# Interview: Michaela Palagyi â?? Vice-president & Head of Working Group for Regulatory Affairs and Biosimilars, Generic Manufacturers' Association of Slovakia (GENAS)

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*Genasâ?? Michaela Palagyi shares the associationâ??s pride in being an affiliate member of Medicines for Europe and how this allows them to liaise more closely with their European counterparts. She also reveals the share of generics in todayâ??s Slovak pharma market: around 60 per cent of volume and slightly less than 50 per cent of overall market value.*

**Could you please start by introducing the purpose, capabilities and scope of offering of the Generics Manufacturers Association of Slovakia (GENAS)?**

GENAS was established in 2000 and essentially represents both local generics players and those multinational generics companies with a presence on the Slovak market. Our purpose and objective is to protect, promote and ensure the common interests of our members in relation to the state authorities, public institutions and any relevant third parties.

We achieve this by assisting in the creation of the Slovak legislation affecting pharmaceuticals production, distribution and ensuring the availability of treatment to wider population of patients on the Slovak market ; by promoting the respect of ethical principles across the industry; and by advocating the economic, legal and professional interests of our members. On top of that, we are able to offer a range of bespoke technical constancy services.

Having an organization in place like GENAS enables our members to forge a common understanding of the national legislation and to speak with a single, united voice when engaging with the authorities, the media and any other stakeholders. We also play an important role in ensuring that European legislation on generics and biosimilars is correctly transposed at national level, which, for a long time, has been a core objective of many of our members.

**What links have you managed to establish with the generics industry at the EU level?**

As of the first of July this year, we have actually been awarded affiliate membership of Medicines for Europe (which is the former European Generics Medicines Association or EGA). This marks great progress of us and allows us to liaise more closely than ever with our counterparts within the European Union and third countries. Not only does this afford us a more â??official lineâ?? when dealing with the Slovak authorities, but it also positions us better in terms of being able to pool and share ideas on best practice.

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**What are your main priorities right now?**

Aside from our ongoing efforts to ensure that EU legislation concerning the generics industry is properly enshrined within the Slovak regulatory framework, we have established dedicated working groups aimed at focusing on what we consider to be critical topics for our members. Right now those topics include: regulatory affairs, biosimilars, ethics, pharmaco-economics and legislative reform. Ethical codex of Slovak pharmaceutical industry (originators and generics) has been revised in 2015. GENAS did approve new generic national ethical codex fully aligned with the ethical codex of European generic association. We are constantly focusing on fairness and ethical behavior across our market segment.

**Comparatively, just how well do generics perform in Slovakia in terms of value and volume?**

Overall generics penetration is not bad, but it could be even better. There is much scope to do much more. Presently, generics account for around 60 per cent of volume and slightly less than 50 per cent of overall market value. The key challenges that our members face are the comparatively tough pricing regime and the frequency of change to those prices. Under the current rules, we are subjected to monthly price revisions and a review of the reference pricing across the EU bi-annually. This can make it challenging for our members to plan ahead and flexibly react to the market changes.

Slovakia performs relatively well in terms of affordability of medicines and the sustainability of public health expenditure, but this is achieved through a relentless squeezing of drug prices, which is, of course, great news for the payers, but frankly makes the operating environment for generics firms quite challenging. To put this in context, Slovak drug prices are always pegged as the third lowest within the EU. Furthermore, if you are entering the market as the first generic, it is mandatory to reduce the price by at least 35 percent.

Originator firms are also subjected to these sorts of ongoing price pressures, but because their profit margins are much fatter, they are better equipped to weather such externalities. Nor do they face the sort of intense competition and race to the bottom on pricing that can often be found in the generics segment.

**Are you suggesting, then, that there should be separate legislation for generics firms?**

Actually, no. Currently, the national legislative norms seem to be aligned with the EU legislation. However, there have been some discrepancies in national legislation classified as infringement of the EU legislation in 2006. It took quite a long time to get national legislation aligned with the EU Directives in some respects. Therefore it is tremendously important to be active in legislative process and monitor compliance with the EU legislation.

Our relationship with originator developers and their association AIFP is actually good. An excellent example would be how we have been joining forces to implement the falsified medicines directive. Our common goal is to create National Medicines Verification system in due time. One area, however, where we donâ??t yet feel there is a level playing field is biosimilars. For certain therapeutic areas especially, the originators seem to be unduly protected and havenâ??t been impacted by the sort of price erosion that you would normally expect.

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We are looking forward to being able to demonstrate to the authorities the benefits biosimilars can potentially bring. We feel there is huge potential to increase patient accessibility to biologics so long as legislation encourages biosimilar usage. At a time when the insurance companies are financially stretched, this could be an excellent way to take some of the costs out of the system and enable patients to gain access to more advanced and appropriate therapies. Rather than the relentless price cutting that Slovak pharma firms are frequently subjected to, this would be a more sensible way to ensure the long-term financial sustainability of public healthcare. Right now, the country still spends considerable resources on drugs for which there are very decent substitutes that are significantly cheaper.

**How receptive is the Slovak public to the concept of generics?**

Slovak patients generally are open to the concept of generic medicine, though there is always more that can be done in terms of communications campaigns. Slovakians tend to be extremely deferential to their physicians â?? the word of the doctor is like the word of god and patients follow their prescriptions to the letter â?? so our main emphasis always has to be on getting the idea of generics drugs accepted within the local medical community itself. What we have noticed is that healthcare professionals in certain regions are much more receptive to generics than in others. There is thus a wide disparity of behavior based on geography, which we still need to surmount through well targeted information and publicity campaigns.

Since 2004, pharmacists have been obliged by law to offer the cheapest product from the reimbursement list so called â??generic substitutionâ?•. Then in 2011, INN prescription was introduced for a particular therapeutic area. Physicians have to prescribe by INN for 300 or so specific molecules. The doctor is, still able to mention the brand name in brackets. However, there is still a space for improvement.

**What are your main goals looking forward?**

We are working hard to persuade the government that generics and biosimilars are an ally and important part of the toolkit in taking costs out of the healthcare system and ensuring long term financial sustainability of public health rather than any old commodity. The fact we have a new government coalition and a new health ministry means we need to start again building the relationships with the authorities. We are keen to ensure the progress made previously is not undone.

One challenge will be in getting voice of generic and biosimilar  industry heard at a time when the new minister has many big items on his desk to deal with such as the unfortunate condition of the public hospital sector and the media interest in the issue of parallel exports and drug shortages. By comparison the pharma industry is in much better condition so not likely to be at the forefront of the ministerâ??s mind. We nevertheless have to make sure the voice of generic and biosimilar industry is well heard and will seek to leverage our new membership of Medicines for Europe and the opportunity of the Slovakian presidency of the EU to that aim.

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