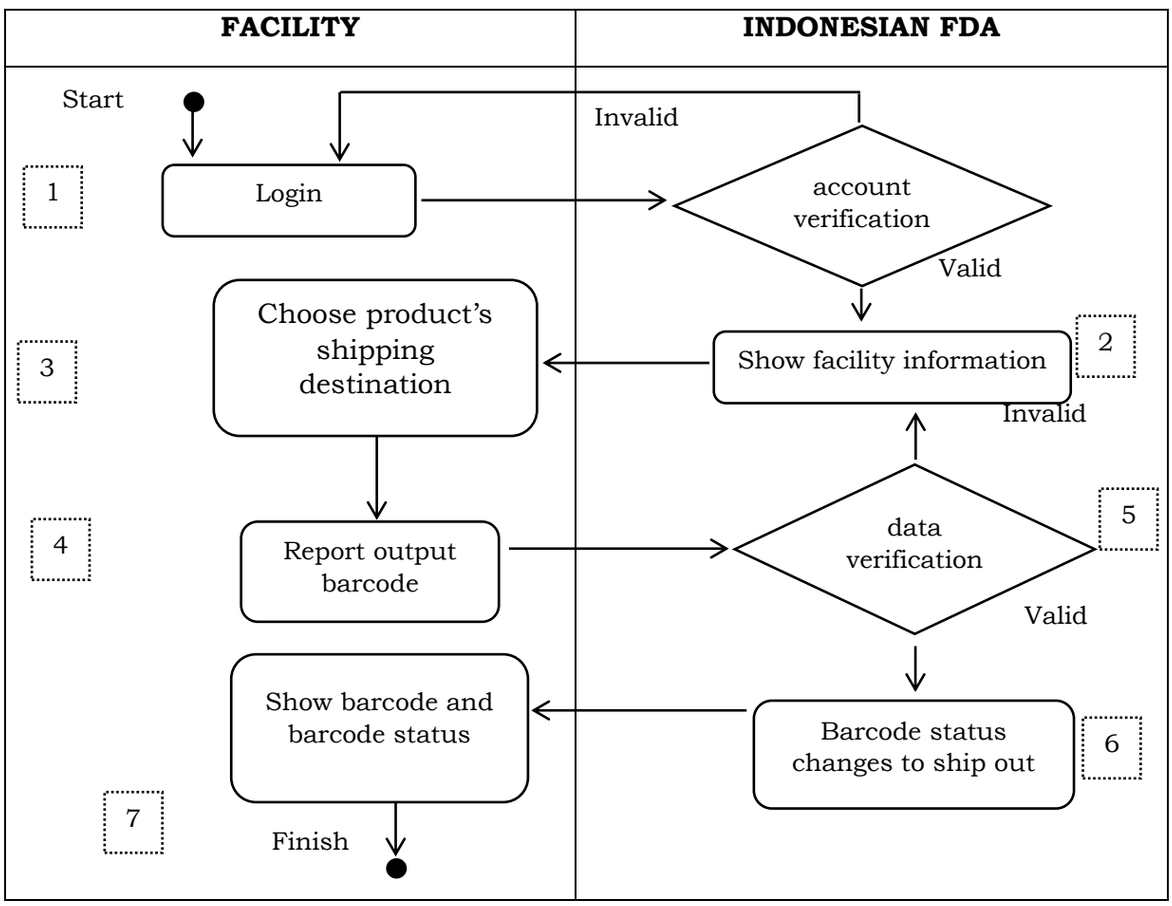

Figure 6. Report on Outgoing Products at Facilities through API and BPOM Mobile

Notes
1) The facility logs into the API.
2) The track and trace application's API displays information on the facility
3) The facility selects the product's shipping destination
4) The facility files an outgoing product report
5) The Indonesian FDA track and trace application verifies the data:
   a) If the data are invalid, return to step number 2 (two); and
   b) If the data are valid, proceed to step number 5 (five).
6) The product's status changes to shipped out.
7) Finish.

b. Through BPOM Mobile

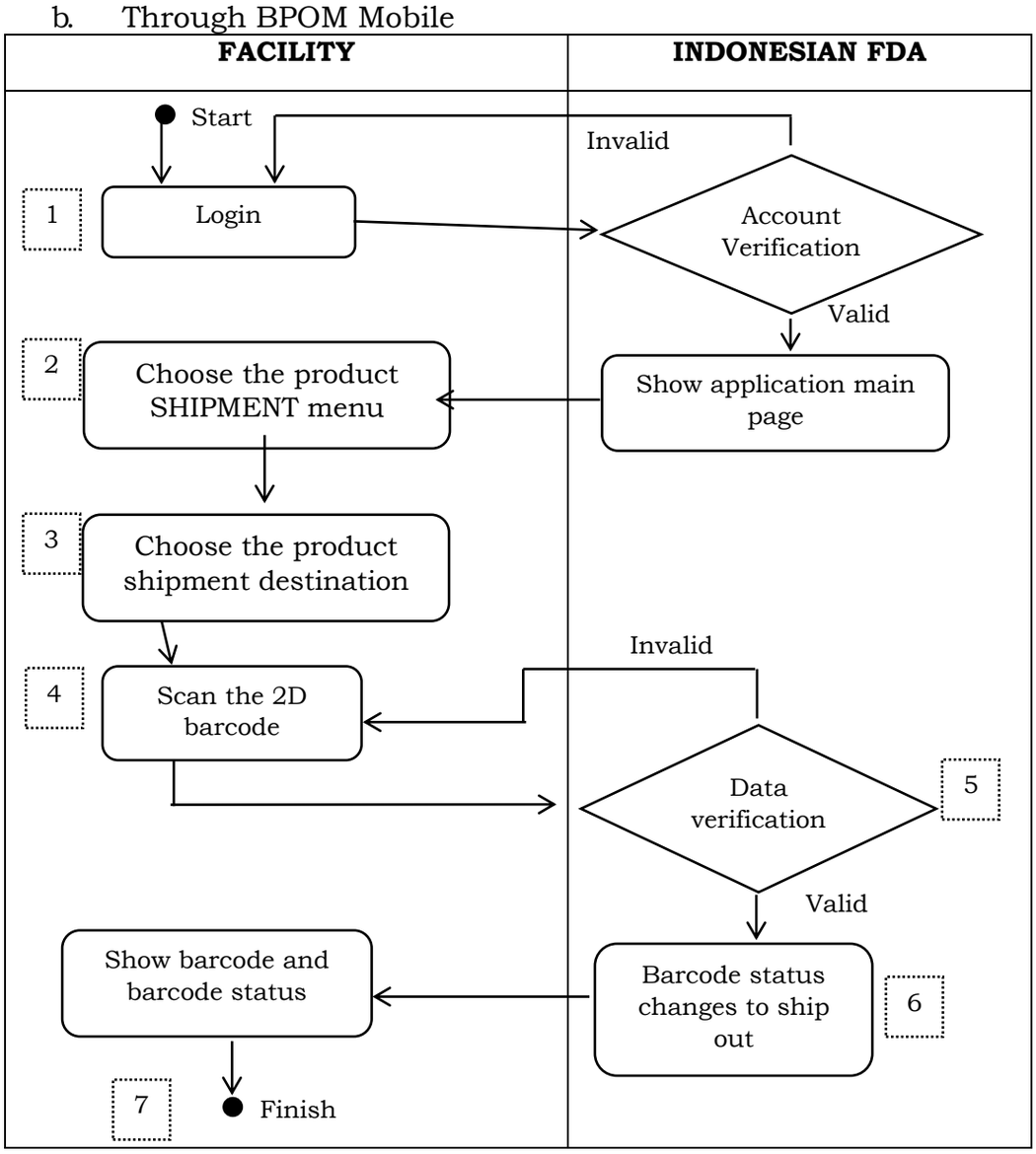

Figure 7. Report on Outgoing Products at Facilities through API and BPOM Mobile

Notes

1) The facility logs into BPOM Mobile.
2) The facility selects the product shipment menu.
3) The facility selects the product's destination.
4) The facility scans the 2D barcode using BPOM Mobile.
5) The Indonesian FDA track and trace application verifies the data:
   a) If the data are invalid, return to step number 3 (three); and
   b) If the data are valid, proceed to step number 5 (five).
6) The product's status changes to shipped out.
7) Finish.

c. Through Upload CSV Documents

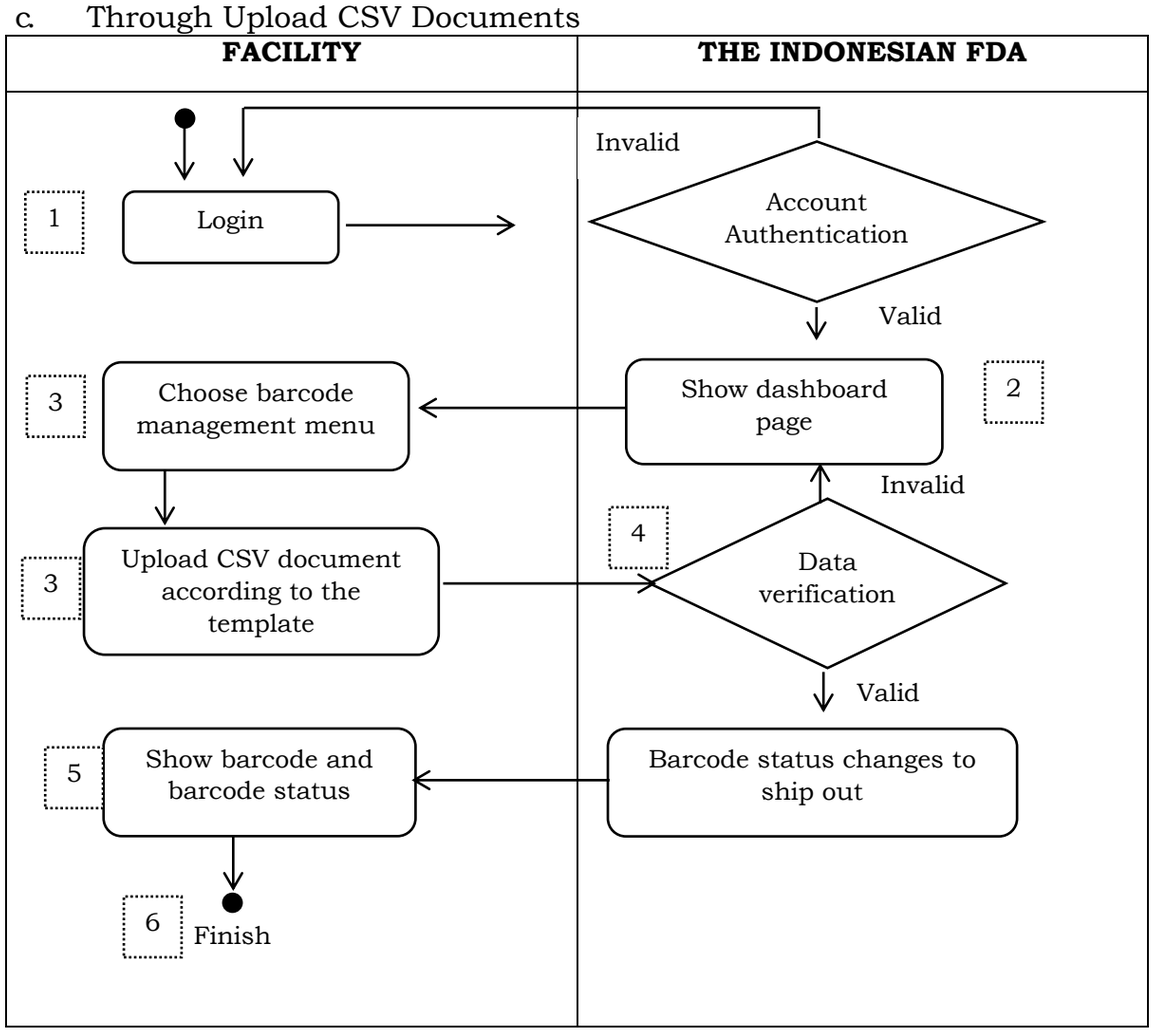

Figure 8. Report on Outgoing Products at Facilities through CSV Documents

Notes:

1) The facility logs into the Indonesian FDA track and trace application.
2) The Indonesian FDA track and trace application displays the dashboard page.
3) The facility selects the barcode management menu.
4) The facility uploads the CSV documents conforming to the template available on the Indonesian FDA track and trace application. The information furnished in the CSV documents includes:
   a) Supplier ID : available at the Indonesian FDA track and trace application
   b) ID of supplier at the place of destination : available at the Indonesian FDA track and trace application
   c) Packaging : product packaging reported corresponds to packaging denoted on Cekbpom.pom.go.id
   d) 2D Barcode : information on the issued barcode. Pharmaceuticals should include primary, secondary, and tertiary codes
   e) NIE : The marketing authorization registered with the Indonesian FDA
   f) The product's expiration date (yyyy-mm-dd)
   g) Batch number or production code
   h) Product identity internationally, if any
5) The Indonesian FDA track and trace application inspects the CSV documents.
   a) If the uploaded CSV documents fail to conform to the template, the process will revert to step number 2 (two).
   b) If the uploaded CSV documents are valid, the process proceeds to step number 5 (five).
6) The Indonesian FDA track and trace application responds by changing the barcode's status, which is displayed on the barcode management menu.
7) Finish.

I. REPORT ON INCOMING PRODUCTS (2D BARCODES FOR AUTHENTICATION) BY FACILITIES

Facilities filing reports on incoming products encompass business actors as marketing authorization holder, distribution facilities, and pharmaceutical service facilities. The facility files a report on incoming products in the form of 2D barcodes with the shipping facility. These 2D barcodes are as follows:

1. Primary codes, or
2. Secondary/tertiary codes (largest packaging) only if the facility use the aggregation process.

a. Through API

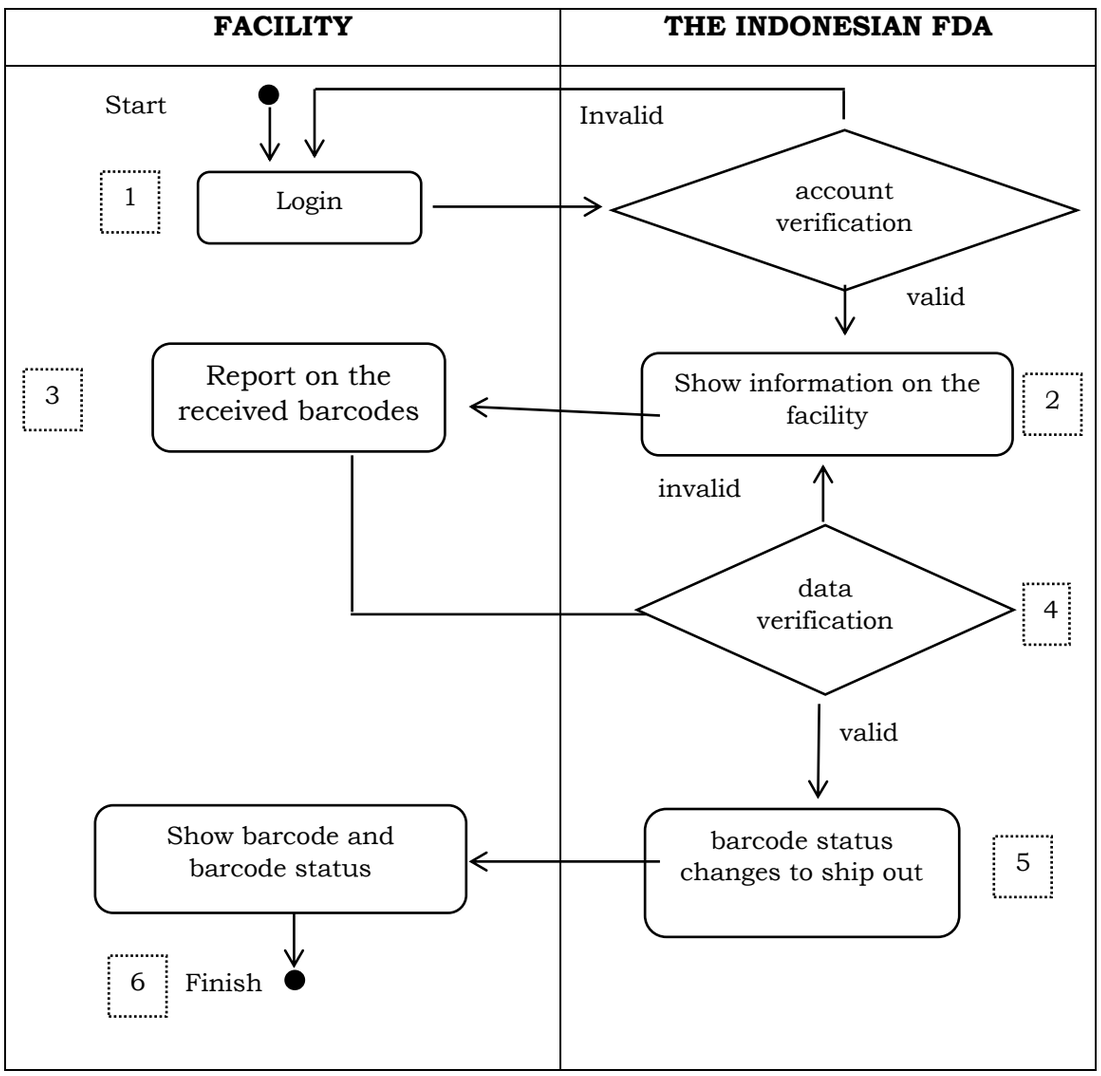

Figure 9. Reporting on Incoming Products through API

Notes

1) The facility logs into the API.
2) The Indonesian FDA track and trace application's API displays information on the facility.

3) The facility files a report on the received barcodes.
4) The Indonesian FDA track and trace application verifies the data:
   a) If the data are invalid, return to step number 2 (two); and
   b) If the data are valid, proceed to step number 5 (five).
5) The product's status changes to shipped out.
6) Finish.

b. Through BPOM Mobile

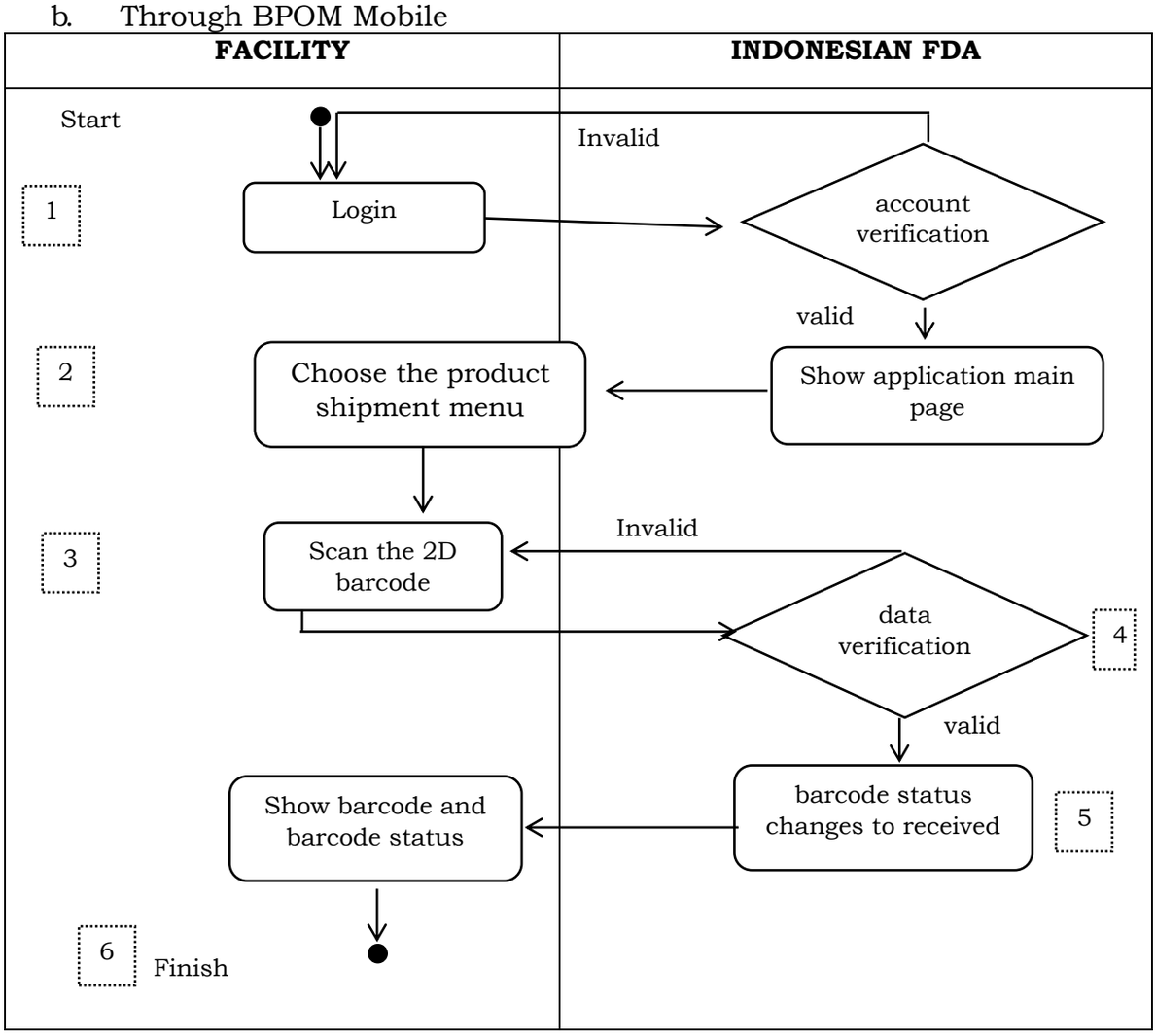

Figure 10. Reporting Flow for Incoming Products by Facilities through BPOM Mobile

Notes

1) The facility logs into either BPOM Mobile or API.
2) The facility selects the product receipt menu
3) The facility scans the 2D barcode using BPOM Mobile.
4) The Indonesian FDA track and trace application verifies the data:
   a) If the data are invalid, return to step number 3 (three); and
   b) If the data are valid, proceed to step number 5 (five).
5) The product's status changes to received.
6) Finish.

c. By uploading CSV documents

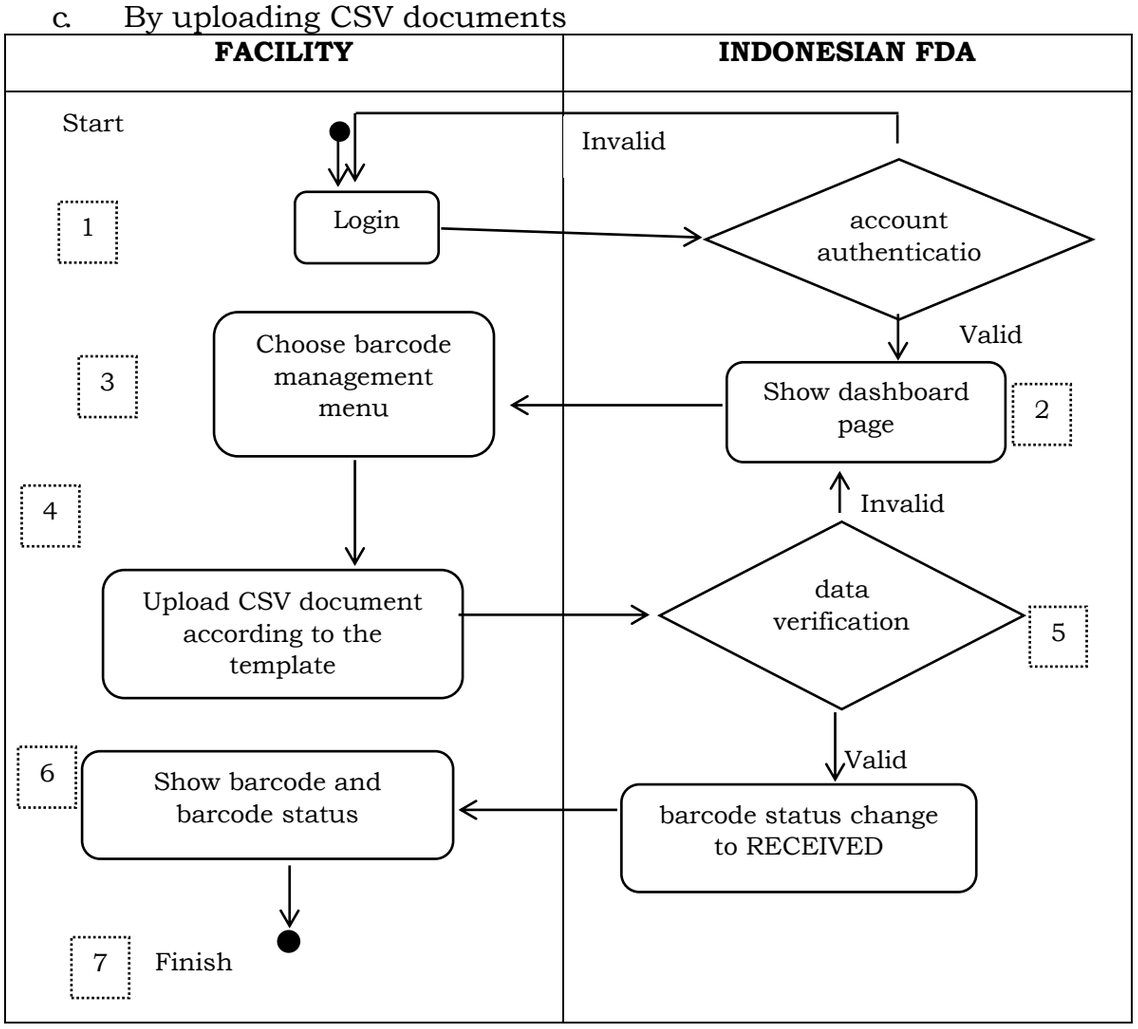

Figure 11. Reporting Flow for Incoming Products by Facilities by Uploading CSV Documents

Notes:

1) The facility logs into the Indonesian FDA track and trace application.
2) The track and trace application displays the dashboard page.
3) The facility selects the barcode management menu.
4) The facility uploads the CSV documents conforming to the template available on the track and trace application. The information furnished in the CSV documents includes:
   a) Supplier ID: obtained through the Indonesian FDA track and trace application
   b) Packaging: product packaging reported corresponds to packaging denoted on Cekbpom.pom.go.id
   c) 2D Barcode: information on the issued barcode. Pharmaceuticals should include primary, secondary, and tertiary codes

d) NIE : The marketing authorization registered with the Indonesian FDA
e) The product's expiration date (yyyy-mm-dd)
f) Batch number or production code
g) Product identity internationally, if any

5) The Indonesian FDA track and trace application inspects the CSV documents.
   a) If the uploaded CSV documents fail to conform to the template, the process will revert to step number 2 (two)
   b) If the uploaded CSV documents are valid, the process proceeds to step number 6 (six).
6) The Indonesian FDA track and trace application responds by changing the barcode's status, which is displayed on the barcode management menu.
7) Finish.

J. PRODUCT SALES REPORT (2D BARCODES FOR AUTHENTICATION) BY PHARMACEUTICAL SERVICE FACILITIES

The facility preparing sales reports is pharmaceutical service facilities. The pharmaceutical service facility reports 2D barcodes in the form of primary codes on products being sold.

a. Through API

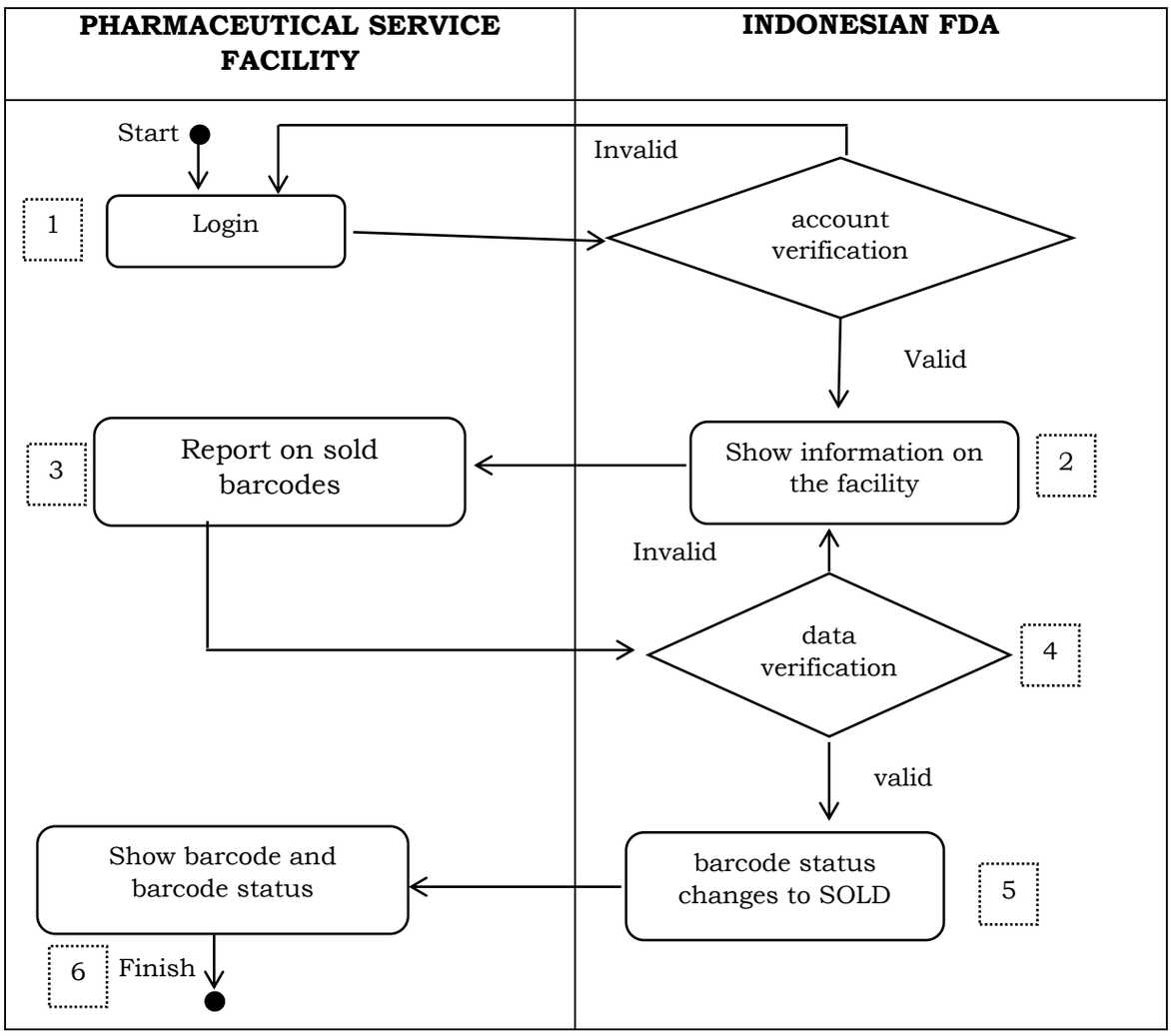

Figure 12. Reporting on Incoming Products through API

Notes

1) The facility logs into the API.
2) The Indonesian FDA track and trace application's API displays information on the facility.
3) The facility files a report on sold barcodes.
4) The Indonesian FDA track and trace application verifies the data:
   a) If the data are invalid, return to step number 2 (two); and
   b) If the data are valid, proceed to step number 5 (five).
5) The product's status changes to sold.
6) Finish.

b. Through BPOM Mobile

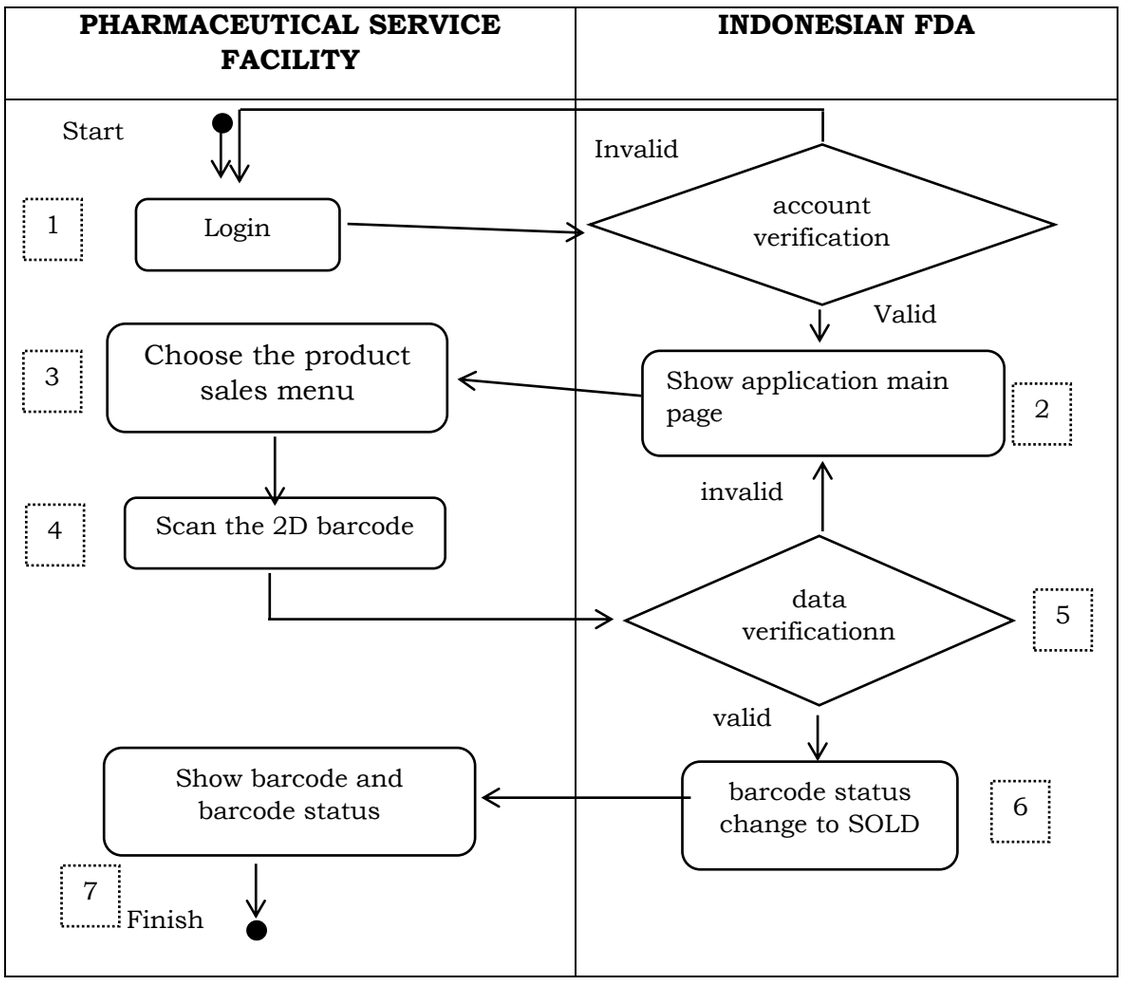

Figure 13. Reporting Flow for Product Sales by Facilities Through BPOM Mobile

Notes

1) The facility logs into BPOM Mobile.
2) BPOM Mobile displays the application's main page.
3) The facility selects the product sales menu.
4) The facility scans the 2D barcode using BPOM Mobile.
5) The Indonesian FDA track and trace application verifies the data:
   a) If the data are invalid, return to step number 2 (two); and
   b) If the data are valid, proceed to step number 6 (six).
6) The product's status changes to sold.
7) Finish.

c. By uploading CSV documents

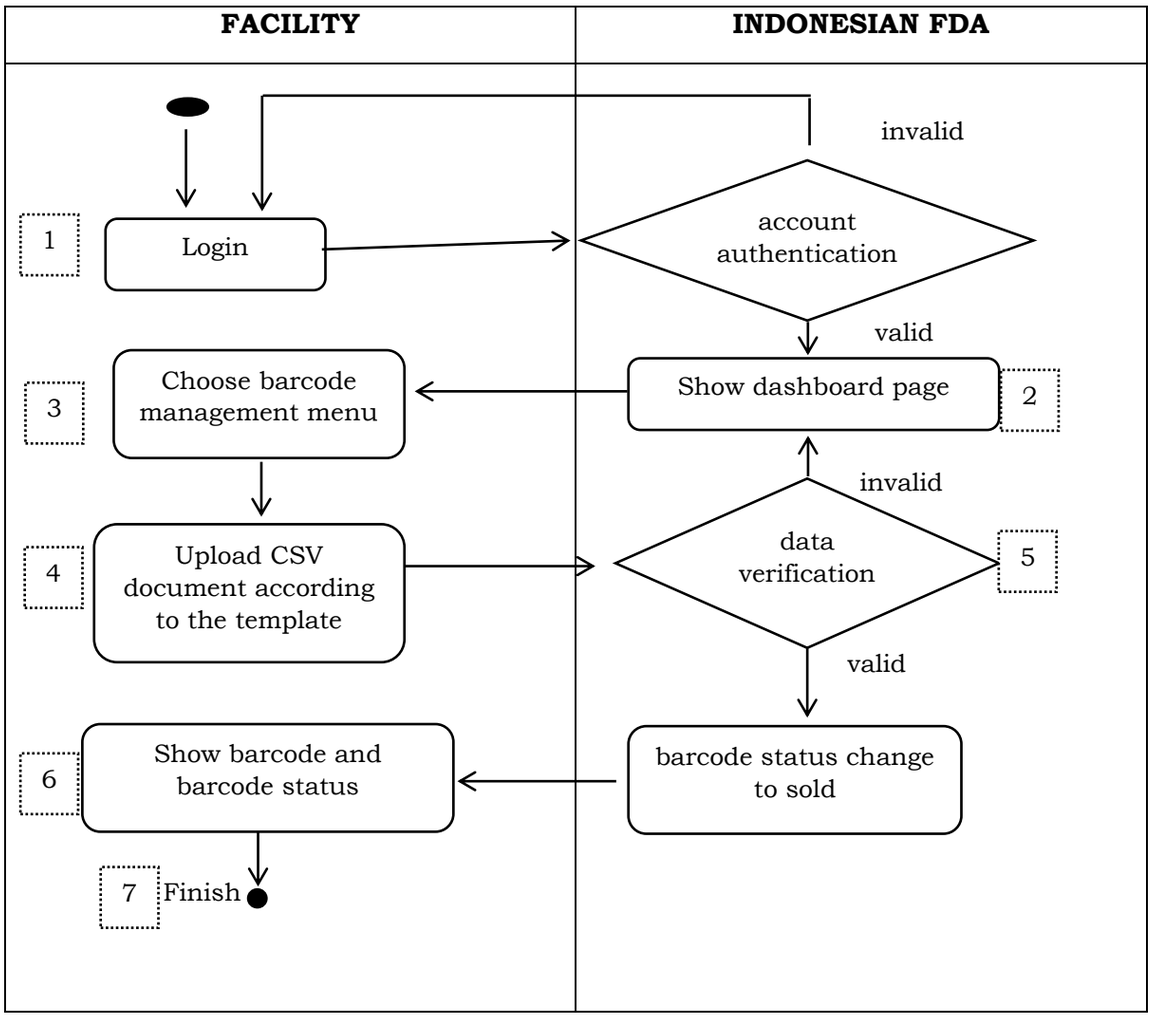

Figure 14. Reporting Flow for Product Sales by Facilities by Uploading CSV Documents

Notes:

1) The facility logs into the Indonesian FDA track and trace application.
2) The Indonesian FDA track and trace application displays the dashboard page.
3) The facility selects the barcode management menu.
4) The facility uploads the CSV documents conforming to the template available on the track and trace application. The information submitted in the CSV documents includes:
   a) Supplier ID : obtained through the Indonesian FDA track and trace application
   b) Packaging : product packaging reported corresponds to packaging included on Cekbpom.pom.go.id

c) 2D Barcode : information on the issued barcode. Drugs should include primary, secondary, and tertiary codes
d) NIE : The marketing authorization number registered with the Indonesian FDA
e) The product's expiration date (yyyy-mm-dd)
f) Batch number or production code
g) Product identity internationally, if any

5) The Indonesian FDA track and trace application inspects the CSV documents.
   a) If the uploaded CSV documents fail to conform to the template, the process return to step number 2 (two); and
   b) If the uploaded CSV documents are valid, the process proceeds to step number 6 (six).
6) The Indonesian FDA track and trace application responds by changing the barcode status displayed on the barcode management menu
7) Finish.

K. RETURNED PRODUCTS REPORT

This flow describes the returned product process between facilities in system development.

a. Through API

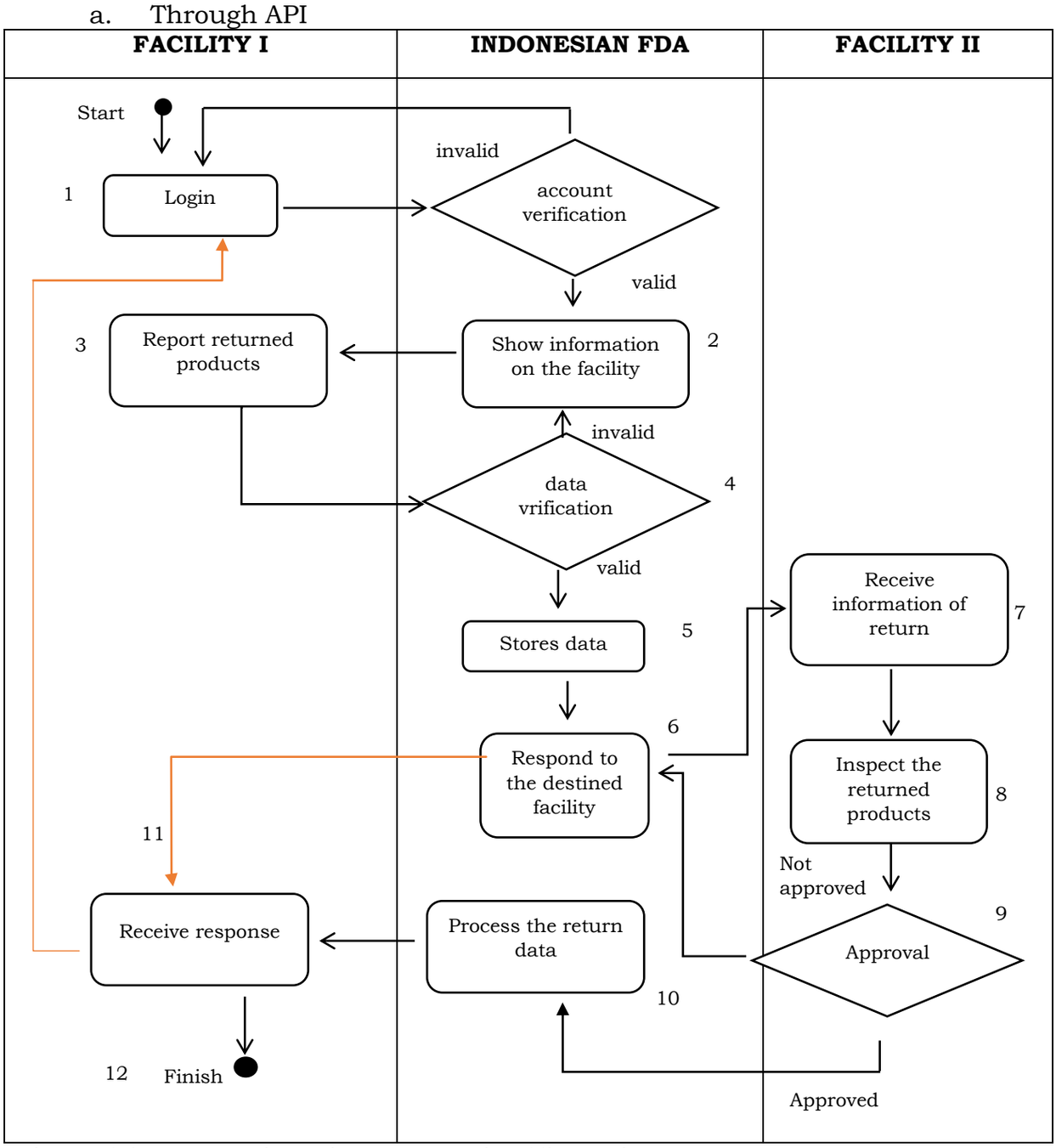

Figure 15. Returned Products Reporting Through API

Notes:

1) Facility I logs into the API.
2) The Indonesian FDA track and trace application's API displays information on the facility.
3) Facility I files a returned products report.
4) The Indonesian FDA track and trace application verifies barcode data:
   a) If the barcode data are invalid, return to step number 2 (two); and

b) If the data are valid, proceed to step number 5 (five).

5) The Indonesian FDA track and trace application stores the returned products data.
6) The Indonesian FDA track and trace application provides information on returned products to the facility of destination (facility II) and responds to the facility, proceed to step number 11 (eleven).
7) Facility II receives information on returned products on the dashboard and by email.
8) Facility II inspects the returned products.
9) Facility II signs off on the inspection.

a) The returned products are signed off on, the application proceeds to step number 11 (eleven); and
b) The returned products are not approved, the track and trace application will give the notification and the activity reverts to step number 1 (one).

10) The Indonesian FDA track and trace application processes the returned products data.
11) A sign off on returned products is either granted or not.
12) Finish.

b. Through BPOM Mobile

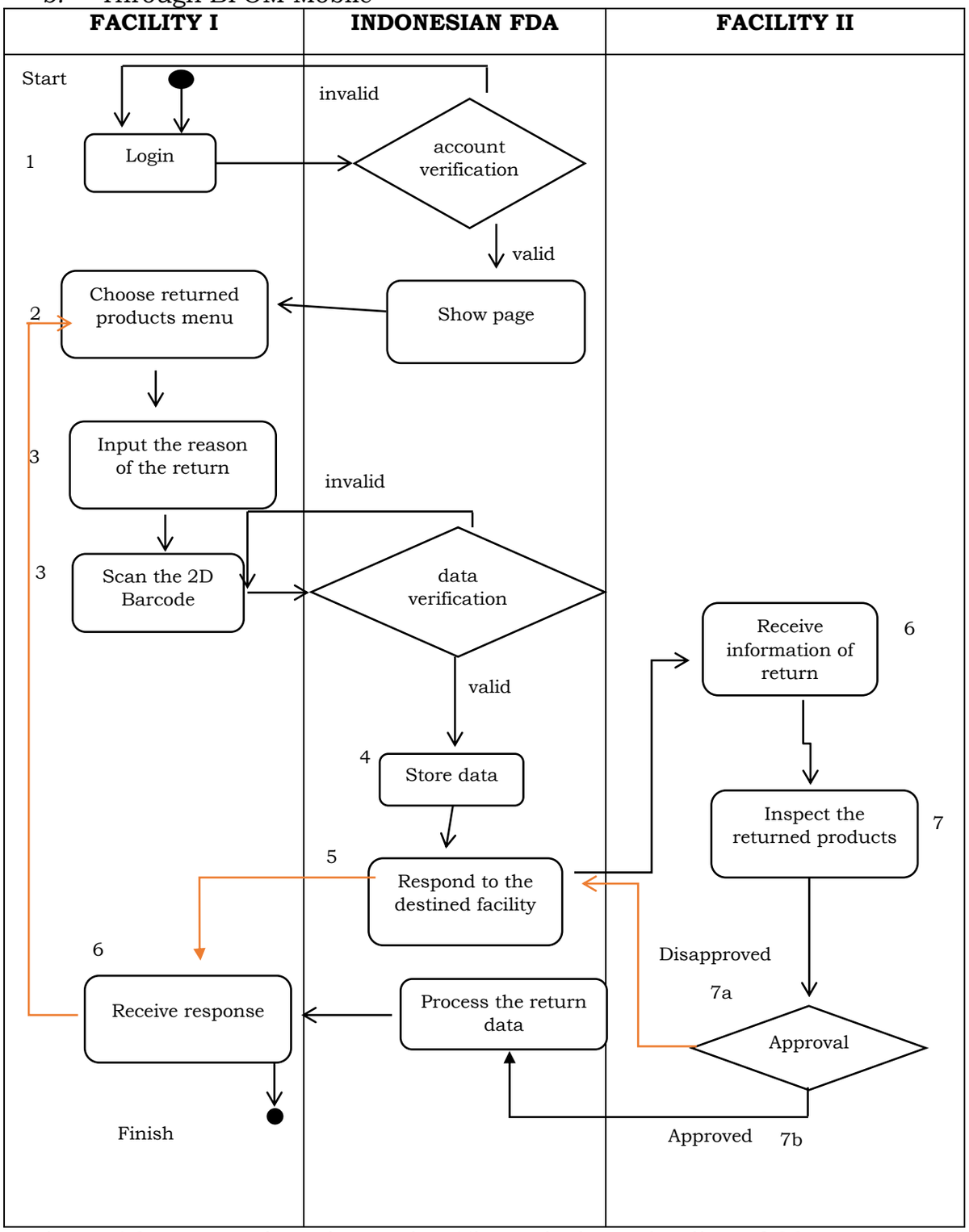

Figure 16. Returned Products Flow Through the Uploading of CSV Documents

Notes:

1) Facility I logs into BPOM Mobile.
2) Facility I selects the returned products menu.
3) Facility I enters the reason products were returned.
4) Facility I scans the 2D barcodes.

5) The Indonesian FDA track and trace application verifies barcode data:
   a) If the barcode data are invalid, go back to step number 4 (four); and
   b) If the data are valid, proceed to step number 6 (six).
6) The Indonesian FDA track and trace application stores the returned products data.
7) The Indonesian FDA track and trace application provides information on returned products to the facility of destination (facility II) and responds to facility I, proceed to step number 12 (twelve).
8) Facility II receives information on returned products on the dashboard and by email.
9) Facility II inspects the returned products.
10) Facility II signs off on the inspection.
    a) The returned products are signed off on, the application proceeds to step number 11 (eleven); and
    b) The returned products are not approved, the track and trace application will give the notification which Facility I receives, and the activity reverts to step number 2 (two).
11) The Indonesian FDA track and trace application processes the returned products data.
12) A sign off on returned products is either approved or not.
13) Finish.

L. PRODUCT RECALL REPORTING

a. Flow for Adding Information on Product Recalls by Business Actors an NIE Holder

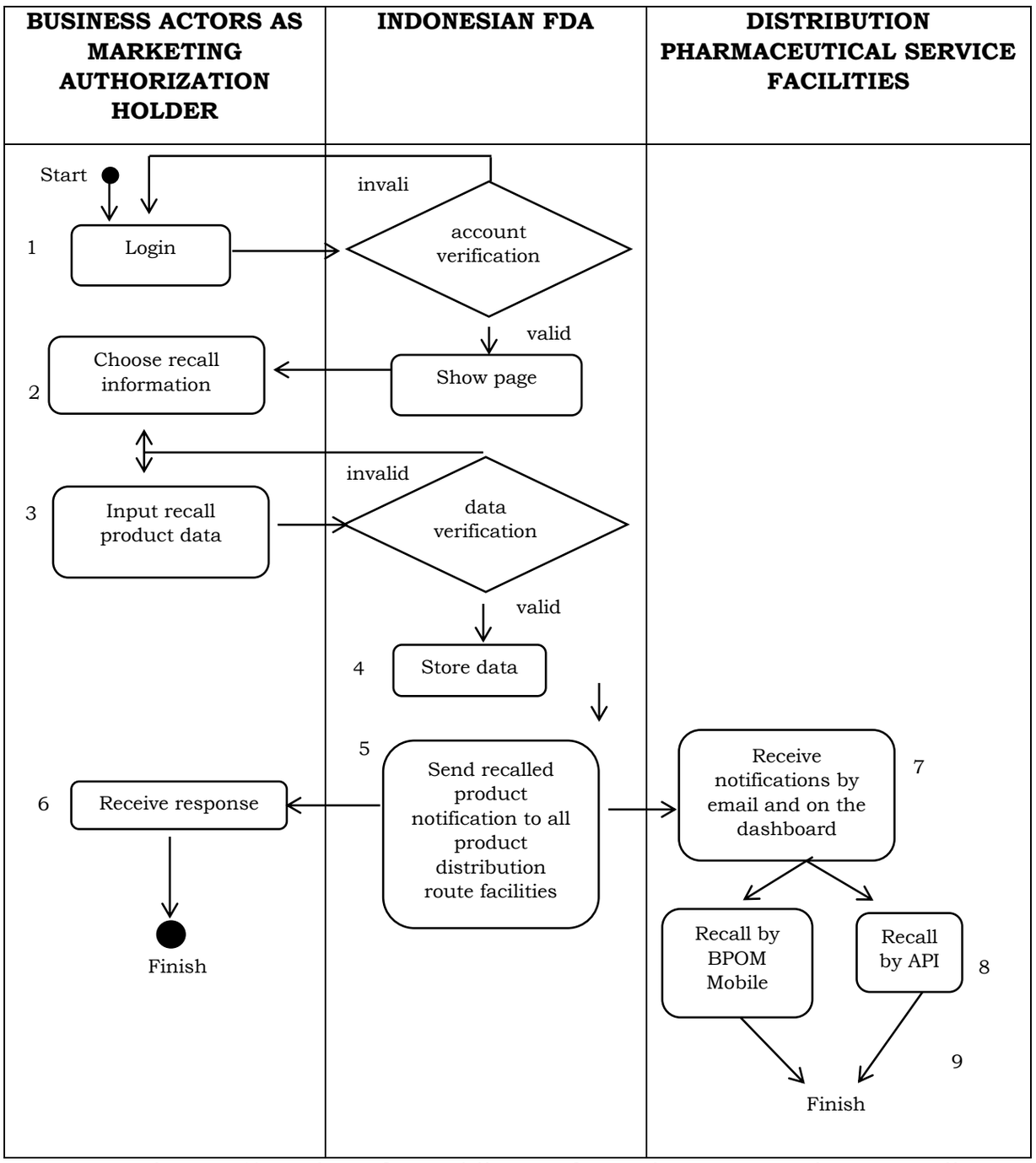

Figure 17. Flow for Adding Information on Product Recalls From Business Actors Possessing an NIE

Notes:

1) A business actor logs into the Indonesian FDA track and trace application.

2) A business actor selects recall information.

3) Recall product data entered encompass:

a) The batch number of the product to be recalled;

b) Reason for the recall; and

c) A recall letter.

4) The Indonesian FDA track and trace application verifies the data:

a) If the data are invalid, return to step number 3 (three); and

b) If the data are valid, proceed to step number 5 (five).

5) The Indonesian FDA track and trace application furnishes a recall product notification to all product distribution route facilities

6) A business actor as Marketing Authorization Holder receives a response on the adding of recall information.

7) The pharmaceutical distribution and service facilities receives a notification by email and on the dashboard.

8) The pharmaceutical distribution and service facilities can make the recall through BPOM Mobile and API.

9) Finish.

b. Product is recalled through the API

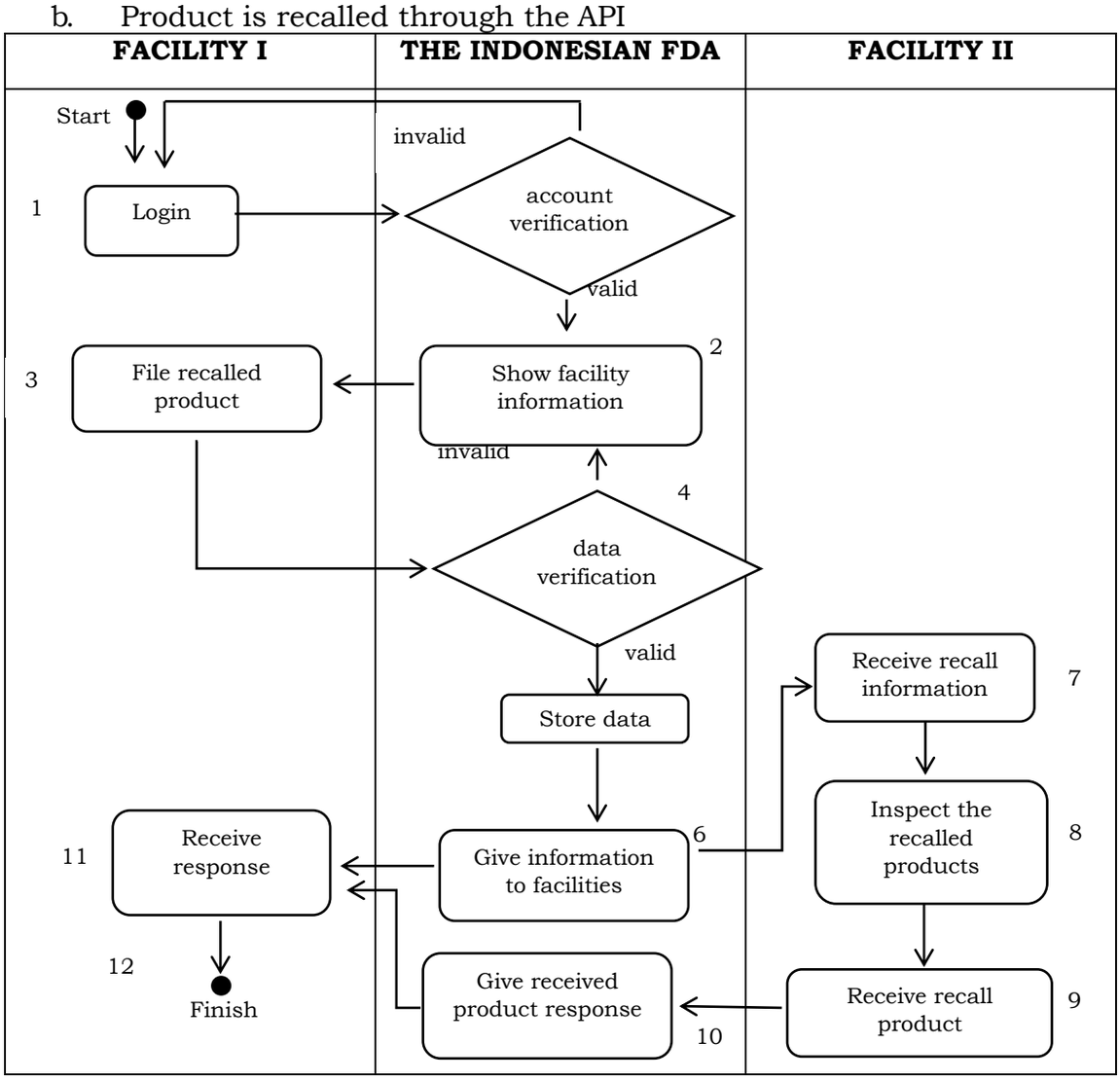

Figure 18. Product recall flow through the API

Notes:

1) Facility I logs into the API.
2) The Indonesian FDA track and trace application's API displays information on the facility.
3) Facility I reports a product recall.
4) The Indonesian FDA track and trace application verifies the barcode data:
   a) If the data are invalid, return to step number 3 (three); and
   b) If the data are valid, proceed to step number 5 (five).
5) The Indonesian FDA track and trace application stores the product recall data.
6) The Indonesian FDA track and trace application provides information on returned products to the facility of destination (facility II) and responds to facility I, proceed to step number 9 (nine).

7) Facility II receives information on recalled products on the dashboard and by email.
8) Facility II inspects the recalled products.
9) Facility II receives the products.
10) The Indonesian FDA track and trace application provides a product received response.
11) Facility I receives the product received response.
12) Finish.

c. Product is recalled through CSV documents

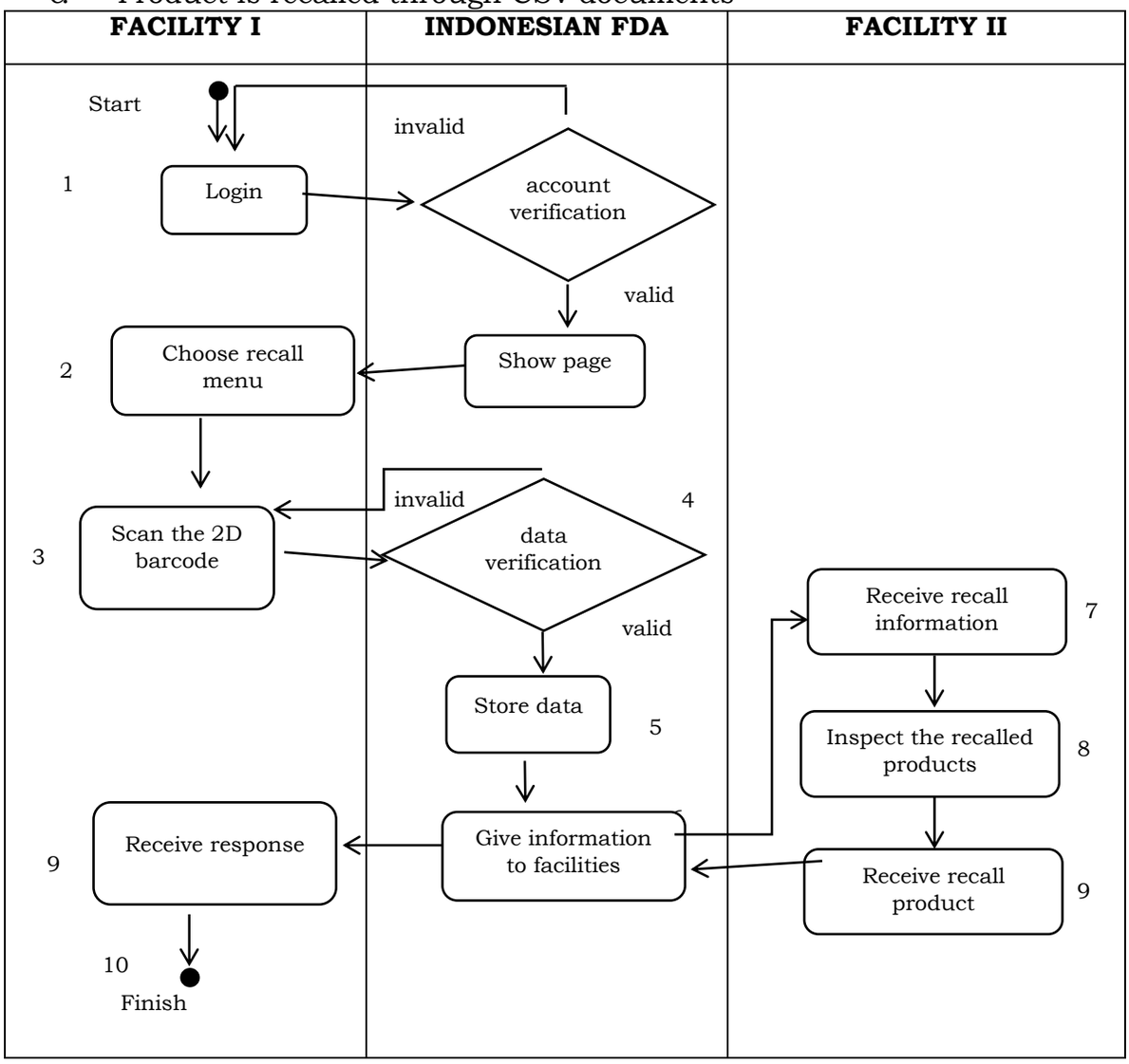

Figure 19. Product Recall Flow Through BPOM Mobile

Notes:

1) Facility I logs into BPOM Mobile.
2) Facility I selects the recall menu.
3) Facility I scans the 2D barcodes.
4) The track and trace application verifies the barcode data:

a) If the data are invalid, return to step number 3 (three); and

b) If the data are valid, proceed to step number 5 (five).

5) The Indonesian FDA track and trace application stores the product recall data.

6) The Indonesian FDA track and trace application provides information on returned products to the facility of destination (facility II) and responds to facility I, proceed to step number 9 (nine).

7) Facility II receives information on recalled products on the dashboard and by *email*.

8) Facility II examines the recalled products.

9) Facility II receives the products.

10) The BPOM track and trace application provides a product received response.

11) Facility I receives the product received response.

12) Finish.

M. THE PUBLIC

a. Product Verification Through BPOM Mobile

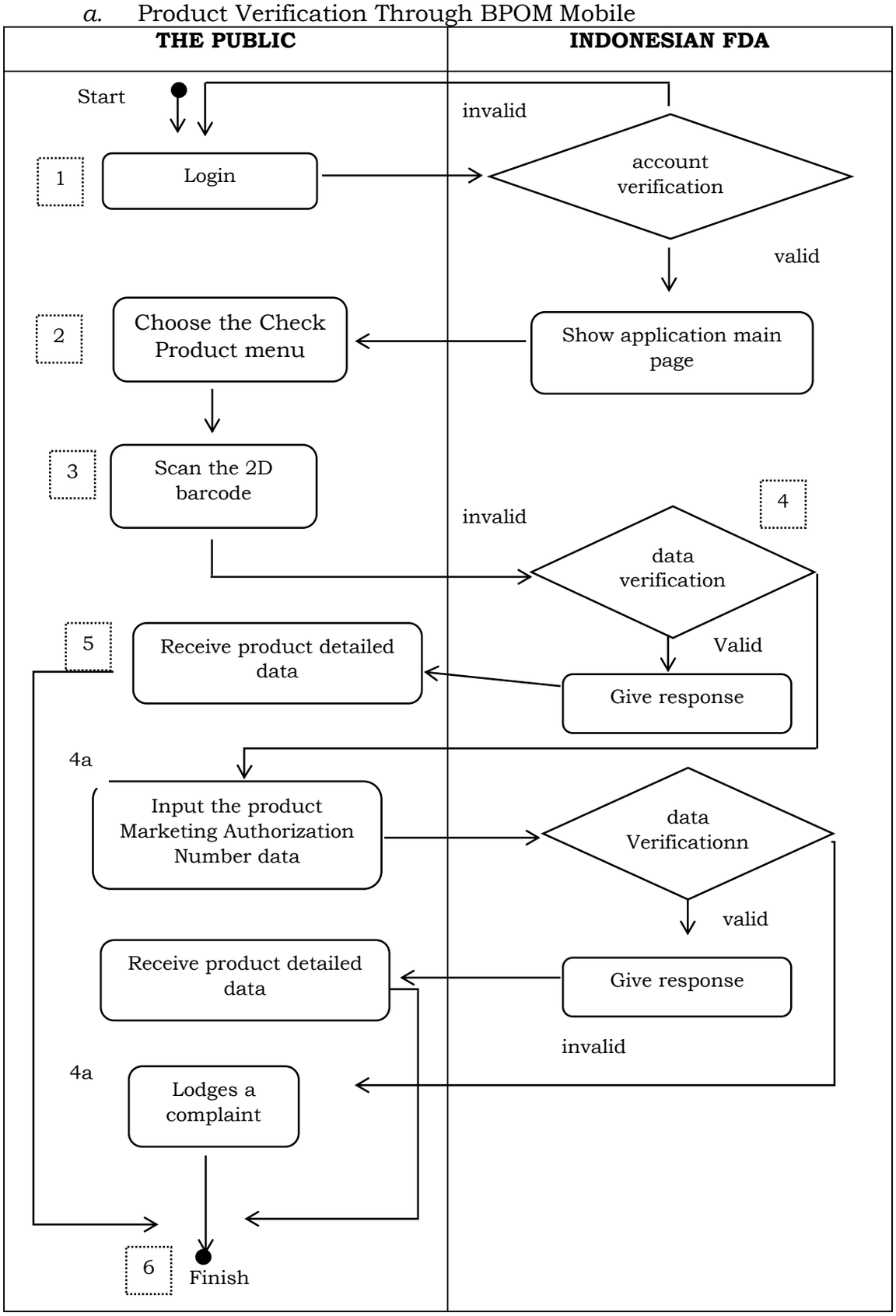

Figure 20. Scanning By the Public

Notes:

1) The public logs into BPOM Mobile.
2) The public selects the Check Product menu.
3) The public scans the 2D barcodes.
4) The Indonesian FDA track and trace application verifies the 2D barcode data.
    a) If the 2D barcode data are invalid, the public inputs the product's NIE data. If the NIE data are invalid, the public lodges a complaint, in accordance with the technical directives on public complaints.
    b) If the 2D barcode data are valid, proceed to step number 5 (six).
5) The public receives information, which at the least holds the following data:
    a) product name;
    b) marketing authorization number;
    c) marketing authorization's validity period;
    d) business actor's name and address; and
    e) packaging.
6) Finish.

b. Complaints through BPOM Mobile

This flow describes the public complaints process for products received by the public.

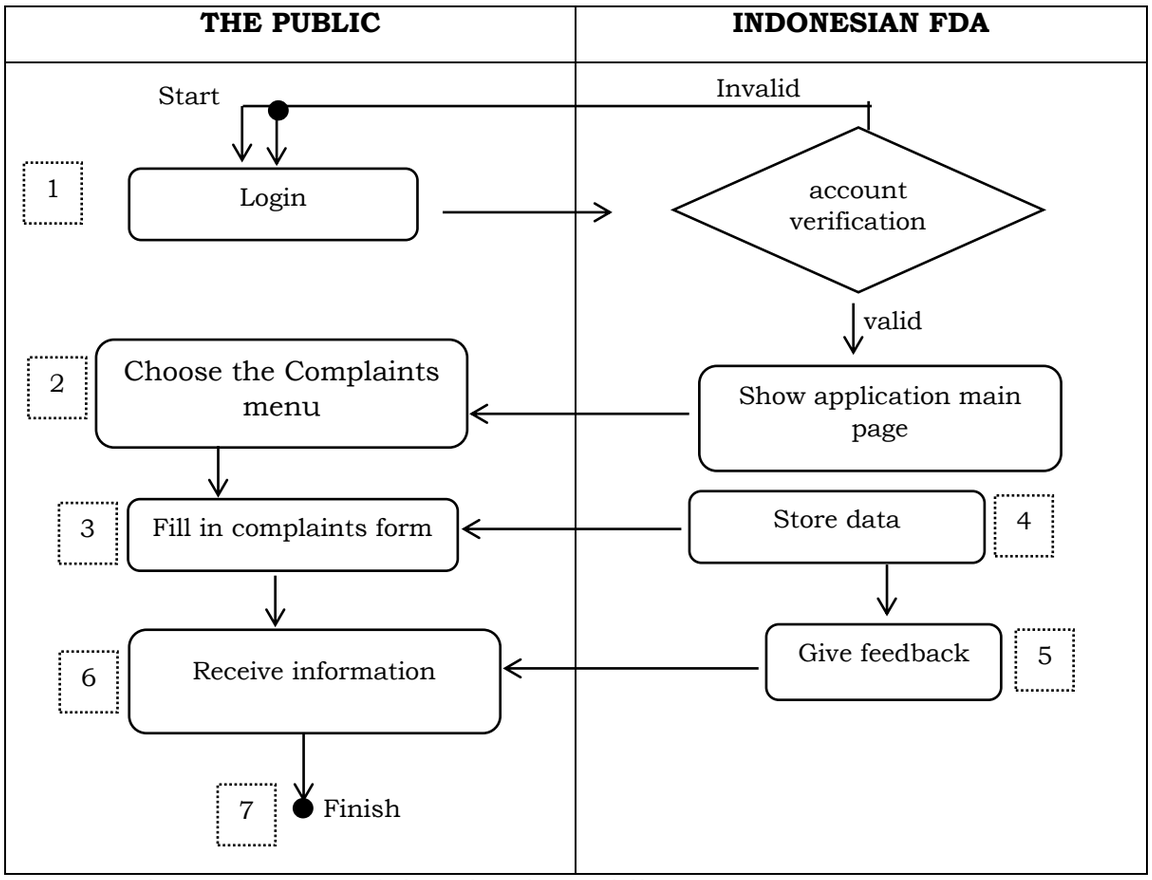

Figure 21. Complaints by the Public

Notes:

1) The public logs into BPOM Mobile.
2) The public selects the Complaints menu.
3) The public lodges a complaint by filling out a complaints form available on the mobile application. Information furnished includes:
   a) Question;
   b) Product Name;
   c) Batch number;
   d) Marketing authorization number;
   e) Supporting photographs;
   f) Purchasing location; and
   g) Purchasing address.
4) Complaints sent in will be stored in a database.
5) The mobile application will provide feedback.
6) The public can view the information on the mobile application.
7) Finish.

CHAIPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO