Consensus Principles
on patient access to safe biotechnological medicines
in Latin America

Biotechnological medicines are those created from live cells or tissues. These medicines have revolutionised the prognosis of diseases that today are treated with greater effectiveness and for which there were previously few successful medicines. To allow patients to have safe access and benefit from biological medicines and their biosimilar follow-ons we must follow regulatory policies, which should reflect the sophistication and individual nuances of these medicines.
Therefore, in acknowledgement of biotechnological medicines' and their powerful impact in patients' lives, the undersigned join in endorsing five core principles to protect safe access to biotechnological medicines.

Distinguishable Biosimilar Naming

Considering the complexity of biotechnological medicines and that these can sometimes cause unexpected secondary effects and very different immunogenic responses;

Considering that the appropriate identification/traceability of the medicine that could be causing an immunogenic response in the patient must be feasible to protect the safety of the patient; and

Considering that in communication about prescribed medicines, physicians and healthcare providers use the common international denomination:

Principle 1. Biosimilar medicines must carry common international distinguishable/differentiable denominations that protect patients' safety, by ensuring that patients and providers can quickly, accurately identify which medicine is used.

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Prescriber and Patient Communication

Considering that it is impossible to exactly duplicate a biotechnological medicine; and that not all biosimilars will be interchangeable with their reference product;

Whereas biosimilar medicines can elicit different patient responses to the biotechnological product of reference; and

Considering that transparency is a cornerstone in quality healthcare; and

Considering that communication between pharmacist, physician and patient allows healthcare providers to monitor patients' condition and optimise the patient outcomes:

Principle 2. It is necessary to determine interchangeability for biosimilars with their reference product based upon rigorous scientific facts; and

Principle 3. Prescribers and healthcare providers should be notified in an timely manner when the biotechnological medicine that they prescribed is being substituted with a biosimilar by the dispensing pharmacist.

Comprehensive Clinical Trial

Due to their sophistication, biotechnological medicines elicit different therapeutic responses in patients and different secondary effects and immunogenic responses.

In accordance with the stage of the disease, the reaction to the treatment with biological medicines can be different;

The clinical testing guarantee safety and efficacy of medicines for patients:

Principle 4. Biosimilar medicines must undergo appropriate clinical trials to gauge their effect and effectiveness at all stages of the disease and patient groups for which they were approved.

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Transparent Prescribing information

Whereas the prescribing information that accompanies a biotechnological medicine instructs and informs physicians about how to effectively, safely prescribe such medicines; and

Whereas biosimilar medicines exhibit slight variations from their biological reference product; and

Considering that the established set for generic medicines' prescribing information does not adequately acknowledge biosimilars' distinct nature:

Principle 5. Prescribing information for biosimilar medicines must be transparent when:

a) ***Identifying the product as a biosimilar***
b) ***Providing the data on specific clinical trials for biosimilars***
c) ***Clarifying which facts derive from the testing of the biosimilar and which from the biological reference product's testing***
d) ***Specifying the stages of disease and groups of patients for which the biosimilar was tested.***

Conclusion

During the Latin American Summit of Patients Organisations, celebrated 9-11th December 2015 in Buenos Aires, Argentina, co-organised by GAfPA (Global Alliance for Patient Access) and IAPO (international Alliance of Patients' Organisations), the patient groups proposed these five principles to protect the safety of patients, secure safe access to biotechnological medicines and biosimilars, and preserve the physician-patient relationship, which is fundamental in healthcare.

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