Académie nationale de Pharmacie

Press release of November 18th 2020

BIOSIMILARS, insulins, heparins and G-CSF

The Academy supports substitution by pharmacists and defines the framework conditions

Validated by the Council on November 18th 2020

Biosimilars are biological medicinal products for which the original patent has expired, and which, like any other medicinal product, must obtain a Marketing Authorisation (MA) from the EMA[i] or the ANSM[ii] guaranteeing their quality, efficacy and safety of use.

While the Social Safety Financing Scheme (SSFP) is currently being examined by Parliament, the National Academy of Pharmaceutical Sciences (NAP) would like to contribute to the debate on its initial conclusions.

The Academy believes that there are no sound scientific arguments to challenge the right of substitution of biosimilars by dispensing and hospital pharmacists in the following cases:

At the beginning of treatment

-when it is possible to substitute a biological drug with an "identical biological" one; that is, when a similar biological drug has the active ingredient and the finished product coming from the same production line as the reference product.

Moreover, since the scientific publications currently available have not demonstrated any risk of immunogenicity, and given the conditions of use of these drugs, **the Academy believes that by the pharmacy and hospital pharmacist may also substitute them during treatment for certain classes of organic drugs, in particular**:

- Insulin
- Low molecular weight heparins (LMWH);
- Nonglycosylated G-CSF3 (Granulocyte-stimulating factor or Granulocyte-colony-stimulating factor).

Pending further advice on other therapeutic classes, **the Academy recommends that the competent health authorities (e.g., the ANSM or the Ministry of Solidarities and Health) draw up a positive list of organic drugs (similar and**

biosimilar ingredients) authorized for substitution (excluding herbal remedies and bio-identical ingredients) by the pharmacy and hospital pharmacists.

The Academy believes that the prescribing physician should be informed *posteriori* of the dispensing of any biological drug and of a substitution by a biosimilar, by means of the "Dossier Médical Partagé" (DMP) and the "Dossier Pharmaceutique" (DP), for example. **The Academy recommends that patients receive appropriate information on biosimilars** and substitution from the dispensing pharmacist and the hospital pharmacist.

Finally, the Academy emphasizes the need to ensure the traceability of any biological product (princeps or biosimilar) intended to contribute to a better understanding of the clinical results of each biological drug, its undesirable effects and possible problems of immunogenicity and/or loss of efficacy.

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[i] European Medicines Agency
[ii] National Agency for the Safety of Medicines and Health Products