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15.01.2020

Tags: USA, Generics, Biosimilars, Association, AAM

The AAM's Chip Davis gives an account of his agenda for 2020, how the association is driving policy in a complex healthcare environment of multiple public and private actors and offers insight as to why there is great room for improvement in the uptake of biosimilar drugs.

One year before the 2020 presidential election, there is a lot of debate in the US pharmaceutical landscape – ranging from subjects like the opioid crisis, unjustified price hikes for drugs that have been around for years and the overall cost of healthcare. From your perspective, what are the key topics for the Association for Accessible Medicines (AAM) in 2020?

At the risk of pushing back on the view that there is no bipartisanship in Washington – there is. Everybody, Republicans, Democrats and Independents, all claims to want lower drug prices.

Public polling shows that the public wants their policymakers to work together to lower drug prices. Where things diverge is the approaches being proposed to get there. House Speaker Pelosi's bill suggests direct negotiation from the government in Medicare and beyond for up to 250 drugs. This is a very new approach that has been talked about for a while but is only now manifesting itself within proposed legislative text.

Others are recommending doing different things to try and create more incentives in the market for branded, generic and biosimilar drugs.

What trends have you seen in US drug pricing in recent years?

It is somewhat ironic that given drug prices are one of the foremost policy issues in the US of cross-party concern going into an election year, the majority of drug prices in this country have actually been going down for three years.

Morgan Stanley tracks month-to-month, year-on-year price inflation or deflation and for 36 of the last 38 months, generic drug prices as a market basket have been going down in the US. That is because they are looking at the entire basket when 90 percent of all prescriptions in the US are generics. And generic drug price deflation will generally serve as a counter-balance for newer medicines, many of which have experienced significant launch prices and annual price increases. This is most notable in the area of specialty drugs and biologics – which account for a low proportion of total prescriptions but increasingly a significantly higher percentage of the total cost.

To be fair, it is important to acknowledge that there is some incredible innovation going on in many therapy areas including CAR-T and Hep C treatments, for example. The question, as we move forward with these six- and even seven-figure treatments is how the US, or any country, is going to be able to finance them.

That is where the generics and biosimilar industry comes in. From a policy perspective, if you believe that the private market can either lead or play a seminal role in helping to control costs, then in every instance where a generic or a biosimilar is available, there should be every incentive get them into the market and encourage their utilization, which will help control overall costs.

In order to influence government and public authorities you need policy instruments. In Europe, universal healthcare is the main driver for lowering drug prices, whereas in the US, private companies administer the care under certain state programs. Given the multitude of state and private actors in US healthcare, how do you aim to drive policy?

The assertion that the federal government does not negotiate prices in Medicare is flawed. The government does negotiate – it does so through outsourcing that responsibility to private entities that have a fiduciary responsibility to drive prices as low as possible. This has resulted in overall

costs in the Medicare Part D, on an annual basis, coming in well below initial budget estimates for the first decade of the program.

In fact, one of the things we need to be increasingly concerned about is that generic drug prices in certain categories have gone down to a point where they are so low that the market price is below the cost of manufacture. Generics are an extremely competitive market, the most competitive industry I have ever seen in terms of price sensitivity. In generics, you are not competing on clinical differentiation; one product is equally safe and effective as another, as regulated by the FDA. What you are therefore left to compete on is price and volume/consistency of supply.

Over the years, there has been a significant consolidation in the number of buyers in the US and generics are often referred to as a commoditized market. That is a fair characterisation when the market is functioning effectively. But by and large, a commoditised is often defined by a significant number of buyers and sellers. If you and I cannot get to an agreement, then someone else and I may be able to. As the purchasing power has increasingly consolidated, there may be less need for 15 companies to manufacture the same generic drug; there is maybe only a need for three to five companies. That might work for a while, but problems emerge if one company decides to exit the market or if a manufacturing issue arises.

One of the things that we have to continue to educate policymakers about is the inherent assumption that generic manufacturers can turn their manufacturing lines on and off with the flip of a switch. In an industry as heavily regulated as ours continuing or discontinuing products takes more than just a couple of weeks.

Our job at AAM – primarily here in the US but also in close collaboration with our sister organisations around the world, such as the International Generic & Biosimilar Medicines Association (IGBA) and Medicines for Europe – is to make sure that even though we are a very different industry than the branded drug business in terms of how the markets operate, the commitment to manufacturing is equally high, and it is not an easy or quick process to and initiate or stop manufacturing particular types of products.

From a policy perspective, we have to ensure that there are sufficient incentives in the system to keep as many competitors in the market as possible – as this is an important mechanism to lower prices and keep them low. The initial exclusivity period after the first generic hits the market in the US is a vitally important incentive. After those 180 days of exclusivity are over, you ideally want multiple competitors to be as ready as they possibly can to enter the market and create even more robust competition which in turn leads to further price reductions.

How does the US compare to other countries in terms of generics penetration?

In the US – in large part because most drugs are delivered through a private marketplace, even for government programs like Medicare Part D – we are now up to 90 percent penetration. There is no other developed market that has as high a generic utilisation rate as the US market. Generics make up 90 percent of all prescriptions and 22 percent of total cost. In comparison, the UK generic penetration rate is at approximately 70 percent but the total cost of generics is actually higher. Overall, we have the highest utilisation rate as well as the lowest total percentage of costs.

That is a great thing for the government, payers and patients, provided that patients are actually getting the benefit of that low cost. What we are increasingly seeing is a discrepancy between a decreasing cost of generic medicines and an increasing cost for patients at the pharmacy counter – particularly Medicare Part D patients.

Patients express their frustration towards our industry when they experience a price increase of their medication. That is understandable, however, in many instances, it is not an actual price increase that led to patients paying more at the pharmacy counter; it is a change or adaptation in their insurance benefit which translates into patients having to pay a higher co-pay for their generic medication.

In certain instances when generics enter the market to compete against the branded product, they experience a much more difficult time getting on insurance plan formularies. And if they do ultimately succeed, it is increasingly at the same price level or higher than the branded product. If the subsequent competition costs the same or even more, then there is no incentive for the patient to switch from a branded to a generic product.

A major factor that contributes to this is that insurance plans and/or their pharmacy benefit managers (PBM) anticipate when the first generic drug for a certain branded product is coming to the market.

Innovative drug manufacturers are increasingly aware that when generics come to market, their only way of maintaining some market share is to compete directly on price.

These days, a number of branded companies will agree to contracts where PBMs ask for higher rebates on branded products, which puts pressure on the branded companies to take a higher price increase. In exchange for bigger rebates, the PBMs ensure that the generic medicine will not be on a given formulary or be placed in a less preferred position on a formulary, which has the effect of

diluting the financial incentive.

We have issued a series of white papers, which show that when generics are available, they are not launching at the rate you would expect. When they do launch however, they are experiencing an incredibly difficult time gaining preferred formulary access in Medicare Part D plans, and that is having a substantial impact on companies that used to be able to assume that once they went to market and launched a generic product, they would be able to generate market share.

So what then are the incentives for generic companies to tap into this market?

Historically, the US was perceived as the most opportunistic market in the world for generics. There is a lot of potential in emerging markets such as the BRIC countries, as well as Mexico and Turkey. Our members, as a global industry, still believe that the US is right at the top in terms of their focus, but it is not the exclusive focus. There are access to medicine issues in the developing world and the developed world; what AAM's members are trying to do is to reconcile this increasing pressure to provide safe, effective and high-quality medicines at the lowest possible price, without running the risk of compromising quality. .

What is the case for manufacturing more generics in the USA?

There is much more generic manufacturing in the US than many people presume. Our latest member survey shows that over 50 billion doses a year of generic medicines are made here in the USA.

President Trump has repeatedly stated that he wants things "made in America". There is a recognition of that and, our members are absolutely willing to engage in that discussion, provided it is realistic and viable – and that policymakers, both members of the administration and of congress, are willing to recognise that generic drugs are under-reimbursed in the US.

If we do not get to the heart of that issue, the ability to increase domestic manufacturing will not be fully realized. We have been very consistent in our communications to policymakers and other relevant stakeholders that we are ready, willing and able to have that discussion, but it cannot be had in a vacuum.

Considering biosimilars, we can see a rather low penetration in the US market, whereas Europe has over 50 biosimilars approved. Where do you think are the key bottlenecks for greater uptake of biosimilars in the US?

It is a combination of perception, fearmongering about the quality of biosimilars, and successful lobbying initiatives from the innovative pharma industry. 25 biologics have been approved in the US but only 12 are actually on the market today. This is not an issue with the FDA or the regulatory process, as we do not have a biosimilar application backlog.

A few things have transpired: we do not have all the policies in place that we should to ensure biosimilar uptake.

One of America's largest health plans, Kaiser Permanente, has created incentives for providers to switch from originator biologic to biosimilar drug and has seen great successes: some biosimilars have over 90 percent market share in their system. Unfortunately, we do not have that policy in place across the board partially due to aggressive lobbying by Big Bio and Big Pharma. There has been an increase in cases of patent abuse [alternatively known as "patent thicketing" – Ed.]. That is why there is no competition to Humira in the US for example, as AbbVie filed countless late-state patents for the product, fully knowing that no generics or biosimilar company would financially be able to go through the requisite litigation process to challenge such an estate. It is no coincidence that Humira is the largest drug in the world and that a significant percentage of its revenue is in the US market.

We certainly respect innovation, but we have to be able to call out anti-competitive behaviour where it exists. Our job is to make sure the follow-on competition; both generics and biosimilars have the opportunity to come to market. If you are one of the 13 biosimilars currently not on the market and you are not able to ensure a launch pathway soon, it will force you to reassess your portfolio of treatments moving forward.

A second issue we have observed is the claim that biosimilars are of lesser quality than an originator product, which is a complete and total red herring advanced by certain companies that have an interest in ensuring they can plant a seed of doubt. To some degree, they have an inherent advantage as they have large sales forces, telling physicians that innovator biologics are tried and tested vis-à-vis biosimilar drugs.

One has to appreciate that in the US, there are commercial sales forces for the originators in physician's offices on a daily basis. The FDA, on the other hand, is not, and neither by and large are biosimilar companies. If biosimilar companies do have sales forces, they are typically much smaller

than the originator companies.

Some of these scare tactics are ultimately going to negatively impact the companies that are involved in it. To be clear, I am not referring to the entire originator industry but only certain companies.

Pfizer, for example, has been very forward-leaning in saying that some of the actions taken by some of their peers in the originator industry in terms of their marketing and education campaigns are not appropriate. They have even gone as far as to file a citizen position with the FDA. This is not just a traditional brand versus generics issue; there is a real difference of opinion within the branded industry.

Biosimilars is an area where both branded and generics companies have a significant investment presence, so there is in fact an opportunity for more cooperation and alignment. We have worked closely with a number of branded companies in regard to education, outreach and awareness to try and refute some of the claims that are not serving the interests of patients in the US

On Capitol Hill we for policies that create more financial incentive for everybody: from the payers to the insurers and the providers. Zero-out co-pays for patients on biosimilars and utilization will go up. We advocate for the creation of a shared savings program. In Medicare Part B, which is where most biologics are reimbursed in the US, the physicians are currently incentivized to prescribe the most expensive products, because the reimbursement rates are more lucrative than those for lower-priced therapies.

One way to combat this system would be for a number of patients to be put on a biosimilar treatment and stabilized long-term. Then, the federal government will realize significant savings and could share some of those savings with providers, who would be gaining valuable experience in treating patients with biosimilars and simultaneously keeping costs down.

What is the most worrying element of the US generics industry for you today?

In May 2018, President Trump unveiled his blueprint to lower prescription drug prices – ‘The Blueprint’. There are four core strategies in the Blueprint.

The first is to increase competition – which directly points to the value provided by generics.

The second is to lower list prices – generics also do that.

The third is to lower out of pocket prices – again when the market is operating as it should patients should have lower out of pocket costs for generics. So the strategies in that document reflect, and rely upon, the importance to the US healthcare system of generics and biosimilars.

Nonetheless, while we are at 90 percent utilisation already, that level is very much at risk because of certain sustainability issue facing companies. We are already seeing increases in drug shortages, where companies dropped out of the market, which is one of the worst things that can happen for patients.

We are seeing fundamental changes to the industry: Generics companies such as TEVA, Mylan and Sandoz are redefining themselves. The changes in the marketplace are unprecedented. What we need to do is make sure that the policy environment keeps up with the changes in the healthcare marketplace, in the US and abroad.

We are in a very strong position in terms of value, but we have to make sure that our value proposition translates into policies that will further encourage competition in generics and biosimilars and ensure the sustainability of both sectors.

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