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Austrian medicines authority positive towards biosimilar interchangeability

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Clinical evidence supporting biosimilar use is growing and for the first time, the Austrian Medicines and Medical Devices Agency takes a positive position on interchangeability. They now state that prescribing biosimilars to treatment-naïve patients and even a change from originator to biosimilar is appropriate, provided it is done under physician's supervision.

Keywords: Austria, biosimilars, interchangeability

In light of the clinical trials leading to the authorization of infliximab biosimilars, PLANETRA and PLANETAS and the recently published NOR-Switch study [1], the Austrian Medicines and Medical Devices Agency takes a position in the state-wide journal of the Austrian social insurance for health system payers gives doctors an updated, more positive opinion about the controversial issue of interchangeability [2].

Decisions related to the interchangeability and/or substitution of biosimilars rely on nationally competent authorities and are outside the remit of the European Medicines Agency (EMA). Individual nations independently decide if a biosimilar should be regarded as suitable for switching. To decide if patients' medication can be switched from the originator to a biosimilar, European Union (EU) Member States have access to the European network of data and scientific evaluations performed by EMA in order to substantiate their decision. As such, the decisions made by the 28 EU Member States rely on their respective national authorities, which could lead to different approaches being adopted by each Member State.

In general, there appears to be broad disapproval of automatic biosimilar substitution by pharmacists without the involvement of doctors [3]. Following concerns from physicians, in 2013, Austria made reassurances that no automatic substitution of a reference product with a biosimilar on the pharmacy level will take place, but that, in accordance with EMA such a decision will always involve a well-informed physician [4]. At that time and acting as a representative of the Austrian Medicines and Medical Devices Agency, the author of this paper, Dr Baumgärtel, recommended that there was a good opportunity for Austrian doctors to increase the uptake of biosimilars by the Austrian health system through promoting their use as starting treatments for new patients, rather than by switching existing patients' therapies to biosimilars [4]. This was based on previous research carried out by the Austrian social insurance system following the introduction of generics. This showed that when a new patient's treatment was started with generics, this had a marked effect on increasing a health systems' generics usage [5], so the same can be expected from biosimilars [3].

It is expected that doctors are likely to come under pressure to select treatment with biosimilars to save money for the public health system [4]. In Austria, biosimilars are priced in the same way as generics. This means that, in a complex system of price reductions, after biosimilar market entry, biosimilars must be priced at 48 to 60 per cent below the cost of the originator, allowing room for substantial savings.

Fortunately, there is now an ever-growing bank of safety and efficacy data related to switching that comes from clinical trials and pharmacovigilance databases for biotechnology products. These include recombinant growth hormones, erythropoietins, granulocyte colony-stimulating factors [5], and more recently data for monoclonal antibody biosimilars like infliximab [1]. As a result, Austria will now take the next step, and open the possibility of switching to biosimilars.

For the first time, the Austrian Medicines and Medical Devices Agency stated following official position: 'Biosimilars are high-tech and high quality products. They are authorized within the framework of European centralized procedures, tested according to highest state-of-the-art knowledge and are assessed to strictest and up-to-date points of view. Prescribing biosimilars to treatment-naïve patients as well as even an exchange of the biosimilar for an originator biological is appropriate, provided that this is done under supervision of the prescribing physician. Data from recent studies, and from safety monitoring and pharmacovigilance trials, are already leading us in a positive direction towards increased biosimilar uptake and interchangeability as well. We expect pronounced evidence to increase even further in the months and years to come' [2].

This position statement is now expected to further increase the uptake of biosimilars and the acceptance of the idea of interchangeability in clinical care. There may also be benefits seen in reduction of the ever-rising costs experienced by Austria's health system.

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References 1 to 6 can be found on page 47.

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