EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Session on identification and traceability of biological products

Introductory remarks and international initiatives

Presented by: Sabine Brosch
Patient Health Protection Unit/P-PV Sector/P-PV-BCS

An agency of the European Union

What is a biological medicine?

- A medicine that contains one or more active substances made by or derived from a living organism to treat diseases and genetic disorders
- A biosimilar medicine is a medicine which is similar to a biological medicine that has already been authorised (the 'biological reference medicine')

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Why is identification and traceability for biological medicines needed?

- The active substances of biological medicines are larger and more complex than those of non-biological medicines
- Their complexity as well as the way they are produced/manufactured may result in small differences between molecules of the same active substance, which may have an impact on the safety profile of the medicine
- Biological medicines are also more likely to be recognised by the body's immune system as 'foreign' and therefore to trigger immune reactions against them

Identification and traceability of biological products – requirements for additional monitoring?

- The Agency, in collaboration with the Member States, has to set up, maintain and make public a list of medicinal products that are subject to additional monitoring
- This includes the names and active substances of:
  - ✓ Medicinal products authorised in the Union that contain a new active substance which, on 1 January 2011, was not contained in any medicinal product authorised in the EU
  - ✓ Any biological medicinal product that was authorised after 1 January 2011

Identification and traceability of biological products – requirements for adverse reaction reporting?

Member States have to:

- Take appropriate measures to encourage patients, doctors, pharmacists and other healthcare professionals to report suspected adverse reactions
  - Organisations representing consumers, patients and healthcare professionals may be involved
- Facilitate patient reporting
- Take appropriate measures to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports
- Ensure that the public is given important information on pharmacovigilance concerns relating to the use of a medicinal product in a timely manner

Identification and traceability of biological products – requirements for adverse reaction reporting?

- Member States have to ensure that all appropriate measures are taken to identify clearly:
  - ✓ Any biological medicinal product prescribed, dispensed, or sold in their territory
- Identification is required based on the:
  - ✓ Name of the medicinal product, in accordance with Article 1(20) of Directive 2001/83/EC
  - ✓ Batch number
- Mechanisms to obtain the identification:
  - ✓ Through the methods for collecting information and
  - ✓ Through the follow-up of suspected adverse reaction reports

Identification and traceability of biological products – what is the link with international standards?

- Identification of Medicinal Product (IDMP) – unique identification at the level of
  - ✓ Substances (ingredients)
  - ✓ Pharmaceutical product
  - ✓ Medicinal product
  - ✓ Package (same medicinal product with different package presentations)
  - ✓ Batch level - outer packaging/ immediate packaging
  - ✓ Data carrier level e.g. bar code

- Article 57(2) provides the basis to establish and maintain a list of all medicinal products authorised in the Union including biologic medicines
- Individual Case Safety Report (ICSR) standard
  - ✓ New format for adverse reaction reporting incorporating the identification of products based on the IDMP standards

Session overview

- Challenges and perspectives from a Regulatory viewpoint
  - Sabine Straus, *Medicines Evaluation Board, Netherlands*

- Views from the European Generic medicines Association
  - Suzette Kox*, European Generic medicines Association*

- Views from the European Federation of Pharmaceutical Industries and Associations/European Biopharmaceutical Enterprises
  - Peter De Veene*, European Federation of Pharmaceutical Industries and Associations/European Biopharmaceutical Enterprises*