Italy

Survey on Biosimilars

The Italian IBD association A.M.I.C.I Onlus and the Italian Group for the study of Inflammatory Bowel Disease have presented the data obtained from a recent survey on knowledge and use of biosimilar drugs. Results show an alarming lack of information about biosimilars drugs. The scientific community and patient organisations deem that an awareness campaign is undelayable in light of the development of the new innovative drugs.

Biosimilar drugs are safe and have great effectiveness and quality: as highlighted by a recent proposition paper by AIFA (Agenzia Italiana del Farmaco: Italian Drug Agency), these drugs grant equal access to treatments and play a key role in healthcare cost sustainability and therapy innovation.

However, less than 50% of patients (46.3%) know about the existence of this treatment, whereas the vast majority has either never had any information about biosimilar drugs or declared to know nothing about it (respectively 45.1% and 8.5%). Furthermore, 73.9% of patients have no clear idea about the similarity between biosimilar drugs and their originator; only 10.6% of patients think that they are equal, whereas 9.2% think that they may be less safe and 12% think that they may be less effective.

For this reason, the use of biosimilar drugs is still extremely limited: only 15.7% of patients are currently being treated with biosimilars, while 14.2% have been treated with them in the past.

Knowledge about these treatments is still scarce; furthermore, patients are currently lacking sources of proper information: less than two out of ten patients (18.9%) currently in treatment with biosimilar drugs declared that they signed an informed consent form.

> **"A little more than 1 out of 10 patiens is being treated with biosimilar drugs"**

> **"Barely 1 out of 2 patients has been informed about their availability"**

A **survey made** by A.M.I.C.I. (IBD Patients Association) in collaboration with the *Italian Group for the study of Inflammatory Bowel Disease* (IG-IBD) involved approximately 1.800 IBD patients (72% treated in hospitals, 23.4% in universities and only 4.7% in private centers) from different Italian regions.

Survey data. The data highlight many problems regarding the knowledge about biosimilar drugs and the similarity to their originator. 57.6% of patients deem their own knowledge about biosimilar drugs as insufficient; 30.1% think to have been sufficiently informed; only 9.6% feel they are knowledgeable about them, while 2.5% believe to have excellent knowledge.

It is important to highlight that patients who feel sufficiently informed about biosimilar drugs (41.1%) are more likely to consider their employment as a useful resource to reduce healthcare costs. The survey also examines the level of compliance among patients treated with these therapies. Only

5.7% of patients refused treatment with biosimilar drugs; this refusal has been caused by fear of side effects (38.2%), fear of it being less effective than their current treatment (14.6%), or both (25.5%). It is important to underline that overall 6.5% of patients refused treatment with biologic drugs, due to fear of side effects (45.5%), but also due to previous ineffectiveness of this type of treatment (34.9%).

As stated by Dr. **Ambrogio Orlando**, IBD Operational Unit Supervisor at the A.O. Ospedali Riuniti "Villa Sofia-Cervello" hospital in Palermo, "the use of biosimilar drugs is an important and vital matter, especially with the ongoing researches and developments of new, extremely expensive treatments for IBDs leading to the necessity to free economic resources in order to sustain IBD healthcare costs. The survey data show extremely useful information that must be taken into account when deciding on the future strategies to improve patient awareness and their knowledge about the existence and employment of biosimilar drugs. Compared to Northern European countries, where the employment of biosimilar drugs reached 80-90%, Italy is still far behind. Given the imminent deployment of new IBD biosimilar drugs, I believe in the necessity of an information campaign aimed at improving patient knowledge on this topic, in coordination with patient associations and Scientific Societies".

"Less than 2 out of 10 patients signed the informed consent form"

Following this survey, IG-IBD (a scientific society and an important reference in dealing with the management of IBD patients) highlighted how "biosimilar drugs should be considered as efficient and safe as their originator, if this equivalence has been proved by studies carried out according to EMA rules. Consequently, the extrapolation of indications is acceptable if the biosimilar drug passes one or more of the obligatory tests needed for the approval of its originator and if the regulatory agencies approve it for the same therapeutic indications".

As stated by Professor **Alessandro Armuzzi**, general secretary of IG-IBD, "patient knowledge about biosimilar drugs should be promoted through education and refresher courses, aimed at encouraging informed choices, with the help of patient associations when possible. A biosimilar drug approved by the EMA should be considered as safe as the originator drug; however, extremely large scale observational studies are still necessary to monitor its long term effects. If biosimilarity has been confirmed, every biosimilar drug can be considered interchangeable with its originator, thus switching from the originator drug to a biosimilar with the same molecule is acceptable. However, switching from a biosimilar to another or switching multiple times should be avoided in absence of any direct and specific proof of the effectiveness and safety of this process. Automatically switching a patient's therapy should be avoided, too: since the physician is the only person accountable for the prescription of a biosimilar drug, this responsibility cannot be delegated to another stakeholder. The switch from an originator to a biosimilar drug should follow an adequate patient education process and require the patient's consent".

Left to right: Prof. Armuzzi, General Secretary of IG-IBD (Italian Group for the study of IBD), Salvo Leone (AMICI Director and EFCCA President), On. Elena Carnevali, XII Social Affairs Commission of the Chamber of Deputies, Ester Maragò, journalist