ASBM EUROPEAN PHYSICIANS SURVEY ON BIOSIMILARS: KEY FINDINGS ON KNOWLEDGE, NAMING, TRACEABILITY AND PHYSICIANS' CHOICE

Executive Summary

From October to November 2013, the Alliance for Safe Biologic Medicines carried out a survey amongst 470 physicians in Europe. This survey focuses on their prescribing habits and understanding of biosimilars, thus reflecting the daily clinical practice in Europe with regards to biologic medicines, including biosimilars.

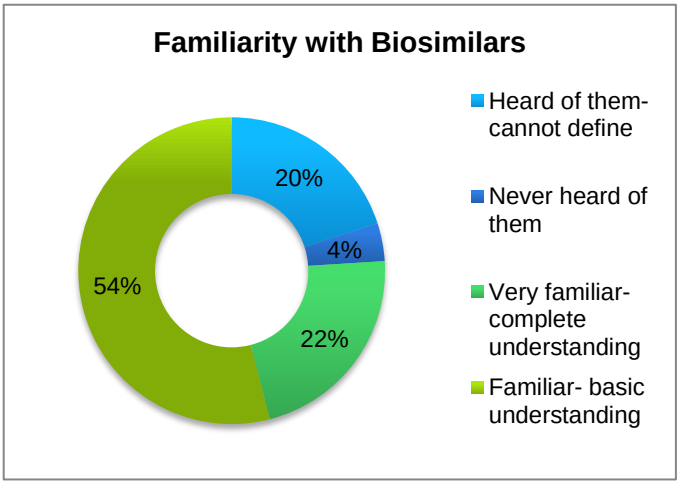
A pan-European survey focused on biosimilars:

470 prescribers, surveyed equally across 5 countries in Western Europe (France, Germany, Italy, Spain and United Kingdom), were invited to share their experience and views on biosimilars via a 15 minute web-based survey. This sample included specialists in nephrology, rheumatology, dermatology, neurology, endocrinology and oncology.
Surveyed physicians are active and knowledgeable clinical practitioners: 81 % have more than 11 years of experience, and 70% of them have more than 50 patient appointments per week, mostly in hospitals (58%) and academic medical centres (24%).

Physicians' knowledge of biosimilars remains insufficient:

- One of the main findings of the survey relates to European physicians' limited knowledge of biosimilars. Only 22% consider themselves as very familiar with them. Whilst a majority (54%) have a basic understanding of biosimilars, a quarter of participants cannot define or have not heard about biosimilars before.

- In addition, 37% of prescribers are unaware that clinical trials in one indication may lead to the approval of a biosimilar in multiple or all indications of the reference product.



A clear naming scheme would facilitate physicians' prescribing and the monitoring of biologic medicines, including biosimilars:

- Respondents think that having the same International Non-proprietary Name (INN) for two medicines implies that these medicines are structurally identical (54%) and have been approved for the same indications (61%),

- When prescribing biologic medicines, 32% use both brand and non-proprietary name (INN) and 30% of physicians surveyed exclusively use the brand name, while 24% exclusively use the non-proprietary name. Prescribing by INN may lead to patients receiving a medicine not intended for them by their physician.

- Similarly, when reporting adverse events, 54% of prescribers use both brand and non-proprietary names, while 29% only report the brand name and 17% only communicate the INN. Results show that using the same INN for two medicines can be misleading and may lead to false attribution of adverse events.

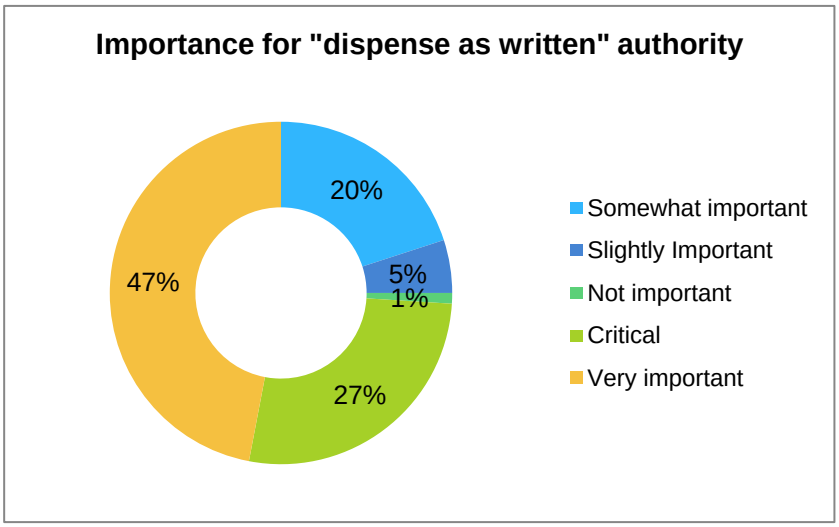
- 47% think that patient can safely receive either medicine, but only 39% agree that these medicines could be safely switched during treatment.

The use of distinguishable INN for all biologics, including biosimilars, is therefore critical to make sure that patients receive the medicine intended by their physician, and facilitate patient safety through effective pharmacovigilance.

Physicians' authority in the treatment of patients should be respected:

- Physicians are very serious about their leading role in deciding whether a patient should receive an originator biologic medicine or a biosimilar. 72% of prescribers consider it "Critical" or "Very Important".

- As a consequence, a majority considers it "critical" or "very important" that the mention "Dispense as Written" on prescriptions should be respected (74%) and that it is "not acceptable" for a pharmacist to determine which biologic medicine to dispense at initiation of treatment (62%).



These results contribute to the ongoing debate concerning biologic medicines and biosimilars and suggest a need for policy changes:

- **Distinct International Non-proprietary Names for biologic medicines, including biosimilars, would contribute to better identification and traceability of all biologic medicines;**
- **Physicians' authority and choice to prescribe either originator biologic medicines or biosimilar(s) should be respected.**

In addition, the education of physicians continues to be a priority requiring further dialogue and collaboration between physicians, authorities and the healthcare biotech industry.

For further information, please contact Michael Reilly, ASBM Executive Director (Michael@safebiologics.org) and Marie Blanchard, EuropaBio Healthcare Officer (m.blanchard@europabio.org).