FIFARMA Position: Transparency in regulatory decision making on the approval for biosimilar products

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Thomas Schreitmueller,
Co-chair FIFARMA Regulatory and Biologics WG
Transparency is a fundamental value in developed societies and is regarded globally as a key feature of a sound national regulatory system. Patients and healthcare professionals have a right to know about the scientific basis for the approval and use of their medicines.


FIFARMA is fully supportive of this kind of thinking and shares the values behind.
The OECD Principles on Governance of Regulators

Accountability and transparency to the public

- Key operational policies and other guidance material should be publicly available.
- Members of the public have channels of complaint and possible redress in relation both to the actions.
- All major decisions made by the regulator shall be accompanied by publicly stated reasons.
- The opportunity for independent review of significant regulatory decisions should be available.
The Success Stories of EPARs and AusPARs (I/II)

- EPAR and AusPAR publication ensures high transparency about the reasons for marketing authorisation of medicines.
- Web traffic data indicate public assessment reports are being increasingly accessed online.
- Scientific progress and stakeholders’ desire for greater information necessitate a continuous evolution in communicating medicines’ information.
- Regulatory agencies can learn from each other when publishing their scientific rationale for medicines approval.

The Success Stories of EPARs and AusPARs (II/II)

• Beyond the conclusion of the regulator, public assessment reports describe:
  • The data submitted to support the request for marketing authorisation
  • the discussions during assessment; for example, regarding data limitations, uncertainties, or different views of parties involved in the evaluation.
  • The value is enhanced in the context of a large amount of unreliable or at least nonvalidated information available, particularly on the internet.

The IPRF initiative on transparency

i-p-r-f.org
International Pharmaceutical Regulators Forum
IPRF recommends a "Public Assessment Summary Information for Biosimilar" (PASIB)

- **Administrative information**
  - Mainly completed by the applicant
  - Contains details of the biosimilar, or SBP, and the reference product, the indications applied for, compliance with legal requirements
  - Links to additional information published by the NRA

- **Data submitted and reviewer summary**
  - The dossier and data content part is filled in by the sponsor, and the review details by the NRA
  - The quality part section would include the identification of analytical methods "at a high level, respecting confidentiality issues"

- **Reviewer conclusions**
  - Should contain concise, high-level conclusions to convey basic information, such as whether the biosimilarity exercise was considered acceptable
  - Can also mention areas where issues were raised during the review, and indicate whether all the claims proposed by the sponsor have been accepted (for example, extrapolation of indications)

*Adapted from: Scrip Regulatory Affairs: 07.04.2016: “IPRF Suggests Global Template for Sharing Biosimilar Assessment Data”

The guidance proposal is an important step toward increasing the transparency on regulatory decision making on a global basis. **When properly applied**, it has the potential to facilitate NRA knowledge sharing and collaboration.
FIFARMA concerns on the PASIB implementation examples (I/III)

- All examples provided e.g. from EMA on infliximab, filgastrim from MFDS on infliximab and trastuzumab refer to “clear-cut” positive regulatory decisions on similarity only
  - The learning experience is limited
  - Examples also should cover cases of gaps in the totality of the evidence and consequently not all indications of the reference product approved.

FIFARMA would recommend to adopt the Summary Basis of Decision (SBD) document from Health Canada on Inflectra (Infliximab) into the proposed format
FIFARMA concerns on the PASIB implementation examples (II/III)

- All of the provided examples would benefit from some more details in the information provided e.g.:
  - The number of RBP batches included in the decision
  - The scientific basis for the detection or exclusion of differences
  - A discussion of differences observed and their (non-)relevance.
  - A thorough discussion on the rationales behind extrapolation of indications

FIFARMA would recommend to have a clearer communication in the PASIB on the product specific scientific basis of similarity
FIFARMA concerns on the PASIB implementation examples (III/III)

• Regulators should provide a convincing and conclusive story to the public on their decision.
  • A checkbox communication e.g. done “according to guideline” may not be considered helpful in the sense of increasing transparency.
  • The goal should be to provide case specific data (similarities and differences), aligned to a story that finally will allow agreement or disagreement of the reader.

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<tr>
<th>Biological activity</th>
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<tr>
<td><em>In vitro</em> Bioactivity (Anti-proliferation assay)</td>
<td>Comparable</td>
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<td>HER2 Binding Affinity (ELISA)</td>
<td>Comparable</td>
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<td>Cell Based Binding Affinity</td>
<td>Comparable</td>
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<td>Clq Binding Affinity (ELISA)</td>
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<td>FcγRI Binding Affinity (ELISA)</td>
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<td>FcγRIIa Binding Affinity (SPR)</td>
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The FIFARMA position on transparency in regulatory decision making on the approval of biosimilar products

A. The FIFARMA Position Transparency in Regulatory Decision Making on the Approval for Biosimilar Products

- It is in the general interest of patients, physicians, healthcare workers, providers, and payers that there is a high level of public trust and confidence in the approval of medical products.
- Developing and maintaining trust with stakeholders in approved medical products depends on other factors, on transparency of regulatory and on their product-specific application.
- Making transparent is a timely manner what regulation applied, under what basis, used for the assessment and what rational is behind a medical product's approval or rejection will allow better informed decision-making at the physician and payer level.
- The recently launched initiative from the International Pharmaceutical Regulators Forum (IPRF) on the publication of Public Assessment Summary Information (PASI) is highly valuable and if properly implemented by regulatory agencies will supplement transparency and ultimately trust with all stakeholders.
- As a good regulatory practice, the availability of public assessment summary information should not be limited to Biosimilars, but should be available to any type
FIFARMA position on transparency in regulatory decision making on the approval for biosimilar products

- It is in the general interests of patients, physicians, healthcare workers, producers and providers that there is a high level of public trust and confidence in the approved medical products.

- Developing and maintaining trust with stakeholders in approved medical products depends, amongst other factors, on transparently developed regulations and on their product specific application.

- Making transparent in a timely manner what regulation applied, what data basis used for the assessment and what rational is behind a medical product’s approval or rejection will also allow better informed decision-making at the physician and payer level.

- The recently launched initiative from the International Pharmaceutical Regulators Forum (IPRF) on the publication of Public Assessment Summary Information for Biosimilar (PASIB) is highly valuable and if properly implemented by regulatory agencies will significantly contribute to transparency and ultimately trust with all stakeholders.

- As a good regulatory practice the availability of public assessment summary information should not be limited to Biosimilars, but should be available to any type of medical product e.g. novel biotherapeutics, vaccines or pharmaceutical products manufactured by chemical synthesis.
Thank You