# Trends and challenges in biosimilars pricing and reimbursement policies in Europe and beyond

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Biosimilars policies are more controversial than those for generics. However, it is only a question of time before progress in biosimilars matches that of generics worldwide.

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Healthcare systems worldwide are under increasing pressure due to the high prices of innovative drugs, especially for the treatment of cancer and chronic hepatitis C, and the ongoing economic crisis [1]. The costs of research and development for new medicines and patent protection have led to high prices throughout the pharmaceutical industry [2]. However, patent expiration of the first biological medicines, e.g. epoetin, filgrastim and somatropin, allowed biosimilar market entry, generating significant savings with no loss of quality, safety or efficacy [3, 4], as was previously observed for chemically-derived medicines and their generic copies [5]. The imminent introduction of several biosimilar monoclonal antibodies (rituximab and trastuzumab among the first) is expected to increase affordability for cancer treatments [6] and to further blur the line between manufacturers of brand-name drugs and copycat medicines. Increasing numbers of firms known for innovative drugs are turning their hands to producing biosimilars, as the cases of infliximab, etanercept and insulin glargine have recently showed [7].

Generics policies have been discussed in the literature for decades [8-11], while the most appropriate approach for biosimilars is a more novel and controversial topic [12-14]. Although Europe can claim the greatest experience (the European Medicines Agency [EMA] approved the first biosimilar in 2006 [15]), other nations are catching up. The US has recently developed a transparent list of licensed biosimilars and interchangeable biologicals, called the *Purple Book* [16], while Australia has extended its substitution policy from generics to biosimilars [17]. Despite recent progress, comparative and systematic evidence on biosimilars policies is lacking. This issue of *GaBI Journal* aims to address this knowledge gap through two large surveys [18, 19].

The first survey manuscript [18] was conducted by European Biopharmaceutical Enterprises (EBE) and examined policies for off-patent biologicals in 32 European countries (the EU-28 plus Norway, Serbia, Switzerland and Turkey). The survey investigated policies in the areas of Health Technology Assessment (HTA), tendering, internal reference pricing, International Nonproprietary Name (INN) prescribing, substitution, interchangeability and quotas. Eight out of 32 countries surveyed required HTA for biosimilars, while tendering on biologicals was widespread (81% of cases, 26 out of 32 countries). Almost half of the countries applied internal reference pricing to biosimilars, but only two countries established therapeutic groups (at the 4th level of the Anatomical Therapeutic Chemical [ATC] classification system). One third of the countries in the survey adopted INN prescribing, but half exempted biological medicines and the use of quotas for increasing biosimilar uptake was limited (22% of cases). Finally, although in most cases physicians still play a key role in treatment decisions, substitution occurred in 19% of the countries and was especially prominent in Eastern Europe. Furthermore, only half of the surveyed countries established an official position on interchangeability.

The second survey [19], Dr Vogler and colleagues investigated pricing, tendering, substitution and INN prescribing policies for biosimilars in 42 countries (the EU-28 plus countries within the European region as defined by the World Health Organization, Canada and South Africa). The similarities and differences between policies on generics and biosimilars were also explored. The results showed that biosimilar price link, where the biosimilar price is set at a fixed percentage of the originator price, has been adopted in only half of the countries in which a generic price link was already in force. Tendering appears to be an effective instrument to generate savings for payers, however, it is mainly applied in the inpatient sector. While generics substitution is in place in most of the surveyed countries, substituting a biosimilar with an originator at the community pharmacy level is permitted only in some countries, mainly in Central and Eastern Europe. Moreover, according to the authors, although INN prescribing appears to be widespread (81% of cases), it is mandatory only in one third of the countries.

Both surveys [18, 19] reveal significant variation in biosimilar policies in Europe. However, while Dr Vogler and colleagues promote similarities between generics and biosimilars policies [18], the EBE (European Biopharmaceutical Enterprises) report suggests there is a need for unique policies that reflect the individual nature of biological medicines [19]. Incongruous findings on substitution and INN prescribing policies between the two studies also highlight the need for further clarifying research. Yet, both research groups [18, 19] agree on the importance of patient trust and physician engagement for a successful strategy to promote biosimilars [20].

In conclusion, one of the most important challenges for policymakers will be establishing effective measures to enhance biosimilar uptake, which will generate savings to fund innovation and ensure the sustainability of healthcare systems. Lessons from generics, along with recent biosimilar experience, should be considered to avoid repeating past mistakes and expected loss of savings. It seems to be only a question of time before progress in biosimilars matches that of generics, and not only in Europe [12].

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