Adrian van den Hoven – Director General, Medicines for Europe

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Over the last ten years, generic medicines have increased access to medicines by over 100% in 7 key therapeutic areas and have provided massive savings for healthcare systems in Europe. In this exclusive interview with Adrian van den Hoven, director general of Medicines for Europe, we discuss the importance of the generic industry, the disparity in generic penetration among the member states and how the Value-Added Medicine Group will improve the lives of patients struggling to manage their disease.

Medicines for Europe is now trying to safeguard the price of generics. How credible is your work on this when for years generic companies have lobbied the low price of their drugs and the savings they represent for governments and HC systems?

I wouldn't say that we're trying to safeguard the price of generics, we are trying to allow competition to determine the price of generics.

It's a healthy thing and the core of the business. The concern is with pricing and reimbursement policies that really aim to achieve the absolute lowest price, even for molecules or medicines that have been on the market for many years and where there's not a lot of profitability left.

What we are really asking for (especially for some of these more commoditized products) is that we stop applying government-mandated price cutting measures. In a few countries we have clawbacks applied to generic medicines and this leads to a lot of medicines being withdrawn from the market.

Also, a lot of government-mandated price cuts are not planned and can happen overnight. That leaves our members scrambling to adjust to that new scenario where they've had no dialogue or discussion about why they are the ones financing new medicines.

When we started discussing this the authorities ignored us and now there are a lot of problems with supply, such as stock-outs. These are disruptive measures that are affecting patients.

The manufacturers sometimes face a higher cost of chemical ingredients, sometimes regulatory costs or new pharmaceutical business requirements — all of these things have added massive costs to our cost of goods.

We're now starting to have more open conversations about how there has to be sustainably priced generics and a more predictable competition driven market, especially for heavily commoditized products.

> More conversations are happening about the sustainability of having the prices so low versus very complex manufacturing, and how we can encourage manufacturers to invest more to make sure that patients and healthcare practitioners always have the medicines that they need.

What are the dangers of a generic market only driven by price? (how critical has this situation become) and where do you think the EU regulatory framework needs work to safeguard generics?

The difficulty that we're seeing is most acute in various central medicines such as anti-infectives which are heavily commoditised.

The case of anti-infectives is dramatic. We are heading deeper into dangerous waters with price cutting measures adding to the pile of suppliers already suffering from a shrinking market as prescriptions decline due to increased control of antimicrobial resistance. This is not a recipe for success as these are the essential medicines of the healthcare system.

We are looking at different solutions, hospital tenders are an example: creating tenders where the companies are encouraged to participate by having more predictability or longer lead times to build up their stock and supply to the hospitals.

Some countries are experimenting with multi-winner tenders so that one company doesn't win them all — it involves talking about the security of supply criteria, not just pricing criteria. These conversations around anti-infectives are starting to happen but not fast enough. There is a big concern over shortages especially around these essential products but also some of those hospital injectable products because of the complexity of production.

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Your Value-Added Medicine Group is a relatively new pillar of Medicines for Europe. Please explain the concept behind value-added medicines. Could this be seen as an attempt to rebrand generics?

Our Value-Added Group is aiming to bring a lot of new and exciting technology that will respond to the profound requests we have received from patients who are really struggling to manage their disease. We have the opportunity to improve a lot of existing therapies and empower patients to better manage their chronic conditions. This type of innovation will be cost-effective, more sustainable and more affordable for healthcare systems.

At the beginning, we got a lot of these questions: Are you just rebranding the same generics with a nice new label or nice packaging? I can attest that this is not the case. You can see that we are working on something new by some of the companies who are joining us, very small startups who are developing technologies for value-added medicines.

Now, what is a value-added medicine? From our definition, it's based on an existing molecule one which is normally off patent but it can be repurposed for a new indication. An example is the generic cardio products which are being tested right now as cancer medicines. Some of our members are working with cancer charities to help with this development because it's very difficult for charities to do this on their own.

Another example is where an existing medicine is used in combination with a product or device.

This could benefit someone who has to take a lot of pills in one day — the pills could be combined to reduce the burden on the patient and risk of error.

Many of our members are working on better respiratory devices for respiratory diseases as it’s very difficult for asthma or COPD patients to manage their condition.

Then there is reformulation which is what a lot of start-up companies are working on — changing the formulation of the products of the same molecule in order to reduce some of the side effects. Through extremely complex manufacturing and formulation technologies, we’re able to modify that profile and that can be very important to many subsets of patients.

Physicians from the pediatric community concerned that there isn’t enough development around established molecule pediatric/neonatal formulations. They are right, there isn’t enough and we are on it.

A big challenge is, refining the business model to give the patients access to this because in most systems in Europe a well-established molecule gets a generic or a molecule price which means it’s the lowest molecule price.

Some countries are starting to evolve on this. We’ve seen in Belgium they changed their legislation to value-added products to be approved on the Belgian pricing reimbursement system to a negotiated system. You still have to negotiate the price, so it’s not a free ride as you have to demonstrate the Value-Added. We’re seeing France making some efforts to get value-added medicines into their pricing and reimbursement system as well although they refer to them as “hybrids.” So, we are starting to see some movement slowly in Europe.

How important is the generic industry in Europe in terms of GDP, employment, production sites, exports etc?

We have calculated that we have about 190000 employees and over 350 manufacturing sites many which have their own R&D sites. So we are very important in terms of manufacturing.

The European Commission EC has recently introduced an amendment to the SPC waiver to enable generic and biosimilar companies to manufacture during that five year period for export.
It is currently going through the legislative procedure.

The EC has estimated 25000 additional jobs would be costable if this would cover exports and what we call day-one launch — stockpiling for launch in Europe.

We are working very hard for it to have the maximum opportunity to create those jobs in Europe. The EC also estimates that this would lower the prices of off-patent drugs in Europe because of the fact that we have costs associated with transfer. With a lot of good drugs, the production is outsourced outside of Europe because you cannot legally manufacture here. So if you want to export to an emerging country or stockpile for day-one launch, you will do it outside of Europe. This is a huge loss of manufacturing employment and opportunity for the region. It also adds cost and makes our drugs more expensive. This amendment to the SPC waiver could reduce costs estimated at around 3/4 billion.

This is also super important for the security of supply. So we were talking about shortages and stock-outs earlier — where you have proximity and production within Europe you can react more quickly to supply and demand. In our sector, these fluctuations in supply and demand happen very fast so having this flexibility to manufacture locally is really important making this SPC manufacturing waiver critical for European medicines supply.

We've got a few more months of tough negotiations I would say.

> When it comes specifically to generics, there is a problem in some countries with measures that harm/prevent generics from competing.

There is still a lot of disparity between EU countries and the rate of generic penetration. Which are the "good" and "bad" students, and what would you prescribe for the bad ones?

You have indeed very different rates. In the UK or Poland, there is around 75 percent generic utilization while Countries like Greece hover around at 25 percent or France 45/47 percent.

What it comes down to is — do you have the policy to encourage competition and the use of generics and biosimilars?

To me, it's obvious that governments have an incentive to do that because the more you use generic or biosimilar medicines the greater the access for the patients. In my opinion that should be the most important driver. You also get greater savings which is what concerns governments.

Germany was the country that moved first on biosimilars and to really drive biosimilar competition into its market. It is the country that has had the most benefit in terms of increased access and savings, mainly because it took on the challenge very quickly and it benefitted much more from biosimilars than other countries in the EU.

When it comes specifically to generics, there is a problem in some countries with measures that harm/prevent generics from competing.

I was recently in Greece where they have very low use of generics mainly due to the clawback tax that is usually applied [in most countries] to very expensive medicine. In Greece, they apply this to all products whether it's an expensive product or a way cheaper generic. The generic companies that are required to pay back this money on a much lower value product where you have much much lower profitability, means they have no profitability whatsoever. Thus many companies withdraw or do not even apply for the generic application. This limits competition. We have the exact same scenario in Romania.

The end result is that either the National Health Service or the patients themselves end up paying the difference between the original product and the generic product.

With biosimilars, it's a little bit more complicated because you need to have "benefit sharing." This means you need to have a system in place to encourage stakeholders to use biosimilar medicines because they must be prescribed by the physician, by brand name as they are not substitutable products like generics.

We have seen very successful models of how to stimulate competition where the prescriber is making the decision. It involves ensuring that a little bit of saving can go towards better care for the patients with additional services such as a nurse. This is something we've done in the UK and it has driven massive utilization and prescription of biosimilars, extensive savings for the NHS and more patients treated through better services.

That's like the nirvana of healthcare and now we see it is definitely doable. It was done in Germany and it's being introduced in France. These models exist they're achievable but you need someone in charge and driving that kind of system to enable that competition to go forward.

> Europe is way ahead of the rest of the world — around nine out of ten of the biosimilars used and dispensed are dispensed in Europe today.

There have been incredibly high hopes for biosimilars and a lot of hype around them. Do you feel that the biosimilars revolution has taken off as predicted?

It’s definitely taken off. It has not taken off as predicted.

We’ve had biosimilars in Europe available for patients since 2006 so they are not new. Europe is way ahead of the rest of the world — around nine out of ten of the biosimilars used and dispensed are dispensed in Europe today.

What has surprised us is that the rest of the world is so far behind us when it comes to using biosimilars especially the slow development of biosimilars in the US as we anticipated that by now their market would be much more competitive.

It’s much easier in Europe for products that are administered and dispensed in a hospital where the advantages of using biosimilars have been very clear. The lower cost of being able to treat more patients is the main driver and we are also seeing huge interest In oncology.

As mentioned before, “benefit sharing” makes things more complicated. This is something relatively new but the payers are now more used to having these conversations with professional societies of physicians and patient associations to introduce biosimilars.

Germany was really a pioneer in this regard because they established prescribing targets with additional rewards. If the physician achieved the prescribing target of a biosimilar they could provide additional services to patients paid for by the local NHS — this was really successful.

Personalised medicine, gene therapies, precision medicine etc seem to be the future – where will generics companies find their place in that environment?

You can say there will be no generic or biosimilar medicines in that space.

If you have really small patient populations and are manufacturing a very small volume of products for those patients, then realistically there is no possibility to bring generic or biosimilar competition to that space. You can get regulatory approval but when coming to the market it would be next to impossible to stimulate that competition. Our experience with biosimilars was that health insurers were incredibly slow [with the exception of Germany] and woke up to biosimilars way too late.

These are large volume, very expensive treatments for many patients.
We see that the payer isn't considering this as important but they will feel the pain when they see that, without competition, the price of these products will never ever come down.

How would you bring a generic or a biosimilar to market and actually be able to sell them at a cheaper price so that the company could recover its costs? We put the question to payers and regulators many times and none are even thinking about this.

This is a mistake. A lot of small population personalized/precision medicine, for example, are in practice, technology platforms for a wide range of subsets of diseases that are targeted and adapted to a precise genomic aspect. Our industry could easily bring competition to the platform, learn and adapt to the specific nature and develop that kind of technology at patent expiry in 10/15 years from now.

However, If the market is segmented it will be very difficult for our members to bring competition in a way that would be cost effective relative to the development costs and their volumes etc. So, there is there's a question mark out there about how to bring competition to the subsets of diseases or small patient populations and there's no answer out there for now.

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Medicine for Europe has around 70 members. Some from Europe, some that are international, some which are part of big MNC and some that are generic only companies… what unites them?

Firstly, almost all of our members have manufacturing operations in Europe. Secondly, the industry is playing a very important role in terms of increasing access to medicines. Generic medicines make up 67 percent of medicines used in Europe and that is going up year on year.

Over the last 10 years, generics have increased access to medicines by 100 percent, meaning they've doubled the access to medicines. This shows that when medicines are very expensive

they’re restricted.

Then there is the Value-Added Medicine Group where we have an opportunity to improve on existing molecules and treatments, especially in areas where there’s little new chemical entity innovation.

Patients are struggling with the management of their disease and are asking for better solutions. So it’s an exciting time. Improving access to medicines and adding value for patients are the positive and motivating factors that really bring us together.

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