MARKET RESEARCH/INDUSTRY ASSOCIATIONS

European report calms common concerns

Commonly voiced concerns around pharmacy substitution of biosimilars, as well as a lack of traceability when prescribed by international non-proprietary name (INN), have largely been allayed by a major market review conducted by market access committee of the Biosimilar Medicines Group within the Medicines for Europe off-patent industry association.

Discussing the key findings of the review of policies in 31 European countries that draws on information provided by national associations and member companies, Medicines for Europe's director-general, Adrian van den Hoven, told **Generics *bulletin*** that while substitution of biological medicines at the retail pharmacy level was typically forbidden in Europe, it was legally permissible in a handful of countries.

However, he pointed out, even in the nine surveyed countries in which pharmacy substitution was not forbidden under law, the review had found that such switching by pharmacists without consulting the prescriber was rare. And in every case, such substitution could be prevented by the prescribing physician or refused by the patient when informed of the pharmacists plan to switch.

Similarly, fears that prescribing by biological drugs by INN would render it difficult to track usage for pharmacovigilance purposes had proven largely unfounded. "Even if prescribing biologics by INN is theoretically possible in some smaller European countries," he observed, "it is not done in practice." "Biosimilars remains a branded market, which is important, because policymakers need to think about how to persuade physicians to prescribe these lower-cost products," van den Hoven stressed. Potential inducements to prescribe biosimilars could include incentives and quotas, he suggested.

As Figure 1 shows, several of the 31 countries lack legislative or less formal measures to promote the prescription of biosimilars.

The Biosimilar Medicines Group's 2017 market review – which is intended for distribution to the association's members as well as to external stakeholders – covers seven main topics: availability, pricing systems, tendering, reimbursement systems, and policies affecting physicians, pharmacists and patients.

As of January 2017, most of the longer established biosimilars – somatropin, epoetin, filgrastim, infliximab and follitropin alfa – were available widely across Europe.

Biosimilar insulin glargine was on the market in more than two-thirds of the 31 countries, and biosimilar etanercept in around half.

Pricing of biosimilars is regulated in all but Denmark, Germany, Sweden and the UK, and even in those countries, mechanisms such as tendering and reference prices are used to monitor and influence prices.

Just over half of the surveyed countries employ external reference pricing, while setting maximum biosimilar prices at a percentage discount to the reference brand is commonplace.

One positive note from the review, van den Hoven outlines, was such pricing discounts were universally lower than the 50%-plus price gap between generics and reference brands usually seen in the small-molecules sector. Given the prevalence across Europe for biological tenders in the hospital sector, he said it was vital that pricing regulations did not suffocate competition before it could take hold.

Most European countries source biosimilars for their hospitals through tenders, the review shows, but there is wide variation in the models used between national and regional models, including bidding processes run by groups of hospitals. Regardless of the model used, van den Hoven explained, Medicines for Europe opposed single-winner national tenders, as these excluded players from the entire market.

Citing a recent agreement in Italy as an example of how competition between multiple supplies could be built into tender systems (**Generics *bulletin***, 13 January 2017, page 6), van den Hoven said single-supplier deals could prove particularly problematic when market uptake was higher than anticipated, such as for etanercept in Europe.

Despite such promising market developments, van den Hoven expressed disappointment and surprise at the review's finding that nearly half of the 31 countries had not developed information and educational materials on biosimilars aimed at patients. "There is still a lot of work to be done in this area," he recognised, stressing that the European Commission and the European Medicines Agency had made a guide for patients available in several languages.

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Country	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Iceland	Ireland	Italy	Latvia	Lithuania	Malta	Netherlands	Norway	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Switzerland	Turkey	UK
16. Is INN prescribing allowed in your country? (chemical and/or biological medicines)																															
Yes		✓	✓	✓	✓	✓	✓[1]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓
No	✓																										✓				
17. If INN prescribing is allowed: - is there a specific guideline/ policy excluding biological medicines?																															
Yes		✓[2]		✓			✓		✓	✓[3]	✓[4]	✓	✓		✓	✓			✓		✓		✓[2]	✓[7]	✓[8]		✓		✓		✓
No			✓		✓	✓		✓						✓			✓	✓[5]		✓[6]		✓				✓				✓	
18. If INN prescribing is allowed and biological medicines are not excluded: - is it applied to biological medicines?																															
Yes								✓[10]						✓			✓[11]	✓[12]												✓	
No			✓[9]		✓	✓																✓[13]				✓[14]					
19. Are measures in place supporting the prescription of biosimilar medicines?																															
Yes, legislative measures								✓	✓			✓						✓													
Yes, recommendations		✓					✓		✓	✓	✓	✓	✓			✓			✓	✓	✓	✓	✓	✓		✓	✓	✓			✓
No			✓	✓	✓	✓								✓	✓		✓								✓				✓	✓	

Figure 1: Prevalence of prescribing by international non-proprietary name (INN) in 31 European countries (Source – Medicines for Europe)