The use of biosimilars in rheumatological therapeutical indications

Statement of The Finnish Society for Rheumatology

Summary in English

1. Original biologicals and their biosimilars are used when the patient does not respond to or tolerate conventional synthetic antirheumatic drugs (csDMARDs).

2. The use of a biological drug (both original drug and biosimilar) of each individual patient should be based on a benefit risk ratio assessment by a specialist who has experience in the use of biological medicinal products. Assessments should include age, present and earlier co-morbidities, other drugs, risk for infections and existing functional ability.

3. The price of the drugs must not be the only criteria for choice of drug.

4. For patients who are treatment naive regarding biologicals, either an original or a biosimilar can be initiated on the same rationale. Identical pre-examinations are applied for original and biosimilar drugs.

5. The switch of an original medicinal product to a biosimilar should be based on a decision made by the treating specialist and after having informed the patient thoroughly. The switch should not be done before efficacy and tolerability of the original drug has been established (not earlier than 3 months).

6. It is recommended that drug trough concentration and anti-drug antibodies are measured before switching to a biosimilar.

7. Substitution at pharmacy level is not acceptable. There is not enough evidence of the safety of such a substitution. Upon the switch, the patient will need guidance and training in the use of administration devices (syringes/autoinjectors), as they may be different.

8. As biosimilars and their reference products have the same non-proprietary name (INN), the commercial brand name should be used in prescription and delivery of the prescribed drug.

9. Extrapolation. The regulatory authorities do not require extensive clinical trials for biosimilars in all therapeutic indications as performed for the reference (original)

drug, in order for the biosimilars to remain cost-effective. The Finnish Society for Rheumatology accepts the praxis of not requiring prospective controlled trials in all patient groups (indications). Therefore, in these patients (post-marketing) especially in children, safety and efficacy parameters should be followed, preferably using prospective, structured (risk management) study plan.

10. Immunogenicity of biological medicinal products. All biological medicinal products are immunogenic. It is recommended that drug trough concentration and anti-drug antibodies are measured at times, especially in patients who experience adverse effects or secondary treatment failure.

11. Traceability of the original and biosimilar biological drugs should be enhanced in order to identify the specific product and its batch number, as required by the Finnish medicines agency and drug suppliers. For the time being, the use of biologicals is registered into local databases and the identification of patients may therefore be difficult. The regulatory authorities have not established a systematic follow up requirement of patients treated with biologicals. This could be performed by utilizing a nation-wide registry. Such registries are supported by public funds in several countries. The current Finnish registry for biologicals in rheumatology, originally established by the Finnish Society for Rheumatology in year 2000, is not yet sufficiently detailed due to lack of funding.

A nation-wide registry with good coverage for patients using biologicals would improve structured follow-up-, regulation requirements and traceability, would improve monitoring of efficiency and safety, as well as promote scientific research and the assessment of cost-effectiveness. Regulatory authorities responsible for the safety of medicines and organisations responsible for the treatment of patients should contribute to funding of such a registry.

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