French Biosimilar Law – No generics-style substitution policy:

In December 2013, the French Parliament passed into law the 2014 Social Security Bill (LFSS) which contains provisions to permit a restricted form of pharmacy-level "substitution" for similar biological medicines. Importantly, the law limits any substitution of similar biological medicines to those patients who are about to commence treatment. The law is clear that patients who have already started treatment on a biological medicine must not have their medicine substituted by a pharmacist.

The new law has received attention across Europe. Some of the recent press coverage, however, has been potentially misleading by suggesting that France is introducing a "generics-style" substitution policy. This is not the case.

EBE believes that it is important that industry, patients and policy makers understand how the measure differs from common generic substitution policies.

The new French law implicitly acknowledges that biosimilars cannot be regarded as interchangeable with the originator product (or with each other). This reflects the fact that such medicines are similar but not identical to each other, and that these medicines have not been assessed in the EU against any accepted scientific standards of interchangeability.

It is because similar biological medicines cannot be regarded as interchangeable, that the law strictly limits any substitution to patients who are receiving their first prescription for the medicine. Having commenced treatment, the law is clear that the pharmacist should ensure that the patient receives the same medicine whenever a prescription is renewed.

In this sense the French law is clearly different from the substitution policies that are applied to generic medicines where patients can often switch between different brands of the same medicine on multiple occasions.

Because the French law permits substitution for initiating patients only, a number of measures will need to be put in place to protect patients from having their medicine substituted after they have commenced treatment. For example, the law allows for prescribers to write on the prescription "initiating treatment" or "no-substitution – continuing treatment". The law also allows for prescribers to state that "no substitution" should occur, even for patients initiating therapy, where the physician believes this to be in the interests of the patient.
Pharmacists will also have to inform prescribers where a substitution has been made and record the full details of the medicine dispensed.
The regulations governing the implementation of the law will be specified via a Decree to be drafted in 2014. Amongst other things this Decree will define the precise conditions under which a pharmacist may substitute a biological medicine, the criteria for determining which medicines may be substituted for each other, and the measures required ensuring that substitution is limited to initiating patients.

A government established taskforce will meet during 2014 to discuss the content of the Decree and other matters concerning biological medicines in France. The taskforce membership comprises representatives from the Health and industry ministries, patient bodies, the medical and pharmacy professions, the pharmaceutical industry and the French National Medicines Agency. The pharmaceutical industry will be represented by AbbVie, Amgen, Hospira, Ipsen, MSD, Roche and Sanofi.

EBE Position

EBE believes that the measures currently proposed are unlikely to be sufficient to protect patient safety and minimize the risk of inappropriate substitution. Much more work needs to be done in the Decree and additional safeguards will be needed as these medicines are not considered to be interchangeable.

Importantly this includes measures to ensure that prescribing is by Brand name. This would allow pharmacists to identify the intended prescription in case it is unclear whether the patient is naïve or already on treatment. In addition up-to-date electronic patient medical records for all pharmacists at the point of dispensing must be available to ensure full information about past prescriptions and traceability in case of adverse events.

Furthermore, EBE believes that is essential that the precautionary principle be evoked in all cases. Specifically should a prescriber omit to indicate whether a patient is initiating or continuing treatment, no substitution should be permitted.

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