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GaBI Scientific Meetings

2nd MENA Stakeholder Meeting on **Regulatory Approval, Clinical Settings, Interchangeability and Pharmacovigilance of Biosimilars**

10 October 2018, Le Meridien Dubai, United Arab Emirates

Regulatory Standards and Practices on Biosimilars in UAE: Safety and Efficacy

Rasha Sayed Salama, MD, PhD, UAE

10 October 2018

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وزارة الصحة و وقاية المجتمع

Regulatory Standards and Practices on Biosimilars in UAE: Safety and Efficacy

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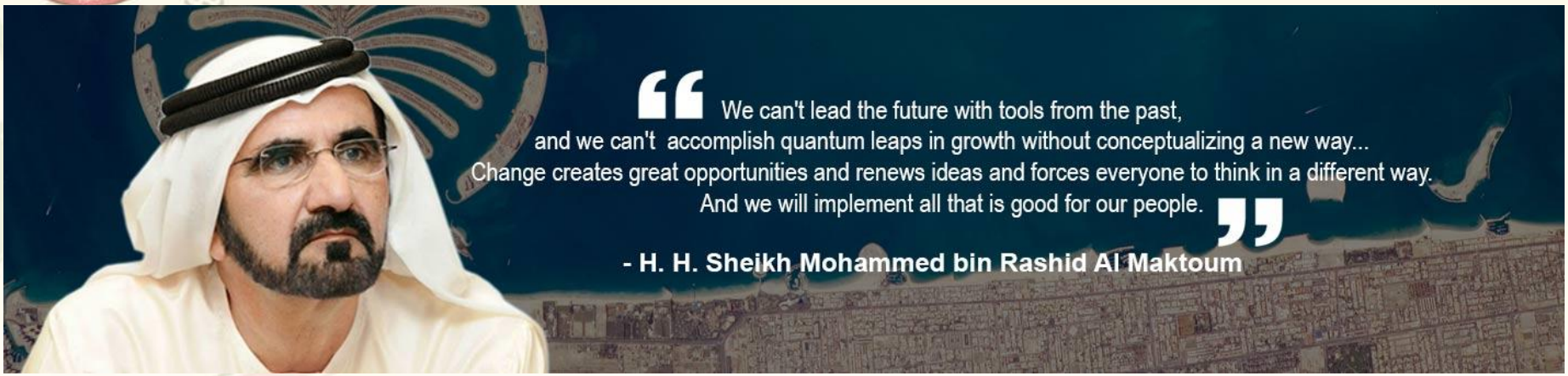
Public Health Policy and Licensing Sector
MOHAP- 2018

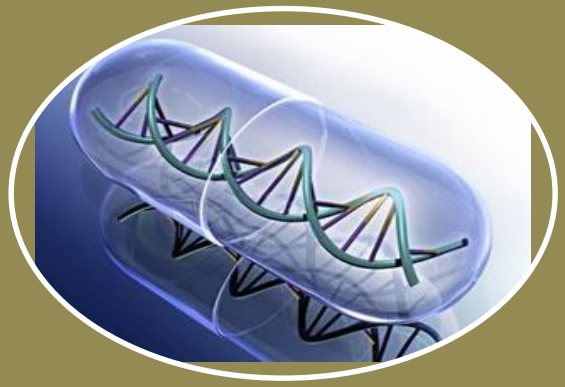
Shaping the Future: Innovative Capacity



The National Strategy for Innovation

- National Innovation Strategy was launched on October 2014 with the aim of making UAE one of the most innovative nations in the world within 7 years.
- The strategy stimulates innovation in 7 sectors: renewable energy, transport, education, health, technology, water and space.
- ***Health:*** The strategy will promote advanced technologies in healthcare services towards Public Health, and also working with strategic partners to support medical and pharmaceutical research and development.

Biological Medicines



Biological medicines are medicines that are made by or derived from a biological source, such as a bacterium, yeast or blood. They can consist of relatively simple molecules, such as human insulin or erythropoietin, or complex molecules such as monoclonal antibodies.

Biosimilars Definitions and Standards according to International Organizations

Definition

- Biosimilar or Biosimilarity means: that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product. (FDA)

Biosimilars Definitions and Standards according to International Organizations (cont.)

- A biosimilar medicine is a biological medicine that is similar to another biological medicine which has already been granted marketing authorization.
- The standard approach to licensing of a generic medicine, where the medicine must demonstrate bioequivalence (that is the bioavailability of the generic medicine must not differ significantly when given at the same dosage under similar conditions), is not sufficient for biosimilar medicines. For licensing in the European Union, the manufacturer of the biosimilar medicine must demonstrate that the medicine is:

✓ Similar to the original reference product, and

✓ Does not have any meaningful differences from the original reference product in terms of quality, safety or efficacy.

(EMEA) European Medicines Agency (2015).

Biosimilars: Simple Facts

Biopharmaceuticals represent one of the fastest-growing segments of pharmaceutical industry.

By 2020 they are expected to represent more than 50% of the market.

Increase opportunity to healthcare services, decrease expenditures.

Cultural and Cognitive Transformation of Biosimilars

- The “cultural and cognitive transformation” is challenging
- “Biosimilars represent a paradigm shift in the way we make a finding of safety and efficacy.”
- Significant progress made within international organizations, and still work is in progress for many clinicians, patients, and other stakeholders
- Best Practice : Support Education Regarding the “paradigm shift”
- Support Further Researches (pre and post Market)

Driving Forces for Emerging Biosimilars

The patents of several biopharmaceuticals have expired, or are about to expire

The potential market of biopharmaceuticals is very large

Pressure to reduce healthcare expenditure and increase patient access to treatment will drive the development of cheaper biosimilars

Examples of Biosimilar Guidelines

- COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP):European Medicines Agency Evaluation of Medicines for Human Use (EMA): GUIDELINE ON SIMILAR BIOLOGICAL MEDICINAL PRODUCTS- ICH
- Health Canada (finalized Guidance on Subsequent Entry Biologics published in 2010)
- Japan (Guideline on quality, safety and efficacy of follow-on biologics was published in 2009)
- WHO (Guidelines on Evaluation of Similar Biotherapeutic Products adopted in 2009)
- FDA (Abbreviated approval pathway for Biosimilars created via the Patient Protection and Affordable Care Act, signed on 2010)
- CHMP guidance also adopted by, e.g.:
  - Australia
  - Malaysia

REQUIREMENTS TO BE FULFILLED FOR REGISTRATION OF BIOSIMILAR PRODUCTS IN **UAE**

REGULATORY FRAMEWORK

A company may choose to develop a new biological medicinal product claimed to be "similar" to a reference medicinal product, which has been granted a marketing authorization in the Community on the basis of a complete dossier in accordance with the provisions of the requirements for the Marketing Authorization.

Comparability studies are needed to generate evidence substantiating the similar nature, in terms of quality, safety and efficacy, of the new similar biological medicinal product and the chosen reference medicinal product authorized.

1. Data on consistency in the manufacturing process:

- **a. Full description of the manufacturing process**
- **b. QC tests and specifications with supporting data as evidence of adequate control of the manufacturing process**
- **c. Data on consistency overtime for one year of full production.**

REQUIREMENTS TO BE FULFILLED FOR REGISTRATION OF BIOSIMILAR PRODUCTS IN **UAE** (cont.)

2. Heterogeneity assessment:

a. Comparability data between the test product and the original product:

i. Demonstration and conclusion that the 2 products are highly similar before and after the manufacturing changes and that no adverse impact on quality, safety or efficacy of the product occurred.

ii. Bioactivity and potency essays as well as surrogate clinical endpoint must be demonstrated

b. Similarity assessment of the finished products:

i. Includes all applicable clinical and pre-clinical data for the finished products in order to fully assess the impact of differences in the process and products on quality, safety and efficacy.

REQUIREMENTS TO BE FULFILLED FOR REGISTRATION OF BIOSIMILAR PRODUCTS IN **UAE** (cont.)

3. Therapeutic equivalence:

a. Pharmaceutical equivalence studies:

i. Identical active drug ingredients

ii. Identical amounts of active ingredients

iii. Identical dosage forms

iv. Identical compendial or other applicable standards of identity, strength, quality and purity.

b. Bioequivalence studies:

i. To be considered bioequivalent, the bioavailability of two products must not differ significantly when the two products are given in studies at the same dosage under similar conditions

REQUIREMENTS TO BE FULFILLED FOR REGISTRATION OF BIOSIMILAR PRODUCTS IN **UAE** (cont.)

4. Safety and efficacy studies:

a. Through clinical studies

b. Post-marketing surveillance

5. Demonstration of immunogenicity:

a. Demonstration of the comparative data of immunogenicity between the 2 products is required evidenced by comparative clinical trials

b. Clinical trial must demonstrate:

i. Purity of the product

ii. Epitope analysis

iii. Animal experiments (conventional animals/relative immunogenicity, non-human primates, immune-tolerant transgenic mice)

6. Pharmacovigilance Plan:

a. Track and trace

b. Recall plan

c. Plan for ADR (Adverse Reaction Report)

d. Bar coding method

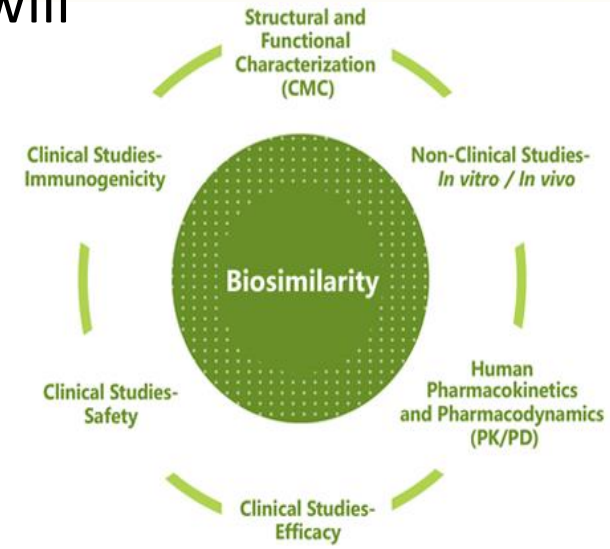
e. Post approval stability protocol and stability commitments

f. Plan of Quality (defect, final formulation package)

UAE Biosimilar Licensing Procedures

- Overseas Biosimilar Products:
  - Follow international guidelines according to the drug manufacturers and approval from international authorities (e.g. FDA, EMA, etc.)
- National Biosimilar Products
  - Follow UAE standards/GCC Guidelines (i.e. Insulin)
- Any Change in the product's specifications or characteristics is considered as a New product and will

  Follow Biosimilarity procedures



THANK YOU