EGA prioritises pursuing sustainability agreements

Supporting national associations on striking sustainability pacts, ensuring added value is rewarded and facilitating single development programmes are among the key priorities in 2016 for the European Generic and Biosimilar medicines Association (EGA), its president, Jacek Glinka, told Aidan Fry.

Jacek Glinka

When asked to list the priorities in 2016 for the European Generic and Biosimilar medicines Association (EGA), its recently-elected president Jacek Glinka needs 10 minutes just to highlight the most pressing concerns. Having created dedicated groups for both biosimilars and value-added medicines, he explains, the EGA has significantly extended its scope, ambitions and number of issues that it is tackling.

Among the key priorities outlined by Glinka during an exclusive interview with **Generics *bulletin*** are: helping national associations to negotiate sustainability agreements with their national governments; ensuring pricing and reimbursement mechanisms reward the innovation of, and investment in, developing biosimilar and value-added medicines; promoting single, global development programmes for generics and value-added medicines, as well as for biosimilars; and maintaining momentum towards manufacturing for export being allowed during the supplementary protection certificate (SPC) period of the reference brand.

Addressing sustainability, Glinka points out that while biosimilars and value-added medicines are increasingly important, generics remain "the core of the business" for most companies. "With this in mind, the role of the EGA is to make sure with every government in Europe we have a stability agreement, in which industry and the government agree on certain parameters for the market for the next three to five years," he explains.

"We are not only concerned about governments introducing price cuts and similar measures that are most negatively affecting industry, but also that they are introducing them *ad hoc*, without the proper notice or discussion," Glinka continues. Such cost-containment measures over the past five years or so have created huge uncertainty in industry that is deterring investment, including in complex products and biosimilars, he says.

Mylan's Glinka – who assumed the EGA presidency from Nick Haggar last year (**Generics *bulletin***, 26 June 2015, page 27) – observes that even industry leaders have pulled out of certain European markets or withdrawn hundreds of products that are no longer profitable. This trend, he warns, will lead towards product shortages.

"In the stability agreements, we want to have a dialogue and agree the parameters that would give us a way to consciously plan our strategic objectives for the next few years and allow us to go into new areas in a more transparent and predictable way," Glinka outlines. This, he says, is vital given that development and registration timelines for biosimilars typically run from five to seven years. "You need to have some sort of visibility what is going to happen when you are locking in money for that time," he stresses, adding that if governments tighten the screw further during that period, the invested capital may be needed simply to survive.

Pledging the EGA's support to national associations in negotiating such agreements, Glinka says the association will share best practice as local examples emerge. "We already have agreements in Belgium and the UK, and we are currently discussing others in Portugal and Spain," he notes.

"It would be good if the European Commission would advocate the idea, recognising that this is good for industry, and encourage member states to move in this direction," Glinka suggests, welcoming any support offered by the press.

Looking broadly at Europe's pricing and reimbursement environment, Glinka says he "would welcome all regulations that promote competition". "In all industries, the more competition is on the market, the better the pricing and access," he observes.

It is vital, he contends, that pricing and reimbursement systems recognise and reflect not only the value to payers and patients brought by biosimilars and value-added medicines, but also the considerable sums invested by industry to bring them to market. "Today these systems are dedicated either to new chemical entities (NCEs) or to generics – there is no room for something that adds value in the middle."

The EGA is advocating for health technology assessment (HTA) and pricing bodies around Europe to redefine their concepts of innovation to include innovation around the known compound, such as changing the delivery mechanism or release profile.

Third path on reimbursement

Alternatively, the association proposes, a "third path" should be created alongside NCEs and generics for value-added or complex products. "These products add tremendous value to the healthcare system, so it is in the public interest to figure out a way to encourage industry to bring these products to market," Glinka maintains. If governments find such a way to "pay us a bit for innovation", he adds, "it would create huge value for patients through modified-release profiles, different delivery forms such as patches, creams and sprays, or combinations that immediately improve compliance, especially for older patients".

However, he acknowledges, the minimal profit margins imposed by repeated short-term cost-cutting measures have left industry largely unable to invest in the patient-compliance studies and similar evidence that might convince HTAs of such products' value.

Including value-added, complex products and biosimilars in tender processes – such as in Andalusia and Germany – is threatening their commercial viability, Glinka warns.

"In the short term, firms have product portfolios in the warehouse. In tenders, they will do everything they can to sell them. They might even go below the cost of goods, because it is better than simply scrapping the drugs," he comments. But in the medium to long term, the consequences of such short-term savings will be severe. Manufacturers will not invest in production

lines for products with minimal or no profit margins, the number of potential suppliers will dwindle and the risk of market shortages will rise sharply, especially if a tender winner has a problem with a key facility. And with few suppliers left, prices will probably rise.

Pointing out that huge financial penalties for failure to supply in tender contracts are a further disincentive to compete, Glinka says the EGA and its national member associations are making some headway. In Germany, he notes, the health insurance funds have entered into a dialogue, even if they have not as yet made major changes to their tender processes.

As pharmaceutical companies increasingly adopt hybrid models situated between the generics and originator worlds – no leading company is now a pure-play generics specialist, Glinka notes – the EGA is finding it has many interests in common with brands body, the European Federation of Pharmaceutical Industries and Associations (EFPIA). "It is one priority for my presidency to figure out how we can cooperate on our many common interests," Glinka proclaims, hailing the two organisations' close alliance on implementing the Falsified Medicines Directive and suggesting the cost of regulatory variations as a potential point of agreement.

Recognising the need for good-quality education and information to address physicians' concerns about biosimilar issues such as extrapolation of indications, he welcomes strong statements made by the European Medicines Agency (EMA) and other regulators that biosimilars have the same therapeutic value as their reference drugs. "But for that to be absorbed by all stakeholders who influence prescriptions – such as oncology centres, key opinion leaders and physicians – the only way is to develop a commercial infrastructure to go out and convince them," he admits. Unless other countries follow Norway's lead in incentivising switching to biosimilars, he believes prescription generation will remain the key commercial model for biosimilars for the foreseeable future.

"If the model is that governments say we have to use our salesforces to convince institutions, that additional cost has to be considered in the pricing and reimbursement systems. The governments then have to give us pricing that will allow us to solve the problem for their benefit," Glinka asserts. Even if local mechanisms promote automatic administration of biosimilars to patients, he adds, pricing must still allow companies' development costs to be recouped.

Reducing the cost of developing generics and more complex, value-added products can be achieved by facilitating single development programmes across major territories, especially the European Union (EU) and the US, the EGA maintains.

"It is just a question of regulation and political will," Glinka insists. "The US Food and Drug Administration (FDA) and the EMA have to find out what is the common denominator, what exactly is the biostudy requirement that they would both agree upon as the solution." If all the EU member states could agree to mutually recognise a regulatory decision made by one of them, this should also be possible internationally, the EGA's president insists.

Hails Commission's technical paper

Glinka commends the efforts being made by the EMA and the Commission on this front, hailing as a important first step the technical paper recently sent to US authorities by the Commission's Directorate-General (DG) Trade that calls for clinical-data requirements for complex generics and hybrid applications to be harmonised (**Generics *bulletin***, 5 February 2016, page 1).

The Commission's support for industry's proposal to manufacture for export during the SPC term also draws praise from Glinka. Stressing that multinational companies will simply build plants outside of the EU to ensure their products reach the market at the earliest opportunity, he urges the EU authorities to help industry invest in highly advanced manufacturing assets that will create skilled jobs.

"For a couple of years, we could complain nothing was happening – now it is happening," he states. "Right now, the Commission is engaging external agencies to make a proper assessment of the outcome, which we believe is a substantial €5 billion (US$6 billion) of added value. And following that, there will be a consultation and the legislative process, so it will take a year or two to come to fruition."

Pointing out that the EGA is not challenging the SPC system as a concept, Glinka warns against any attempt to broaden SPC protection as the Commission invites bids to conduct a legal review (**Generics *bulletin***, 29 January 2016, page 1). Any such broadening would, he says, harm patient access and weaken originators' spur to keep innovating. G

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