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PERSPECTIVE

Substantial savings with generics in Austria – and still room for more

Christoph Baumgärtel, MD, MSc

Austria has seen considerable savings with generics, due to its unique pricing system. Generic medicine penetration is, however, not as advanced as in other European countries. Additional savings could be made, provided certain measures are implemented.

Keywords: Austria, generics, price

Generic medicinal products are subject to detailed authority assessment in Austria, including the thorough examination of safety and efficacy data. The competent medicines authorities in Austria, and in the European Union (EU), will only issue authorization for their respective markets if all applicable legal and scientific requirements are fulfilled. It is now obvious for most experts in the fields of clinical prescribing and dispensing, after more than 30 years of worldwide experience with generics, that generic drugs present a safe and efficacious alternative to established medicinal products [1, 2]. They are rigorously tested and their safety and efficacy is continuously controlled.

In contrast to originator products, which usually undergo an expensive and protracted development that can take up to 15 years, the development of generic drug products is a relatively quick and inexpensive process. This allows generic drugs to be sold at a lower price. In fact, the increased use of generic medicines is essential to sustain healthcare systems faced by an ever-increasing pressure on resources [3, 4]. Ageing populations and the continued launch of new premium-priced medicines, priced at over Euros 70,000 per patient per year or course are some of the factors causing these pressures.

Austrian health insurance will pay for a patient's medicine if that medicine is listed in the so-called *Erstattungscodex* (Austrian reimbursement code). The Main Association of Austrian Social Security Organisations decides whether a new product will be listed. To do this, they assess efficacy and value of a new medicine by conducting a pharmacological evaluation, a medical-therapeutic evaluation and a health-economic evaluation. Before a medicine can be listed, its therapeutic value is compared with that of existing medicines, and average prices for those medicines across the EU are taken into account. For generics, this procedure is an abbreviated one and follows fixed, unique rules.

The moment the first generic drug enters the market; it has to be at least 48% below the price of the originator. This price reduction has gradually increased – from 44% in 2004, to 46% in 2005, finally reaching 48% in 2006. If the company that produces the originator wants it to stay in the reimbursement code, it will need to decrease the originator's price by 30% within three months. When a second generic drug enters the market, it will need to be priced 15% below the price of the first generic drug to become listed; a third generic drug must be priced at an additional 10% below the price of the second generic drug. Remarkably, the price of the originator and also of the first and the second generics must again go down to the price of the third generic drug within three months if they are to stay listed. At this point, prices are 60.2% below the former originator price. However, this does not mean that every product after that will have the same price forever; every marketing authorization holder can, and usually will, lower the price again, to have a prescribing advantage. Further price decreases are often seen down to -80% or -90% of the former starting price of an originator.

It is estimated that Austria currently achieves savings of up to two billion Euros a year thanks to cheaper generics and their price lowering effect on originators [5]. It was reported recently that Austria's healthcare payers could have saved an additional quarter of a billion Euros in 2011 if physicians had prescribed generics to all patients whenever they were available [6, 7]. This is only theoretical, however, as it would mean a 100% generics penetration rate in the replaceable segment. Taking into account a more realistic generics penetration rate of 75%, a more likely saving would have been Euros 150 million. The generics penetration rate in Austria is currently slightly above 40%.

A new study has again underlined these potential savings for Austria [8]. The nationwide cohort study showed that substituting originators with generics could save up to Euros 72 million in just three therapeutic indications: hypertension, hyperlipidaemia and diabetes mellitus. This study at the Center for Medical Statistics, Informatics and Intelligent Systems (CeMSIIS) at the Medical University of Vienna, Austria, analysed data collected from 8.3 million people across Austria between 2009 and 2012 (equivalent to 98.5% of the insured population of Austria). The study concluded that potential annual savings of 18% would be possible if generics uptake was stepped up in these three disease areas, which currently cost the annual health budget Euros 401 million.

Author: Christoph Baumgärtel, MD, MSc, Senior Scientific Expert, Coordination Point to Head of Agency, AGES Austrian Medicines and Medical Devices Agency and Austrian Federal Office for Safety in Health Care, EMA European Expert, Vice Chair of Austrian Prescription Commission, 5 Traisengasse, AT-1200 Vienna, Austria

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Health insurance companies spent Euros 231.3 million on anti-hypertensive medicines, Euros 77.8 million on lipid-lowering medicines and Euros 91.9 million on medicines for diabetes. The calculations show that substituting these medicines with cheaper generic versions could have saved Euros 52.2 million (22.6%), Euros 15.9 million (20.5%) and Euros 4.1 million (4.5%) respectively, in costs.

Importantly, some additional measures might be necessary to achieve these ambitious goals in Austria, where the generics penetration rate is currently no better than average compared with other European countries. For example, Austria has not implemented pro-generics measures such as INN (International Nonproprietary Name) prescribing, compulsory substitution, reference pricing, additional copayments for a more expensive product than the referenced price, or financial incentives to prescribers, dispensers or patients. This means that Austria mainly relies on its pricing system and on doctors prescribing generics.

These additional measures must be taken if a higher generics penetration rate and the full savings potential is to be achieved by Austria [5]:

- Enhanced training and education of prescribing physicians, dispensing pharmacists and patients
- Starting therapies with, and whenever possible, switching therapies to, generic drug products
- Creation of a financial incentive system to intensify use of generics
- Prohibition of originator rebates in kind and of all forms of free samples of originators in hospitals
- Improve counselling and guidance provision by prescribing physicians and dispensing pharmacists to encourage patients to accept generics

It remains to be seen how big the overall savings will be for national health budgets in Austria, not only with generics, but also taking biosimilars into account, as more and more of these products are now entering the market. Globally, it is expected that, over the next 10 years, biosimilars could save more than US$40 billion in health costs worldwide. Biosimilar prices are expected to be 15% to 35% below the originator biologicals prices [9]. The same savings are anticipated not only worldwide, but also just for the US market, suggesting that potential worldwide savings could be considerably higher [10]. Savings of at least Euros 11.8 billion are expected between now and 2020 with the use of biosimilars in Europe alone [11].

Regarding biosimilars, no specific data in this interesting field is yet available for Austria. However, the Austrian Main Association of Social Security Organisations has made it clear that it will price future biosimilars in the same way as they currently price generics, which means that premium priced biotechnology drugs, including monoclonal antibodies, will see pronounced price reductions of 60% or more. Since the question of substitution and switching from an originator to a biosimilar is not yet answered, it is expected that the biosimilar penetration rate in Austria will not, at least to begin with, be as high as that seen with generics. It is expected that only new patients will be started on a biosimilar, since switching for existing patients is not yet fully endorsed [12]. The saving potential in Austria could grow further with the increasing availability of new biosimilars. It is estimated that more than 300 monoclonal antibodies are in development in more than 200 indications, and that more than 20 blockbuster biotech drugs will lose patent protection by 2020. This, coupled with the fact that the use of biologicals is growing at a much higher rate than the overall pharmaceutical market, suggests there will be more room for considerable savings in Austria.

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