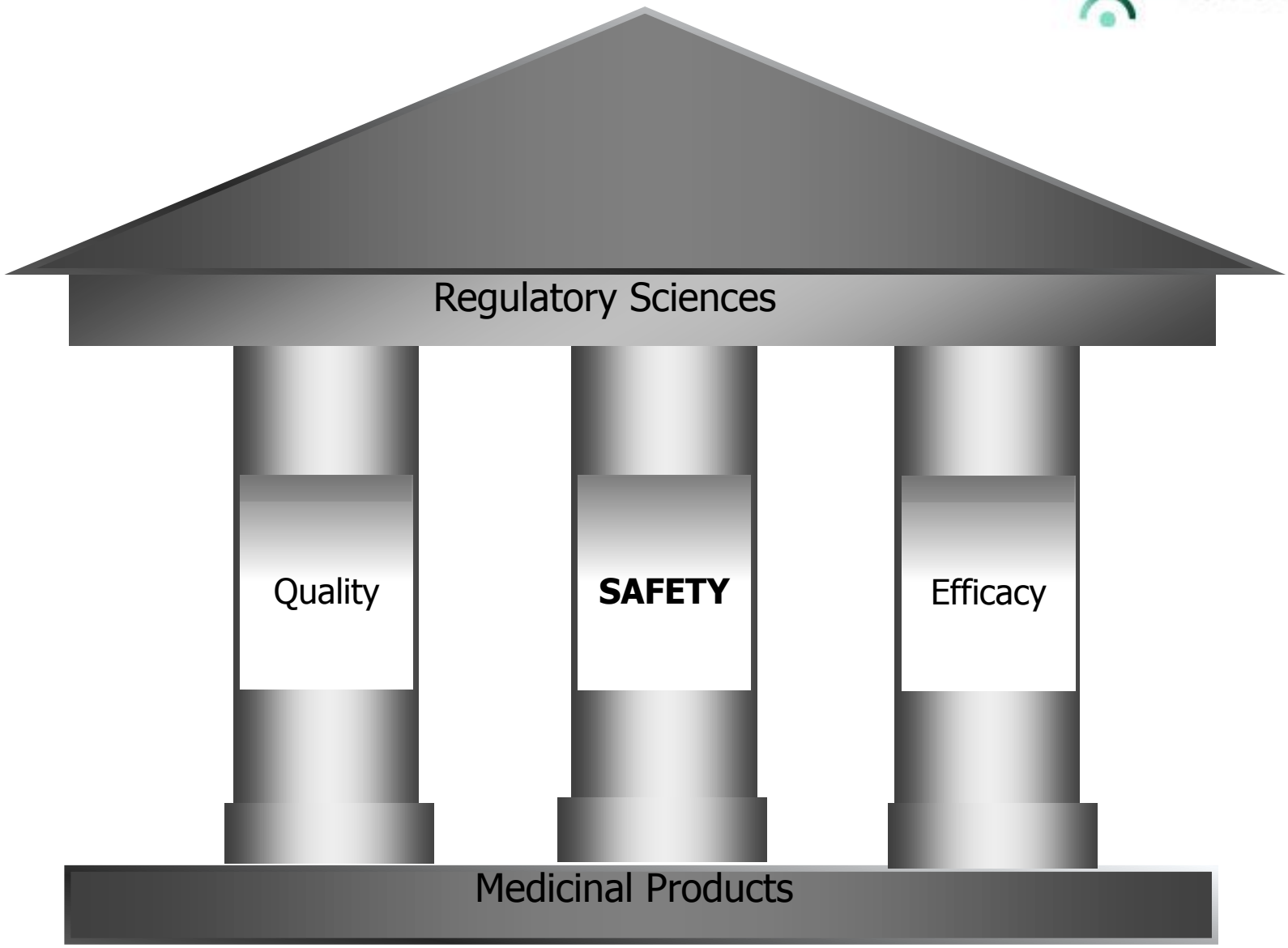
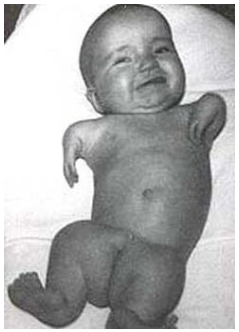
MALTA MEDICINES AUTHORITY

Pharmaceutical Regulatory Perspective: Patient Safety

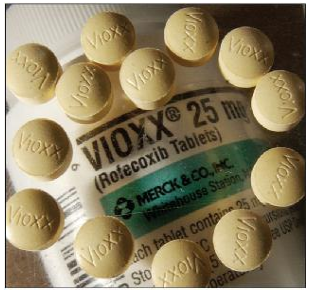

Regulatory Sciences
Quality
SAFETY
Efficacy
Medicinal Products

Evolvement of regulation

Sulphanilamide in diethylene glycol (lethal solvent) 1937



Thalidomide disaster 1961

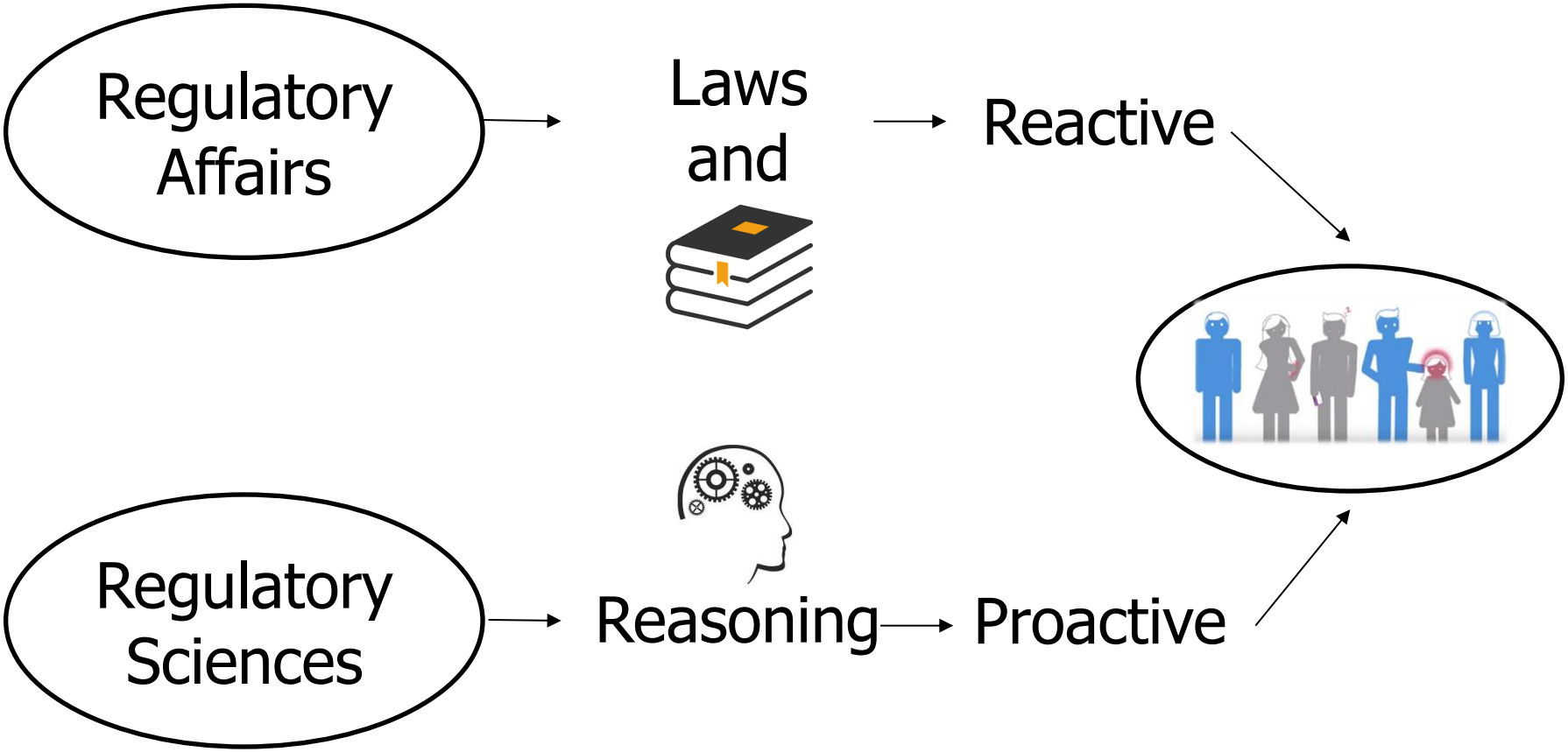


Rofecoxib withdrawal 2004

Stimulated regulatory reforms

Medicinal product assessment

Moving towards regulatory sciences



The role of the medicines regulatory authority in patient safety

The regulatory authority is responsible for the **constant monitoring of the safety of medicines** after authorisation

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Pharmacovigilance

Pharmacovigilance definition

The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem (WHO 2002)

World Health Organization

Objectives of Pharmacovigilance

MALTA MEDICINES AUTHORITY

Preventing harm from adverse drug reactions

- to patients, healthcare professionals and the public

Promoting safe and effective use of medicinal products

- within or outside the terms of marketing authorisation or from occupational exposure

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IS THE PRIMARY MEANS OF DATA COLLECTION FOR POST-AUTHORISATION SAFETY SURVEILLANCE OF MEDICINAL PRODUCTS

The ADR reporting system

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WHO CAN REPORT SIDE EFFECTS?

PATIENT

Calling

DOCTORS

ONLINE FORM CONSUMERS REPORTING

ADR FORM

By post or email

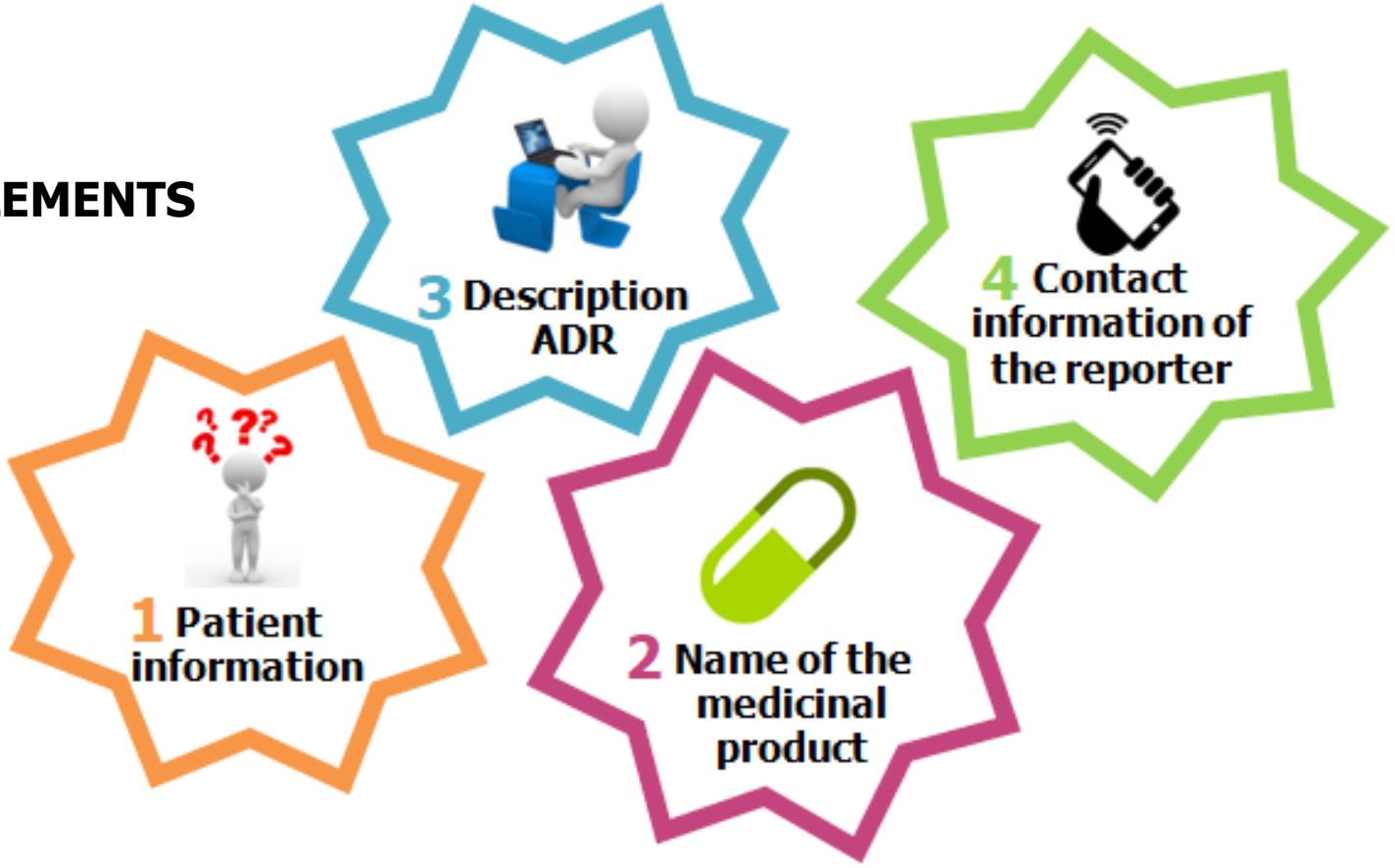
MEDICINES REGULATORY AUTHORITY

PHARMACEUTICAL COMPANIES

EUDRAVIGILANCE

Minimum requirements for a valid report

4 DATA ELEMENTS



Teaching how to report ADRs

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Better quality of information

Better and more effective signal detection

Outcomes of ADR reporting

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PSURs
Analysing the benefit-risk balance of a drug product

DHPCs
Disseminate urgent information on risks/safety issues

Safety Circulars
Disseminate information on ongoing reviews on medicines

RMPs
Holistic plan to minimise the risks associated with medicines

Safety Recalls
The withdrawal of medicinal products with negative benefit-risk balance

Pharmacovigilance Inspections
Ensure that MAHs fulfill their pharmacovigilance obligations

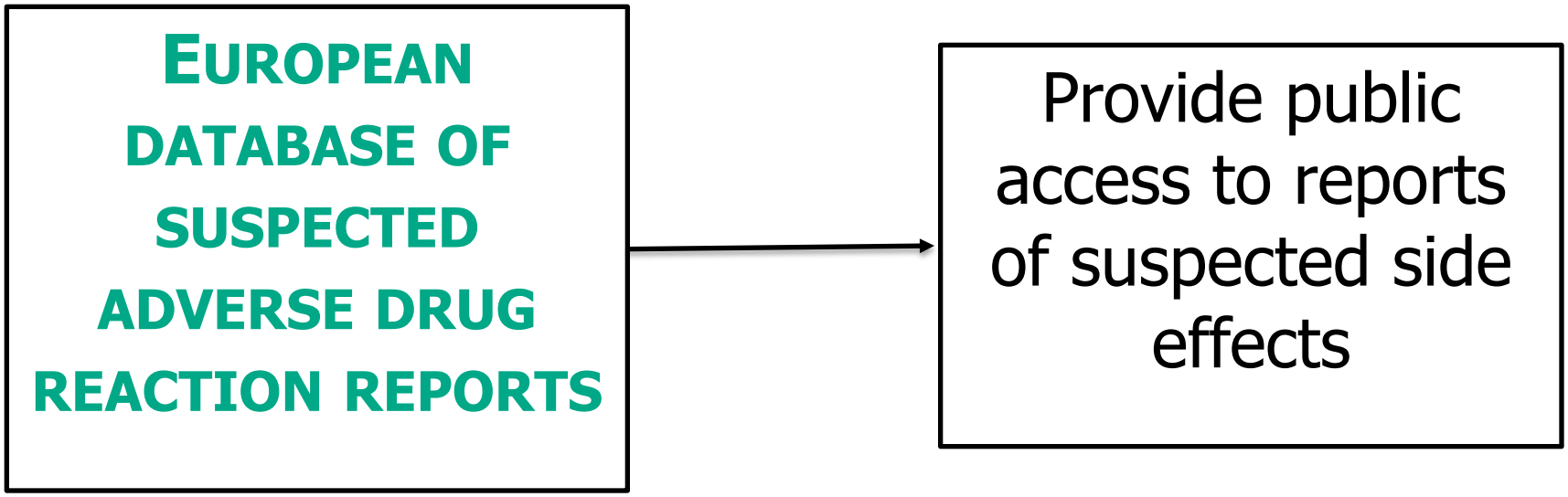
PSURs: Periodic Safety update Report

DHPCs: Direct Healthcare Professional Communication

RMPs: Risk Management Plan

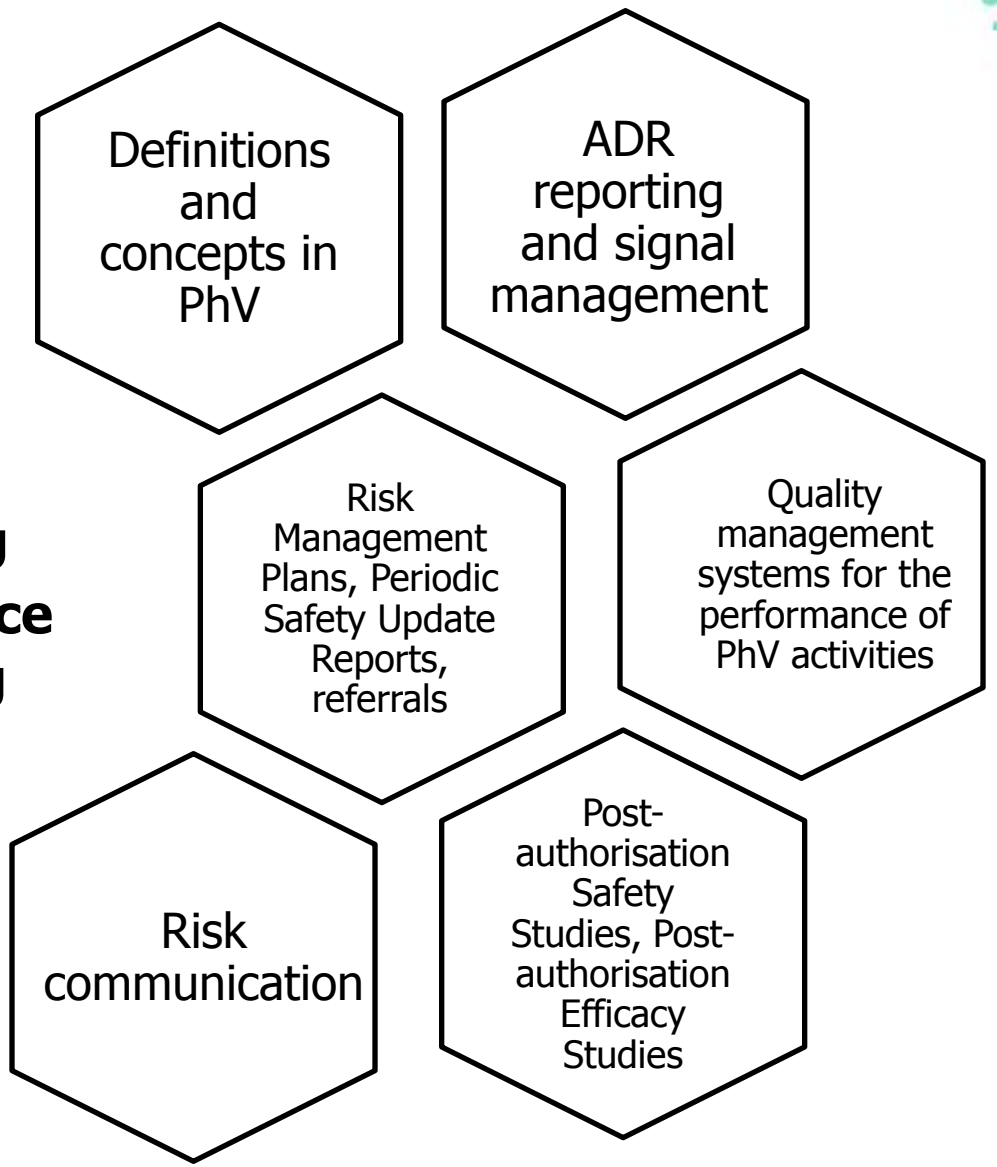
MAHs: Marketing Authorisation Holder

ADR database



LINK:
http://www.adrreports.eu

Topics for Pharmacist Education in EU Pharmacovigilance (PhV) and Drug Safety



MALTA MEDICINES AUTHORITY

THANK YOU FOR YOUR ATTENTION

The mission of the Medicines Authority is to protect and enhance public health through the regulation of medical products and pharmaceutical activities.

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