Voluntary Recall of Pharmaceuticals

OUTLINE :

- Latar Belakang
- Recall
- Regulasi yang terkait

LATAR BELAKANG

Manufacturing
Regulatory Compliance – Marketing Authorization

Target

Provide an assurance that commitment described in Registration Dossiers are fulfilled when releasing a batch for sale according to Marketing Authorization.

Process

Review the compliance of current manufacturing practices against the Technical Part of Registration Dossiers

Principles

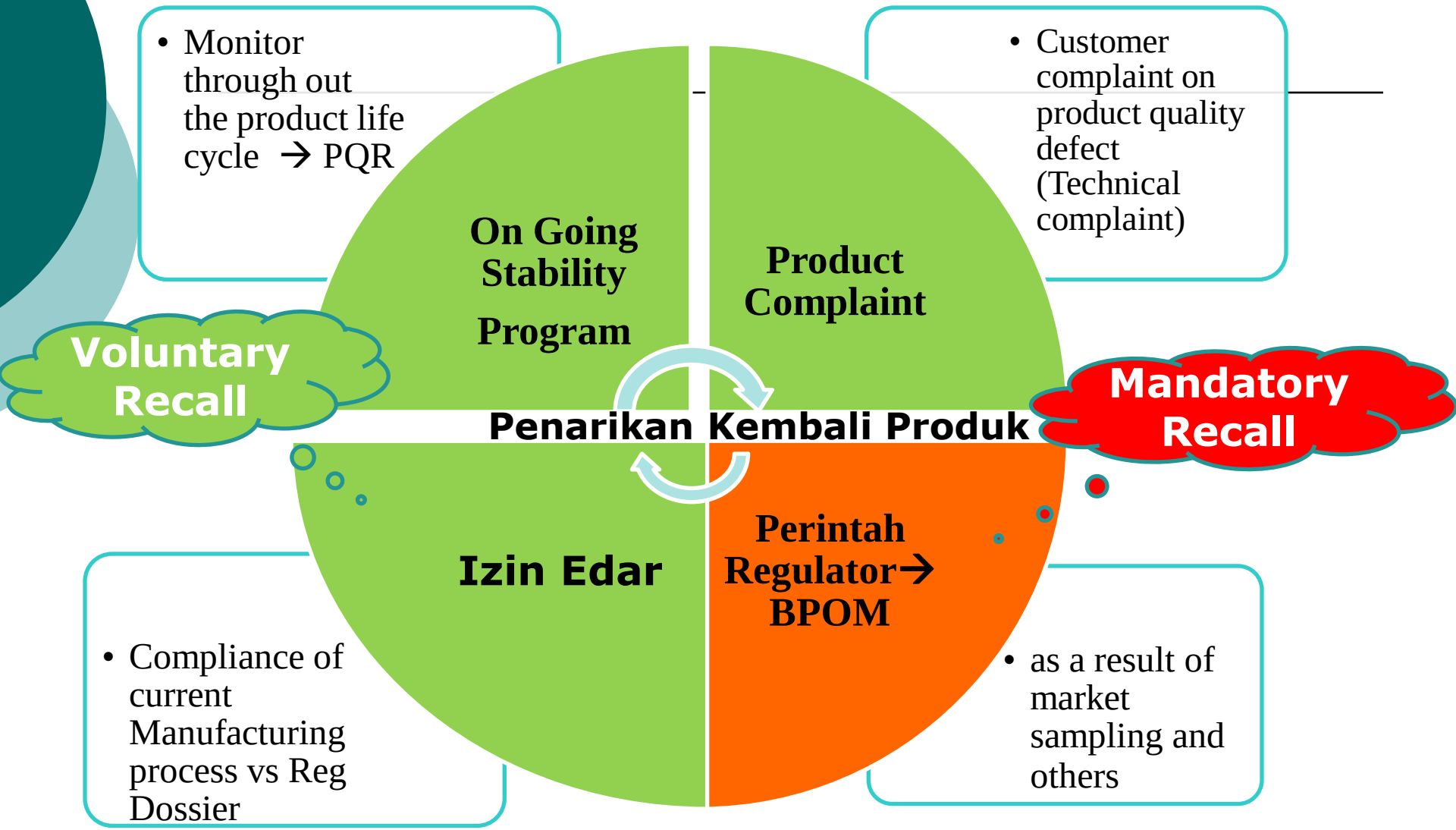
Each product is reviewed by comparing its current manufacturing practices and Registration Dossiers lead to identify any gaps to resolve.

RECALL

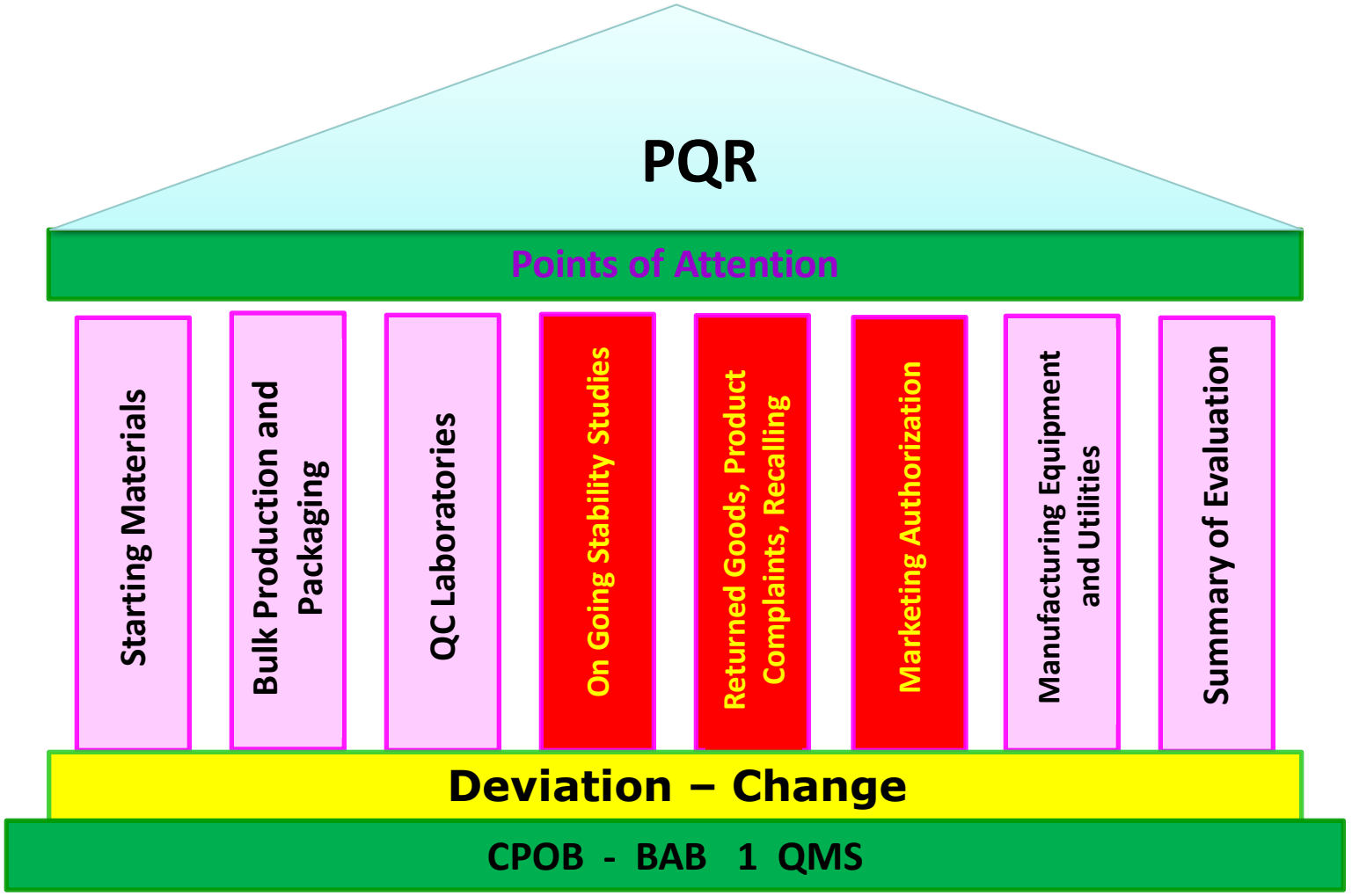
Why Recall ?

- Product recall is a valuable means of **dealing with product defects** where the **health and safety of consumers may be at risk.**
- A product recall may also be necessary to **protect reputation and goodwill**, and to avoid criminal prosecution or civil lawsuits.

RECALL – Penarikan Kembali Produk

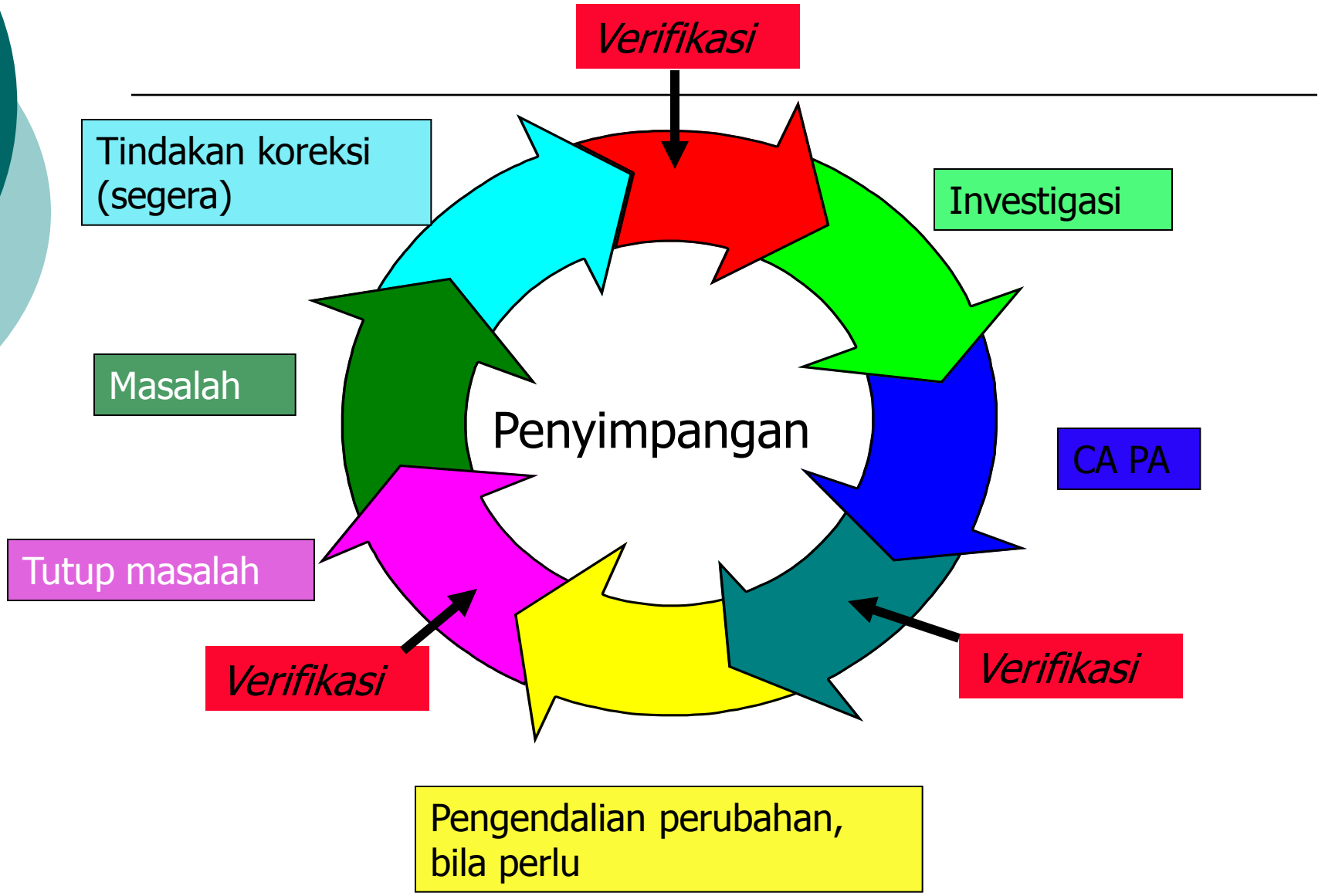


Potensi untuk *Voluntary recall*



Potensi untuk *Voluntary recall*

Siklus penanganan penyimpangan



Potensi untuk *Voluntary recall*

Kajian

- Kesesuaian izin edar → keabsahan izin edar , teks penandaan dan desain , no izin edar , jenis kemasan primer dan jumlah isi , kondisi penyimpanan dan masa kedaluwarsa

Voluntary Recalls Notice Principles

Its should :

1. have **sufficient information** and **motivation** for consumers to identify the product and its actual or potential hazards, and to respond and take the stated action.
2. clearly and concisely state the potential injury or death.
3. be written in local language, easy to be understood by the targeted consumers
   - ❑ The language should be simple, avoid or minimize the use of highly technical or legal terminology.
4. targeted and tailored to the specific product and circumstances.

Voluntary Recalls Notice Principles

- may be written, electronic, or in any other form agreed upon staff and the firm.
- may be transmitted using an electronic medium and in hard copy form.
- acceptable forms for communicating include, but are not limited to:
  a) Letter, website posting, electronic mail, or text message;
  b) Press release or recall alert;
  c) Video news release, radio news release
  d) Newspaper, magazine, catalog, or other printed publication;
  e) Advertisement, newsletter, and service bulletin; and
  f) Social media

➔ The most effective way is using a direct voluntary recall notice - form of voluntary recall notice.

Voluntary Recall Notice Guide

Should include the information set forth below :

1. **Terms.**
   should stated the word “recall” in the heading and text.
2. **Date.**
   Include its date of release, issuance, posting, or publication.
3. **Heading - Introduction**
   should be brief and communicate :
   - ✓ the name of the firm conducting the recall
   - ✓ the type of product being recalled
   - ✓ the hazard
   - ✓ the name of distributor, importer, exporter or retailer responsible for effectuating the remedy for consumers
   - ✓ the name of the retailer, if the firm is the exclusive retailer of the product.

Voluntary Recall Notice Guide

4. Product description

- a clear and concise statement of the information that will enable consumers to readily and accurately identify the specific product and distinguish the product from similar products.
- descriptive information that should appear but not be limited to:

a) product's name, including informal and abbreviated names
b) product's intended or targeted use population (e.g., infants, children, or adults);
c) product's information such as model names, colors, sizes etc
d) product's codifications : batch numbers, stock keeping unit (SKU) numbers, etc
e) dates of manufacture and sale, state the month and year in which :
   - the manufacture of the product began and ended
   - the month and year in which the retail sales of the product began and ended
f) Identification and exact locations of product tags, labels, and other identifying parts, including specific identifying information found on each part
g) Price, state the approximate retail price or price range of the product
h) Product photographs.

Voluntary Recall Notice Guide

5. Description of action being taken

a clear and concise statement of the actions considered (example) :

a) stop sale and distribution
b) recall to the distributor, retailer, or consumer level
c) rework
d) request return, and provide a replacement
e) request a return, and provide a refund

6. Statement of number of product units.

approximate number of product units covered by the recall, including all product units manufactured, imported, and/or distributed

Voluntary Recall Notice Guide

7. Description of substantial product hazard

a clear description of the product's actual or potential hazards that giving rise to recall and its should

- enable consumers and other persons to readily identify the reasons that a firm is conducting a recall
- enable consumers and other persons to readily identify and understand the risks and potential injuries or deaths associated with the product conditions and circumstances giving rise to the recall
- described :
  1. the product defect, fault, failure, or flaw, and/or problem giving rise to the recall
  2. the type of hazard or risk, including, by way of example only, burn, fall, choking, laceration, entrapment, or death
  3. a statement that the hazard "can" occur when there have been incidents or injuries associated with the recalled product

Voluntary Recall Notice Guide

8. **Identification of recalling firm.**

   identify the firm conducting the recall by stating the firm's legal name and commonly known trade name, the city and state of its headquarters, and Web domain or other effective communication system with the firm

9. **Identification of manufacturer.**

   identify manufacturer (including importer) of the product and the country of manufacture by stating : the manufacturer's legal name and the city and state of its headquarters

10. **Identification of significant retailers**

    a. The retailer was the exclusive retailer of the product
    b. The retailer was an importer of the product
    c. The retailer has multiple stores nationwide or regionally
    d. The retailer sold, or held for purposes of sale or distribution in commerce, a
    e. Significant number of the total manufactured, imported, or distributed units of the product
    f. Identification of the retailer is in the public interest.

11. **Region**, the areas where the product was sold, or distributed

Voluntary Recall Notice Guide

14. Description of incidents, injuries and deaths

- summary description of all incidents, injuries, and deaths associated with the product;
- conditions or circumstances giving rise to the recall,
- as well as a statement of the number of such incidents, injuries, and deaths

15. Description of remedy

- Each remedy available to a consumer for the product conditions or circumstances giving rise to the recall, such as : refunds, replacements etc.
- All specific actions that a consumer must take to obtain each remedy like instructions on how to participate in the recall. Example :contacting a firm, returning the product to the retailer etc
- All specific information that a consumer needs to obtain each remedy and to obtain all information about each remedy, include : manufacturer, retailer, and distributor contact information etc

Voluntary Recall Notice Guide

16. Compliance program.

    Contain a reference to applicable compliance programs or requirements, as appropriate.

17. Other information.

    Contain such other information as the Commission and the recalling firm deem appropriate.

PRODUCT RECALL PROGRAM

Introduction

- Indication → product may represent health hazard to the patient / consumer
- Recall procedure → effectively remove the product from circulation to prevent its consumption
- Recall action → should be undertaken in an efficient and speedy manner

Recall Committee

- Set up within the company
- Each member has spesific responsibilities

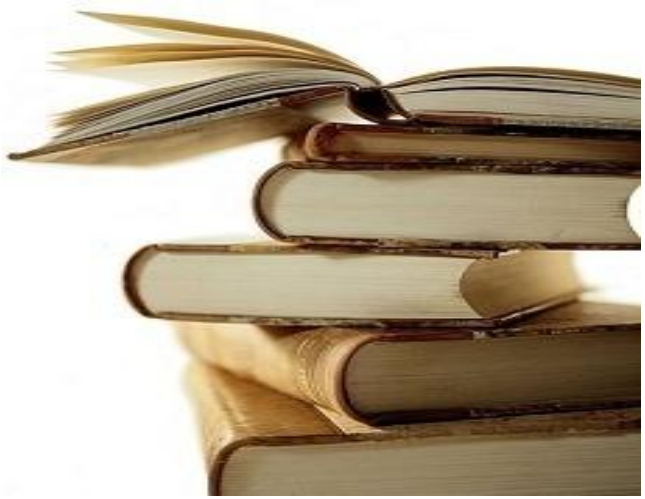
Implementation

- Voluntary recall → initiate by the Marketing Authorization holder
- Mandatory recall → initiate by BPOM
- Mock recall

Regulasi yang terkait dengan *Recall*

REGULASI TERKAIT → 1

- Peraturan Ka BPOM RI 8195/2012 , tentang Penerapan Pedoman CPOB
- Peraturan Ka BPOM RI 09938/2011 , tentang Kriteria dan Tata Cara Penarikan Obat yang tidak memenuhi standar dan / atau persyaratan



Peraturan Ka BPOM RI 09938/2011 , tentang Kriteria dan Tata Cara Penarikan Obat yang tidak memenuhi standar dan / atau persyaratan

- **Penarikan wajib (mandatory recall)** adalah penarikan yang diperintah kan oleh Kepala BPOM RI.
- **Penarikan Sukarela (voluntary recall)** adalah penarikan yang diprakarsai oleh Pemilik Izin Edar
- **Sistim Kewaspadaan Cepat (rapid alert system)** adalah pemberitahuan secara cepat BPOM antar negara tentang obat yang tidak memenuhi standar dan /atau persyaratan keamanan ,khasiat,mutu dan penandaan

ILUSTRASI PENARIKAN OBAT

- Penarikan obat dilakukan untuk obat yang TMS berdasarkan :
  - Hasil sampling dan pengujian oleh BPOM
  - Laporan keluhan konsumen
  - Sistim kewaspadaan cepat (rapid alert)
  - Temuan kritikal saat inspeksi CPOB

  } **Mandatory recall**

  - Informasi dari pemilik izin edar → **Voluntary recall**

Peraturan Ka BPOM RI 09938/2011 , tentang Kriteria dan Tata Cara Penarikan Obat yang tidak memenuhi standar dan / atau persyaratan

Kelas I	Kelas II	Kelas III
Terhadap obat yang dapat menyebabkan efek serius terhadap kesehatan dan dapat menyebabkan kematian	Terhadap obat yang dapat menyebabkan penyakit atau pengobatan keliru yang efeknya sementara dan dapat pulih kembali	Terhadap obat yang tidak menimbulkan bahaya signifikan tetapi alasan lain dan tidak termasuk Kelas I dan II
termasuk namun tidak terbatas pada • **obat yang telah memiliki izin edar yang tidak memenuhi persyaratan keamanan ,** • **terkontaminasi mikroba untuk sediaan injeksi dan tetes mata** • **terkontaminasi kimia yang menyebabkan efek serius ,** • **labelnya tidak sesuai dengan kandungan dan/atau kekuatan zat aktif ,** • **ketercampuran obat dalam lebih dari satu wadah ,** • **kandungan zat aktif salah dalam obat multi komponen yang menyebabkan efek serius terhadap kesehatan**	termasuk namun tidak terbatas pada • obat yang labelnya tidak lengkap atau salah cetak , • brosur atau leaflet salah informasi • terkontaminasi mikroba pada sediaan yang non steril , • terkontaminasi kimia atau fisika , • tidak memenuhi spesifikasi keseragaman kandungan keragaman bobot, • uji disolusi , • uji potensi ,kadar, • pH, pemerian , kadar air atau • stabilitas, kedaluwarsa	termasuk namun tidak terbatas pada • obat yang : tidak mencantumkan no bets dan/atau tanggal kedaluwarsa, • tidak memenuhi spesifikasi waktu hancur , • volume terpindahkan ,atau keseragaman bobot , • pH sediaan oral cair, • penutup kemasan rusak, obat tidak memenuhi standar dan/atau persyaratan yang tidak termasuk obat yang harus dilakukan penarikan berdasarkan Penarikan Kelas I dan Kelas II

TINDAK LANJUT RECALL

Voluntary recall

- Dalam hal voluntary recall , setelah menerima laporan tentang obat yang TMS maka BPOM meminta kepada pemilik izin edar (Industri Farmasi pelapor) ,
  - Investigasi penyebab obat TMS
  - Hasil penarikan obat yang TMS

  → BPOM melakukan *evaluasi efektivitas hasil penarikan* dan *CAPA*

EVALUASI CEPAT TINDAK LANJUT RECALL

- **Efektivitas hasil penarikan**
  - dilihat dari Return rate (%)

    $$\frac{\text{number of returned}}{\text{number of distributed}} \times 100\% = \ldots\ldots\% \text{ (limit : 100\%)}$$

  - Pemenuhan target waktu sesuai yang ditentukan oleh pemilik izin edar (lihat surat penarikan kepada distributor)

Indonesian GMP - CPOB 2012
CHAPTER 9
HANDLING OF PRODUCT COMPLAINTS AND PRODUCT RECALLS

Voluntary dan Manaftory Recall

Penarikan Kembali Obat Jadi

Prosedur Tetap / Protap

* *Personel yg bertanggung jawab*
* *Team Penarikan kembali obat jadi dng tanggung jawab masing-masing*

Pelaksanaan :
- *Sesegera mungkin setelah diterima laporan tentang produk yg cacat mutu atau adanya laporan yg merugikan*
- *Disertai dengan embargo, sesuai kebutuhan*
- *Prosedur harus menjangkau ke tingkat konsumen*
- *Pemeriksaan kembali harus cepat, efektif & tuntas*

Dokumentasi :
- *Catatan distribusi*
- *Pemberitahuan penarikan kembali obat jadi*
- *Rekonsiliasi hasil pemeriksaan*

Penanganan Produk :
- *Identifikasi & status*
- *Terpisah dari produk lain & terperinci*
- *Penanganan lebih lanjut*

Mock Recall :
- *Evaluasi efektifitas prosedur penyelenggaraan penarikan kembali obat jadi*

Tindakan lanjutan recall :
- *Pengumpulan dan evaluasi data di laboratorium*
- *Pengumpulan dan evaluasi data proses termasuk kajian resiko mutunya*

私はすべてがうまくいくよう願ってる

Watashi wa subete ga umaku iku yō nega~tsu teru

どうもありがとうございました ….

Domo arigatogozaimashita

Terima kasih