Hope and concern

The ancient way of curing disease was the administration of natural products to the patient. The next step in drug discovery resulted from advances in chemistry. After isolation of natural active ingredients, synthesis in the laboratory of identical or variants ensued. Thereafter, development of therapeutic artificial molecules augmented our pharmaceutical armamentarium. However, polypeptides or proteins such as monoclonal antibodies can not be produced in vitro. Genetic techniques were evolved to cover this scientific field. These products are produced in living organisms and therefore such products are called biologic drugs or biologicals.

Marketing of a new drug (whether biological or chemical origin) is protected by a finite patent which expires at 20 years since the application. After patent expiration, other pharmaceutical companies have the right to reproduce the drugs which reach the market at a lower cost than the first-original one. The similar chemical drugs are called generics. The similar biologic drugs derived form a special category and are called biosimilars.

Biosimilars are biological macromolecules. It is essentially impossible to reproduce an identical to the original biosimilar. Although the proteins consist of the same peptide sequence, the post transcriptional modifications and differences in purification and processing result in a slightly different final product. This inherent variation, although perhaps of no clinical significance has triggered the development of special requirements for their approval supported by relevant legislation. Part of the comparability proof is a randomized clinical study comparing the biosimilar to the innovator for at least one common end-point. . Each country has its own legislation in Europe, however all of them obey to the EMA (European Medicines Agency) regulations and law which controls each country’s drug legislation in Europe. The reason for development and accepting biosimilars is financial. It is hoped that competition among producers (pharmaceutical companies) would lower the usually very high prices. This would result in reduced therapeutic expenses covered either by the patient or the health system of each country.

Responsibilities of pharmaceutical companies are described as pharmacovigilance. This is achieved by post-authorization studies testing safety and immunogenicity. An expert is appointed in each pharmaceutical company to collect and monitor such data. Every biosimilar product should be easily tracked and identified at the clinical level (traceability) so that useful information is not lost. In order to achieve that, three characteristics must be available : the INN, the brand name of the biosimilar, the batch number. These characteristics are to be stored at the dispensing pharmacy long term in order to relate any to the proper batch. In addition, physicians are required to provide the brand name of the prescribed biosimilar, contributing to the identification of efficacy and safety this way. Pharmacist are also discouraged to substitute the prescribed biosimilar. Hence the question of when interchangeability is permitted remains to be determined.

Collaboration of pharmaceutical companies, doctors and pharmacists will lead to the proper use of biosimilars for the benefit of the finances of health systems and indirectly for the benefit of the

patients.

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