Reclassification of medicines in Singapore: Initiating switching to increase access

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Outline

- Introduction: HSA
- Aim of Reclassification
- Access control of medicines in Singapore
- Mechanisms to increase access
- Factors influencing level of access

HSA
Health Sciences Authority

VISION

To be the leading innovative authority protecting and advancing national health and safety

MISSION

- To wisely regulate health products
- To serve the administration of justice
- To secure the nation's blood supply
- To safeguard public health

Applied Sciences Group | Blood Services Group | Health Products Regulation Group | Corporate Services Group

Drug Regulation

Role of the Therapeutic Products Branch

- Evaluation and approval of new and generic therapeutic products to ensure that they meet standards for quality, safety and efficacy
- Post-approval evaluation throughout products' life cycle
- Reclassification of medicines

Aim of Reclassification

- To enhance public access to safe and effective treatments through reclassification of medicines, in support of national health policy and objective

Background

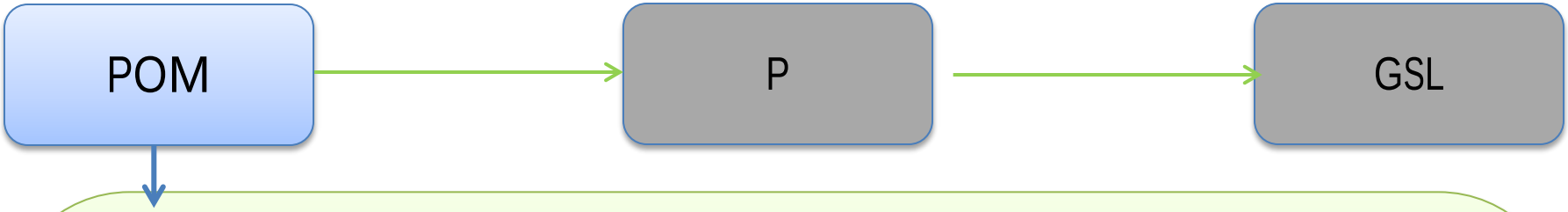
At present, there are 3 levels of access controls for medicines:

- Prescription Only Medicines **(POM)**
  - Can be obtained from a doctor or upon a doctor's *prescription* (abbreviated henceforth as *Rx*) from a pharmacy through a pharmacist

- Pharmacy medicines **(P)**
  - Can be obtained without a prescription from a pharmacy through a pharmacist

- General Sales List medicines **(GSL)**
  - Can be obtained freely from any retail shop (e.g. supermarket, convenience stores)

Guiding principles for access control (POM)

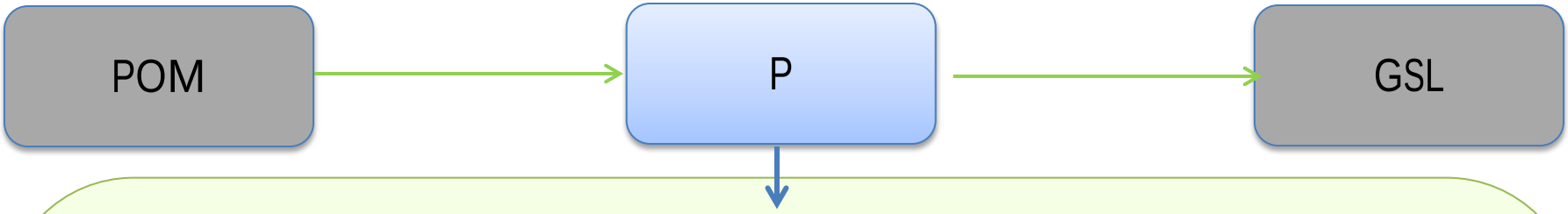


Needs to be prescribed and used **under doctor's supervision**:

- The condition to be treated needs to be diagnosed and treated by **doctor** (e.g. cancer, infections, heart disease); or
- Can cause **serious side effects** which require doctor's monitoring; or
- Contains a **new active pharmaceutical ingredient**; or
- There are **public health concerns** (e.g. abuse potential, social concerns)

Examples: oral antibiotics, medicines for chronic diseases such as hypertension, diabetes, asthma

Guiding principles for access control (P)

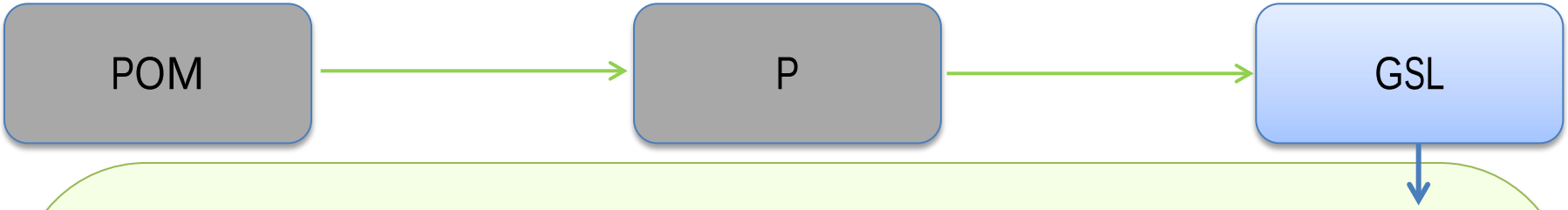


Needs to be used **under pharmacist supervision**:

- The condition to be treated can be appropriately assessed by **pharmacist**, and
- The directions of use, side effects, contraindications and drug interactions only require **reinforcement by pharmacist through counselling**, and
- The natural course of the disease / condition, the duration of symptoms are **self-limiting**, and
- The **product packaging and labelling are appropriate** and provide sufficient information to allow correct use by public.

Examples: medicines for cold, proton pump inhibitors for heartburn, nicotine replacement therapy, topical steroid cream for rash

Guiding principles for access control (GSL)



Can be used safely by public **without medical supervision**:

- The condition to be treated is a **minor ailment** which can be identified by the patient, and intended for short term use only , and
- The directions of use, side effects, contraindications and drug interactions are **easily understood by the patient without needing pharmacist's intervention**, and
- The natural course of the disease / condition, the duration of symptoms are **self-limiting**, and
- The **product packaging and labelling are appropriate** and provide sufficient information to allow correct use by public. Quantity per pack should be limited to short-term use only to deter excessive intake of the medicine.

Examples: paracetamol for mild fever and pain, topical creams for mild fungal infections

Mechanisms to increase access

- Reclassification can be initiated by:
  a) Application by company
  b) HSA
  c) Any interested third party

Mechanisms to increase access

Application by company (POM to P or P to GSL)

- Provide evidence that medicines is sufficiently safe for use with reduced or without medical supervision
- Proposed labels and pack size are consumer-friendly

Mechanisms to increase access

Initiated by HSA (POM to P)

- Exemptions for supply of POM without prescription under specified conditions
- Active ingredient specific rather than product specific

Case study: Omeprazole

- Indications: duodenal ulcer, gastric ulcer, Zollinger-Ellison syndrome, heartburn
- Specified conditions for P
  - Indicated only for heartburn
  - Maximum daily dose (MDD) of 20mg
  - Max supply not exceeding 14 days supply
- Product remains as POM if indications continue to include duodenal ulcer, gastric ulcer etc and not fulfilling MDD and pack size requirements
  - Pharmacist can dispense without a prescription subject to specified conditions
  - Supply is accompanied by PIL produced by the Pharmaceutical Society of Singapore (PSS)
- Product legally classified as P if fulfills the above requirements, with consumer packs accompanied by a Patient Information Leaflet (PIL)
- Losec (POM) vs Omesec (P)

Mechanisms to increase access

Recommendations by third party

- e.g. Professional bodies such as the Pharmaceutical Society of Singapore (PSS), Singapore Optometric Association (SOA), etc

Factors Influencing Level of Access

- Increase access needs to move in tandem with the emerging healthcare model (e.g. expansion of role of pharmacists), social culture (readiness of population for self-medication)

- Lack of commercial interest by companies despite mechanisms to increase access

Thank You

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