

Interchangeability of biological drugs: Considerations about the approval of biogeneric formulations in Chile Intercambiabilidad de medicamentos de origen biológico (biofármacos): Consideraciones acerca de la aprobación de formulaciones biosimilares (biog

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Once drug patents expire, the health authorities can approve the registry of similar products. They must request to the manufacturer, the bibliographic background of the original product and the analytical results that certify drug quality. An inspection of the premises of the manufacturer is also required. The main goal of this approval is to decrease cost, considering that the original product is usually more expensive. This is a current situation due to the imminent expiration of the patents of many biopharmaceutical products. Therefore, in Chile, the Public Health (ISP) and the Ministry of Health should consider that for this kind of products, until now, there are no interchangeable generic drugs, and that the similar drugs that are offered have a different chemical composition, since they have been manufactured through different processes. In the case of biological drugs (e.g. erythropoietin, somatotropin, heparin) the quality and homogeneity depend from the manufacture process. |