Biosimilar Medicines

Media Kit

PhAMA

1ST NATIONAL BIO-THERAPEUTICS

Outline

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About the Event

0900am Welcome address
Mr Yew Wei Tarn, President, PhAMA

0910am Opening Remarks
Y. Bhg. Dato Fisah A Rahman, Senior Director of Pharmacy Services, Ministry of Health

0930am Evolving Regulatory Landscape & Challenges in Evaluating Biosimilars
Pn. Arpah Abas, Deputy Director/ Head of Biotechnology Section, National Pharmaceutical Control Bureau, Ministry of Health

1015pm Coffee Break

1030am Size does Matter ?
Professor João Eurico Cortez Cabral da Fonseca, Head of the Rheumatology Research Unit at the Instituto de Medicina Molecular and Professor of Rheumatology and Biomedical Engineering, University of Lisbon, Portugal.

1130am Regulating the Development and Approval of Biosimilar Monoclonal Antibodies – Considerations on Some Regulatory and Clinical Topics
Dr. Thomas Schreitmueller, Head, Regulatory Policy, Biologics, Roche

1315pm Case Presentation
1. **Indication Extrapolation**
   Professor João Eurico da Fonseca
2. **Interchangeability and Substitution**
   Dr Paul Cornes, Consultant Clinical Oncologist, UK
3. **Biologic Qualifier – An INN Proposal**
   Dr. Thomas Schreitmueller

1415pm Launch of PhAMA Biosimilars Position Paper
Ms Leah Goodman, 1st Vice-President of PhAMA

1435pm Coffee Break

1450pm Breakout Session & Panel Discussion
See overleaf for sessions

1620pm Wrap Up of Full Day
Ms Kathleen Yeoh, PhAMA

1635pm Closing
Mr. Muru Annamalai, 2nd Vice-President of PhAMA

Key Terminologies at a Glance

- **Chemical medicine/Small molecule medicine -** A medicine which is manufactured from chemical compounds with defined structures and characteristics.

- **Generic medicine** - A medicine which is developed once patent of approved chemical/conventional medicine expires. They contains the same active pharmaceutical ingredient as to the original conventional medicine thus, generic medicines can be substituted for the original chemical/conventional medicine.

- **Biological medicine/Large molecule medicine/Biologics** - A biotherapeutic product that contains active substances that are produced by, or extracted from, living organisms.

Key Terminologies at a Glance

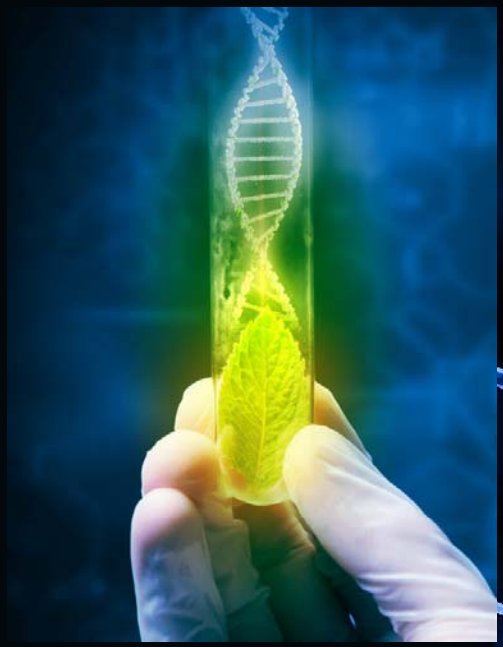
- Reference Product - The biological medicine that has already been approved is called the reference product.

- Biosimilar medicine/Biosimilars - A biotherapeutic product which is produced once the patent of the reference product has expired . It is similar in terms of quality, safety and efficacy to approved biologic/reference product.

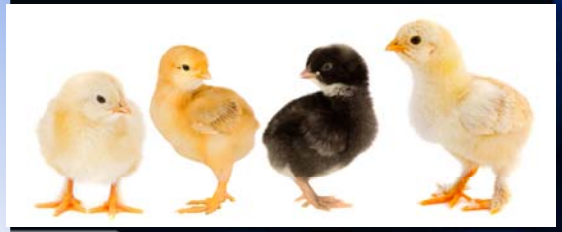
- Automatic substitution - If pharmacist substitutes a certain prescribed product by another equivalent product without the knowledge of the prescribing physicians it is terms as automatic substitution.

Biological Medicines & Biosimilars: An Overview

- Biological medicines/Biologics
  - Large, complex molecules produced from living organisms using biotechnology techniques.
  - Relatively new medicines used to treat serious long-term diseases.
- Biosimilars are medicines developed once patent of approved biological medicine (called reference product) expires.



Biosimilars are highly similar to the reference biological product in terms of quality, safety and efficacy but can never be exact copies.



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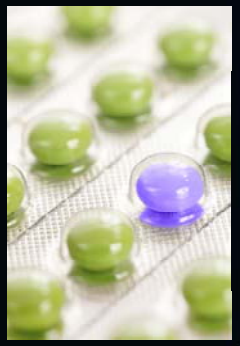
Benefits of Biosimilars

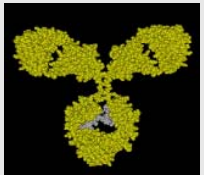
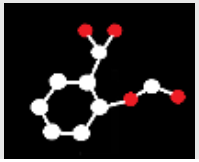
- Provide an alternative therapeutic option to the original biological medicine or reference product.



- Are available at a lower cost compared to the original reference product.

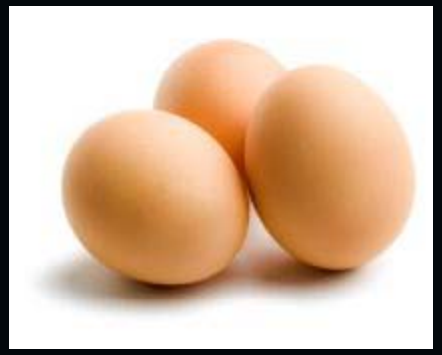
- Provide more treatment options for patients with serious diseases and increase their accessibility to high quality medicines.

How Different are Biosimilars Compared to Generics?

	Biosimilars	Generics
Manufacturing process	Complex/multifaceted	Simple/straightforward
Size	Large molecules	Small molecules
Example	Monoclonal Antibody 	Aspirin 
Origin	Manufactured from genetic material of living cell cultures or DNA technologies[1]	Synthesized in a laboratory or extracted from natural sources
Composition & Nature	▪ Active ingredients are not identical to the innovator product ▪ Manufacturing process affects the characteristics of the final product[2]	▪ Active ingredients are identical to the innovator product ▪ The manufacturing process does not affect the final product

1. APG, 2011. Procurement and Prescribing Practices for Biologics in the UK, 29 June 2011.
2. Schellekens H. *Nat Rev Drug Discov*. 2002;1:457–462.

Biosimilar Production:
The Process is the Product



Crumble

Cream

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Regulatory Framework for Biosimilars

- Biologics go through a rigorous research process and government approval to ensure they will have the same effect on efficacy and safety as the reference biologic.

National Pharmaceutical Control Bureau

- In Malaysia, the National Pharmaceutical Control Bureau is responsible for granting marketing authorisations for biotechnology products.

Well defined, science based and transparent approval process for biological products that helps achieve patient safety and reduce complexity/cost of manufacturing is the need of the hour.

PhAMA Recommendations on Biosimilars

All biologic/biosimilar prescriptions should be written by brand name and not by International Non-proprietary Name (INN).

A biologic or biosimilar medicine cannot be considered immediately interchangeable and therefore not automatically substituted without the knowledge and consent of the treating physician.

Patients should be kept fully informed about their medication and should be consulted if changes to their treatment are made.

The summary of medicinal product characteristics (SmPC) should clearly indicate the source of information contained within it, such as relevant clinical studies or that it has been derived from evidence about the originator product.

Biosimilar medicines should be subject to clinical practice guidelines for the management of all relevant diseases where biosimilars exist in the treatment armamentarium.

Tenders which are undertaken involving biological medicines should not seek to source a single product only.

Extrapolation of indications for biosimilar products should be evaluated on a case by case basis.

A rigorous implementation of these recommendations by all stakeholders is paramount to protect patients.

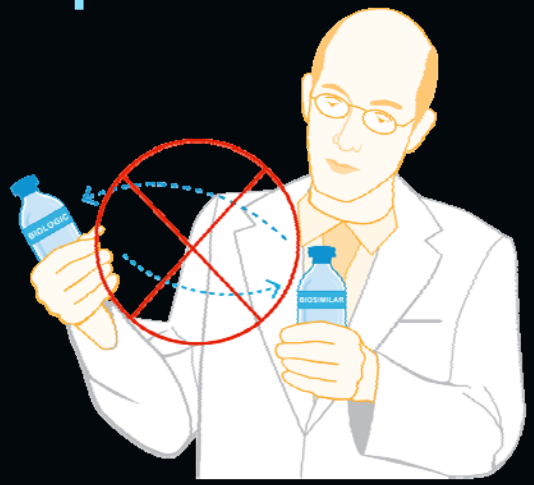
PhAMA Proposes to Assist Ministry of Health

- There remains an unmet need for the education of HCPs on the integration of biosimilars into therapy.

- PhAMA offers to assist MOH to co-design and conduct the educational programs on the appropriate use of biologic medicines.

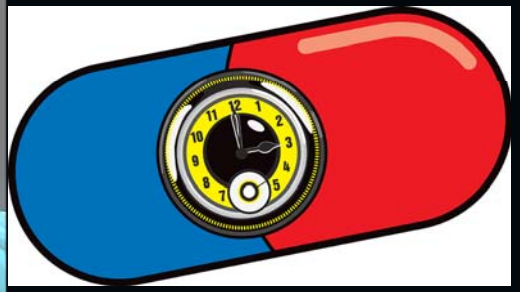
- PhAMA strongly encourages relevant medical associations and Health Authorities to include a section on 'Biosimilar Safety Considerations in Clinical Practice' when updating their clinical practice guidelines.

To Protect Patient Safety:
The Major Goal of Biotherapeutics



- Automatic substitution of biologics is currently not possible.
- Require long-term observation of the biosimilar by government authorities.
- Require unique names for each biosimilar.
- Test the biosimilar for each disease that is meant to be treated.

The Future for Biologics/Biosimilars



The future for many pharmaceutical firms is in biosimilars given the due patent expiry of the current biological medicines.

Securing the future for the safe use of biologics and biosimilars is the major endeavor.

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Biosimilars: A Quick Recall

- Biosimilars are large, complex molecules produced from living organisms using biotechnology techniques and are used to treat serious long-term diseases.
- Developed once patent of approved biological/reference product expires.
- It is highly similar to the reference product in terms of quality, safety and efficacy and thus provide an alternative therapeutic option.
- Are available at a lower cost compared to the original reference product.
- Provide more treatment options for patients and increase their accessibility to high quality medicines.