Pharmacovigilance: Monitoring Side Effects Around the World

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#ATA62Pharmacovigilance

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In Person and Virtually

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The Voice of Interpreters and Translators

Outline

- What is pharmacovigilance?
- Who does it?
- When does it happen?
- Reports
- Real world examples
- Opportunities for translation

What is Pharmacovigilance?

What is pharmacovigilance?

WHO: *The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem.*

Activities involved:

- Evaluate the safety of drugs and therapeutic biologic products
- **Monitoring/surveillance**
- Analyze safety signals
- Recommend regulatory action
- Communicate safety information

Who is involved in pharmacovigilance?

- Regulatory agencies
- Pharmaceutical companies
- Healthcare providers
- Patients

Pfizer

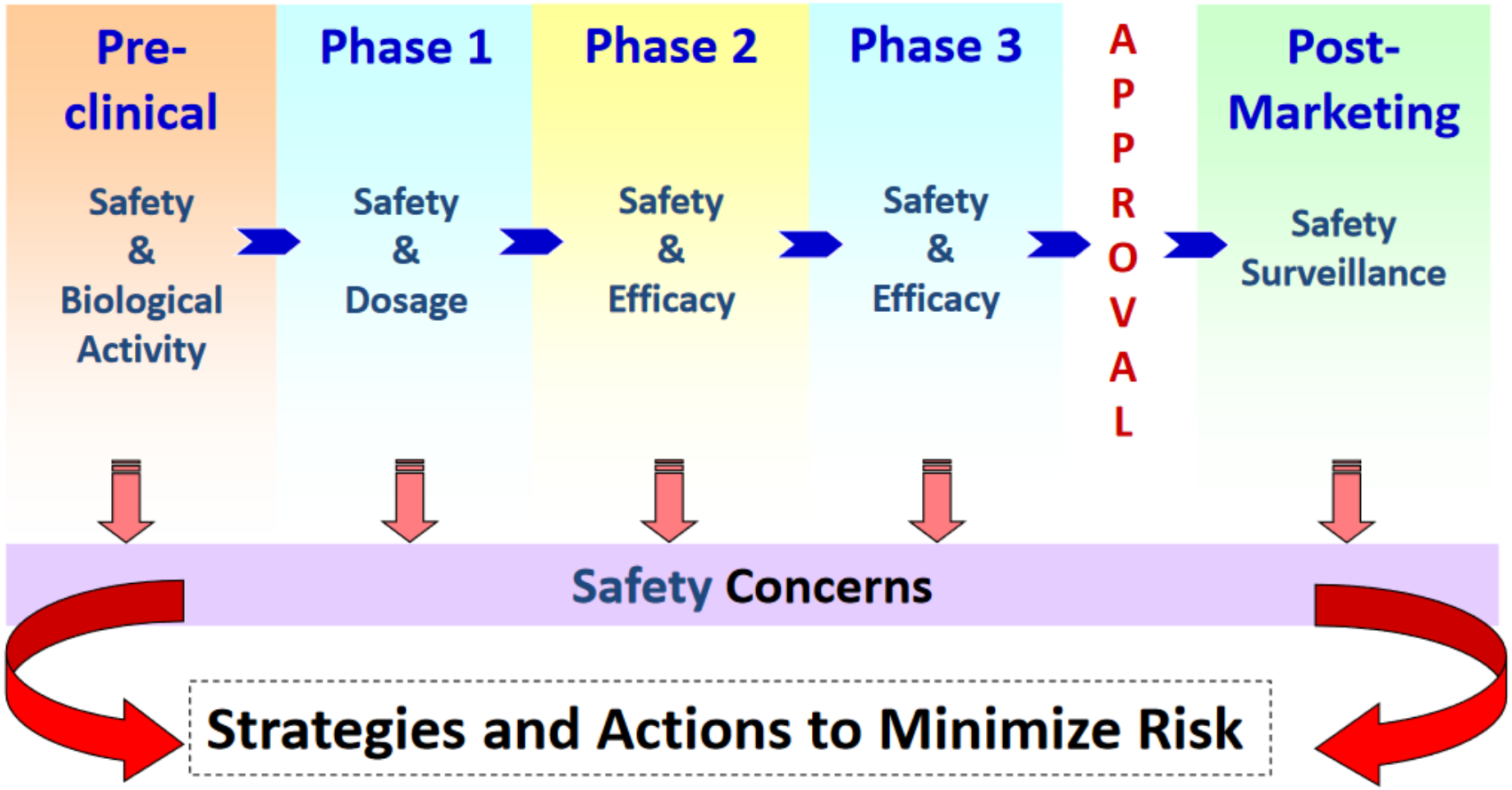
FDA

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

NOVARTIS

BAYER

When does pharmacovigilance take place?



Source: FDA

When does pharmacovigilance take place?

- Post-marketing surveillance
- Under 21 CFR 314.80 post-marketing safety reports must be submitted to the agency for the following:
  - 15-day Alert reports: Serious and unexpected adverse experience from all sources (**domestic and foreign**)
  - Periodic Adverse Experience Reports: Domestic spontaneous adverse events that are:
    - Serious and expected
    - Non-serious and unexpected
    - Non-serious and expected
    - Quarterly for the first 3 years, then annually

What does pharmacovigilance look for?

Adverse Drug Experiences as defined by US Regulation (21 CFR 314.80)
Any undesirable event that is associated with the use of a drug in humans, whether or not considered drug-related and occurs in the course of the use of a drug product in professional practice. This may include:

- Drug overdose
- Drug abuse
- Drug withdrawal
- Any failure of expected pharmacologic action

What does pharmacovigilance look for?

Serious Adverse Experiences result in any of these outcomes:

- Death
- Life-threatening adverse experience
- Inpatient hospitalization – new or prolonged
- Persistent/significant disability/incapacity
- Congenital birth defect
- Other serious: based upon appropriate medical judgment, they may jeopardize the patient and require intervention to prevent a serious outcome

Elements of a pharmacovigilance report

Four main elements required:

- Patient
- Drug product involved
- Adverse event
- Reporter (patient, doctor, caregiver)

Elements of an informative report

- Description of adverse event
  - Suspected and concomitant product therapy details (e.g., dose, dates of therapy)
  - Patient characteristics (e.g., age, sex), baseline medical condition, co-morbid condition, family history, other risk factors
  - Documentation of the diagnosis
  - Clinical course and outcomes
  - Relevant therapeutic measures and laboratory data
  - Dechallenge and rechallenge information
  - Reporter contact information
  - Any other relevant information

Source: Guidance for Industry - Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment, March 2005

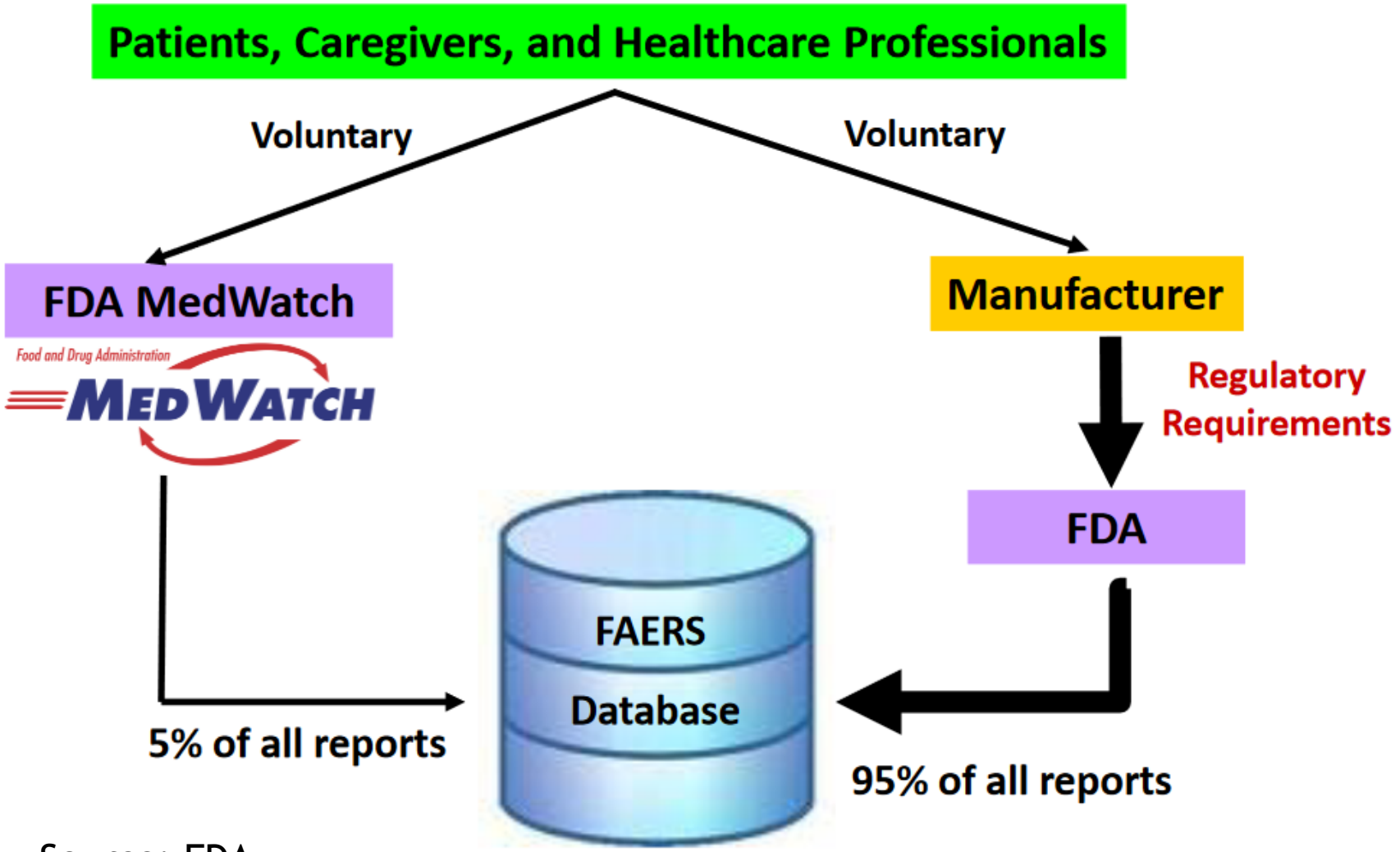
Report types

- Adverse events reported during a trial
  - Reported to the trial sponsor who must file a report with the governing regulatory agency
  - Includes serious adverse events which have an expedited reporting timeline and non-serious adverse events that are reported during periodic updates
- Spontaneous reports
  - A communication from an individual (e.g., health care professional, consumer) to a company or regulatory authority
  - Describes a suspected adverse event
  - Passive and voluntary reports

Spontaneous Reports

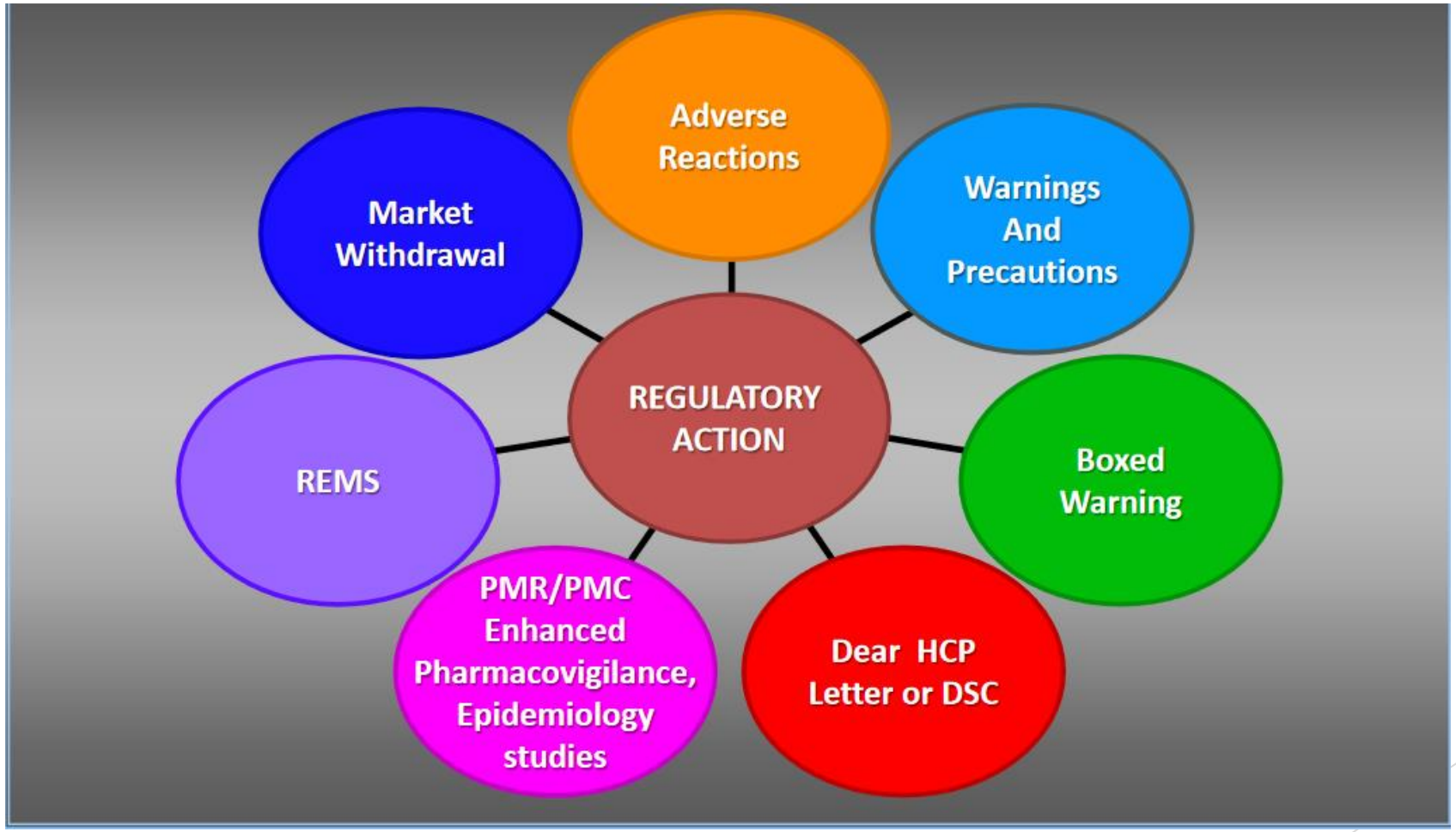
- Reports in medical journals (e.g. case reports/series)
- Reports submitted to the companies or regulatory agencies directly (e.g. VAERS, MedWatch)
- Reports in the media (e.g. newspaper article)
- Reports on social media (Facebook, Twitter, WhatsApp, etc.)

How post-marketing reports get to the FDA



Source: FDA

Possible Regulatory Actions After Reports



Source: FDA

Real world examples

Thalidomide

- Severe birth defects if taken by pregnant women
- Resulted in tighter drug testing and reporting of side-effects.
- Lead to the creation of modern pharmacovigilance

Essure

- Less invasive method of permanent contraception
- No issues flagged in initial studies
- Permanently withdrawn from the market in 2018

COVID-19 Vaccines

- Effects in pregnant/breastfeeding women
- Effects in children
- Rare side effects & allergies

VAERS

v-safe℠ after vaccination health checker

Opportunities for translation

- Pharmacovigilance is everywhere and the information to be translated can take many forms
- Pharmacovigilance is international – because many drugs are sold in many countries, companies must comply with the reporting requirements in all the countries where the drug is sold regardless of where the report originated
- Regulations require prompt reports be submitted to the regulatory authorities within a certain time period depending on the nature of the event – serious and unexpected within 15 days, otherwise quarterly for the first 2-3 years a drug is on the market then annually thereafter

Opportunities for translation

- Most pharmacovigilance translation takes place within the context of either serious adverse event reports from clinical trials or spontaneous reports during post-marketing follow-up
- Many different types of documents or text types involved:
  - Media and medical journal articles
  - Social media posts (e.g. Facebook, Twitter, Instagram, WhatsApp)
  - Medical records
  - Letters and questionnaires from the company seeking additional information

Helpful Resources

- Information on Regulations and Guidelines:
  - U.S. FDA Good Pharmacovigilance Practices: https://www.fda.gov/media/71546/download
  - EMA: https://www.ema.europa.eu/en/pharmacovigilance-legislation
  - Health Canada: https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/reporting-adverse-reactions-marketed-health-products-guidance-industry.html
  - ICH: https://database.ich.org/sites/default/files/E2E_Guideline.pdf

- Useful Resources:
  - MedDRA (Medical Dictionary for Regulatory Activities): a multilingual dictionary providing the preferred international terms. Developed as part of the ICH as a clinically validated international medical terminology dictionary-thesaurus used by regulatory authorities and the biopharmaceutical industry. Link below provides access to the English version. https://bioportal.bioontology.org/ontologies/MEDDRA
  - EDQM Standard Terms: European database covering pharmaceutical dose forms (also known as dosage forms), routes and/or methods of administration, units of presentation, and containers, closures and delivery devices, for medicines both for human and for veterinary use in 34 languages https://www.edqm.eu/en/standard-terms-database
  - CTCAE (Clinical Terminology Criteria for Adverse Events): a set of criteria for the standardized classification of adverse effects of drugs developed by the U.S. National Cancer Institute https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_8.5x11.pdf

Questions?

END

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