Interview: Robert Sauermann â?? Head, Department of Pharmaceutical Affairs, Main Association of Austrian Social Security Institutions

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05.09.2017

Tags:

Austria, Association, Social Security, Reimbursement, Regulatory Reform, Healthcare

Robert Sauermann, head of the department of pharmaceutical affairs in the Main Association of Austrian Social Security Institutions, which publishes the national code of reimbursement, provides an in-depth look into how drugs are assessed before being placed onto the reimbursement list as well as the challenges faced when negotiating with the pharmaceutical industry. Furthermore, he gives an insight into the introduction of generic and biosimilars into the market and the reform developments he would like to see enacted in the future to create a more sustainable Austrian healthcare system.

Could you please introduce to our international readers the Main Association of Austrian Social Security Institutions and the role of the Department of Pharmaceutical Affairs?

The Main Association of Austrian Social Security Institutions (Hauptverband der Ã¶sterreichischen SozialversicherungstrÃ¤ger) is the strategic and coordinating entity of the Austrian statutory insurances: health insurances, pension funds and workers compensation board. The Department of Pharmaceutical Affairs shapes pharmaceutical policy from the perspective of the social health insurances. Our main task is to publish the code of reimbursement (Erstattungskodex, EKO), the comprehensive list of all drugs eligible for reimbursement by the Austrian health insurers in the outpatient setting. It is our aim to ensure that patients have access to innovative high-quality drugs

while in the meantime maintaining financial stability of the social security system. At our department, we are working together in a diverse team of physicians, pharmacists, economists, data analysts and legal professionals.

What are the parameters for a drug to be chosen for the code of reimbursement?

When a company applies for a certain drug to be on the reimbursement list they must provide an evidence-based argument through documents and data. It is a three-step evaluation. The first step is a pharmacological evaluation, in which the degree of innovation is classified and comparator drugs are identified. The second step is a medical therapeutic evaluation in which the new drug is compared to alternative drugs already on the reimbursement list, and a justification is made if the new product provides an added therapeutic benefit, with the degree of benefit being classified as well. Lastly, the appropriate price is evaluated taking into account several aspects, such as the medical classification and the EU average price. For example â?? if a drug provides drastic improvements for patients in need, it may be reimbursed at a higher price than the comparator drug.

On a product level, a new drug which provides equal benefit to what is already on the reimbursement list can be included in the code of reimbursement if it is a certain amount cheaper. Companies are asked to provide evidence of a drugâ??s effectiveness as well as data on their expectation of the number of prescriptions as this impacts the overall healthcare budget. If the expected impact is considerable, we talk with the companies on how to ensure adequate access for patients, while containing cost increases for the system.

On the overall budget level, we are driving forward the introduction of generics as original drugs offer no therapeutic benefit over a comparative generic. The health insurances are guiding doctors to prescribe more cost-efficient drugs as this will lower expenditures in certain areas and create the much-needed financial headroom for innovation in other areas.

All in all, it is a balancing act. We must find the equilibrium between drug prices, which have risen drastically in several therapeutic areas in the last decade, and overall benefits to the Austrian patients. Thus far, we have been able to ensure quick access to relevant innovation. A recent QuintilesIMS report indicated that Austria is the sixth fastest country, behind the US, Germany, Finland, the UK and Norway, to get a drug from regulatory approval to being launched onto the market. The report looked at the average time from regulatory approval to full reimbursement access in European countries and the US in 2015.

How transparent is the department during the negotiations with the pharmaceutical companies?

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The current healthcare system ensures that access to drugs and their prices are equal throughout each region of Austria in the outpatient sector. There is an electronic workflow for company submissions. Evaluation details are accessible for the respective companies, and they can respond if there are dissenting opinions. We have transparent criteria at which price a drug can be reimbursed. If inclusion of a drug in the code of reimbursement is rejected or companies feel it has been treated incorrectly they have the option of appealing this decision in court.

What we do see is that pharmaceutical companies are not overly transparent in pricing, often not being able to concretely justify inappropriately high prices on the basis of the submitted evidence for a drugÂ´s therapeutic value. Many times, they criticize us, but our first priority must be the needs of the Austrian patients and the sustainability of the health system, not the commercial desires of a company. We are very open to discussion with the pharmaceutical industry to achieve reasonable

and sustainable prices, as long as they can provide sufficient evidence to back their therapeutic and financial claims. However, for a drug â??being newâ?• alone is not enough to be called â??innovativeâ?• and demand higher prices â?? real innovation must result in a significant added therapeutic benefit.

How important is ensuring budget caps are kept under a watchful eye?

In 2014 the European Council noted that the pricing of many new innovative drugs is extremely high compared to current European healthcare budgets and this has the potential to destabilise healthcare systems. Also in Austria in 2014 and 2015 the overall spending on pharmaceuticals rose by over five percent per year due to the introduction of only about two innovative, but expensive products. This critical situation led to an agreement between the statutory health insurances and the pharmaceutical companies paying relevant clawbacks in 2016-2018 to stabilise the system. This shows that there is a sense of responsibility on both sides.

What everyone must understand is that we have mutual interests in maintaining a sustainable health system, which is not destabilized by excessive growth in pharmaceutical expenditures due to excessive price claims. Only when we continue to ensure good access to needed medicines because we have a well-functioning healthcare system industry will we be able to generate remarkable and stable revenues in the long run. Of course, we are interested that the industry provides innovative products. This highlights the thin line we walk between giving the patients what they need and keeping all funds in check.

In which areas do you see needs for improvement and possible reform?

The hospital and outpatient setting should collaborate in harmonized prescription and procurement of drugs, and we are laying down the foundations currently for these reforms. In this context coordinated drug tendering across both sectors would be a future possibility. This could also include biosimilars and would allow companies to gain a large market share of their drug, in exchange for an attractive price that puts less strain on the healthcare system. This could be a win-win for health insurers and pharmaceutical companies. All changes should result in improved quality of pharmaceutical therapies for the patients and a more efficient health system.

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A strong generics market is a way of relieving stress on healthcare budget caps. What steps have been put in place to increase the market share of generics in the advanced Austrian Healthcare system?

In Austria, as patents expire and generic waves are launched onto the market, prices cascade with the originator being the most expensive, then the next wave cheaper and so on. At a certain point, the originator will have to equal the price of the generics. This creates a calculable environment for companies to launch products as they can easily budge, due to the lack of a tendering process.

In theory, this system and the valid principles of economic prescribing should always result in the most economical products being used, regardless of who is the producer (originator or generic). However, we have seen this is not always the case because strong marketing of the benefit of brand names is quite effective. We must continue to change the Austriansâ??, at times, sceptical mentality toward generics. Health insurances are guiding doctors by giving them accessibility to the code of reimbursement online and in their software, allowing them to access an economic tool that lists the same drugs in order; cheapest to most expensive. Furthermore, we should discuss to change the way drugs are prescribed to remove bias towards certain brands, moving from a solely brand name prescription system to one based on drug nomenclature.

How are companies incentivized to bring biosimilars onto the Austrian market?

The biosimilar market is characterized by some peculiarities. Companies make a strong argument that biosimilar prices should be elevated compared to generics due to higher development and production costs. On the other hand, when they enter the market, there are generally significantly less competitors compared to generics and price reductions start from the high initial price levels of biologicals. In Austria, with a change in legislature this past spring, the burden of the pricing cascade for biosimilars was eased in comparison to generics. We expect that this further improves market entry and access to biosimilars.

All in all, we believe that the successful introduction of biosimilars is an important key factor with huge potential for healthcare systems across the globe. This applies to Austria as well, and our aim is to promote competitive prices and that doctors across all sectors of the health care system are motivated to prescribe biosimilars.

Where do you see the Austrian healthcare system evolving in the coming years?

Overall, I believe the Austrian healthcare system allows for high quality and good access of drugs for Austrian patients. The Austrian outpatient sector offers a transparent and attractive environment for the pharmaceutical industry and patients. We envision increased collaboration of the outpatient and hospital sector, resulting in the joint procurement and tendering of treatments to create a more efficient, streamlined system.

Furthermore, we believe that international collaboration will be an important factor in the coming years. Companies are acting globally. Hence, also public institutions need to partner-up to exchange information and establish fair pricing structures and healthcare environments. Austria is now a member of the BeNeLuxA group, based on an agreement signed by the ministers of health of Belgium, the Netherlands, Luxemburg and Austria, to enhance international collaboration in the areas of health technology assessment, horizon scanning, information sharing and pricing. Hopefully, this will support us to improve processes and come up with forward-thinking solutions for Austria.

Finally, we need to continue to monitor and improve our structures. It is our task that drugs are being correctly assessed as well as optimally introduced and used in Austria. At the same time, we should also constantly evaluate the effectiveness of already existing treatments and the changing needs of the population to ensure â?? above all â?? that Austrian patients have sustainable access to the medical treatments they need.

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