Interview: Catherine Bourrienne-Bautista â?? Director, GEMME (GÃ©nÃ©rique, mÃªme medicament â?? Generics, same medicine), France

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The director of GEMME reveals how the French generics market is young in comparison to other European countries â?? where generics were on the market twenty years before they became available in France, how today the French Ministry of Health is sending a clear signal about the importance of generics in France through the â??plan national de promotion des mÃ©dicaments gÃ©nÃ©riquesâ?•, and why it is vital to get across to the general public the fact that generic medicines are of the same quality as branded products.

Generic market penetration in France has experienced tremendous growth over the last decade. In what ways has the French generics model been an example of success?

The progression made by the French generic market has been fast. It is a young market in comparison to other generic heavyweights such as Germany, the UK and the Netherlands, where generics were on the market twenty years before they became available in France. We have succeeded in going from having just one box in twenty for generics in 2002 to one in three in 2013. However, we are still very far behind countries such as Germany and the UK where the ratio is around seven. We still need to work hard to achieve the same results. Unfortunately, the rate of progression has slowed significantly over the last year and the generic market has reached a plateau at around 31 percent. In terms of volume, there was an increase of two percent from 2013 to 2014 but this was due to new products without which the market would have fallen by two percent. The reason for this regression is that, whereas in Germany prescriptions increase once a product becomes generic, they decrease in France because there is no more promotion from the industry or the laboratories.

In terms of improving the system, I think it is always possible to learn from other models. However, the fact that a model was very successful in a country such as Germany, does not mean that it will necessarily have the same success in France.

According to your website 55 percent of the medicines consumed in France are produced in France. What can be done to ensure more production is carried out on French territory?

First of all, if we are to increase the level of production taking place in France, we need to ensure that there are no more price cuts because if they are cut anymore the margins will be too small. The challenge is that companies wanting to produce their products in France, and Europe, are faced with more social and environmental obligations and the cost of labour is higher than somewhere such as Asia. Therefore, when companies are deciding where to have their manufacturing facilities, these points can influence the final decision.

Secondly, stock piling should be made legal in Europe because, at the moment, the transition time between patent expiration and getting a product to market is very long. Laboratories are able to start stockpiling in India and China so if they could prepare the products in advance in Europe, it might ensure more production within Europe. At the moment, a lot of products are made exclusively in Europe but, unless action is taken, this will change and companies will choose to manufacture elsewhere to reduce the delay between patent expiration and launching their generic product.

Since 2011, there have been several new pieces of legislation in favor of generics. What impact have these had on generic market penetration in France?

One of the most important measures is the â??tiers payant contre gÃ©nÃ©riquesâ?• (third-party payment of generics) which was initially introduced in 2012. In 2013, they introduced a new phase which obliges pharmacists to give patients generic products whenever possible unless the doctor has stipulated that the medication â??cannot be substitutedâ?•. As such, when patients hand over their prescription they will be given the generic option and if they refuse this in favor of the branded product they will have to pay and then apply for reimbursement afterwards. The system is unlikely to change so that innovators are not reimbursed because this is simply not in the French mentality. Nonetheless, this new phase has had a very positive impact on the market.

Another very recent initiative which has the potential to increase generic market penetration is the *plan national de promotion des mÃ©dicaments gÃ©nÃ©riques* (Generic Plan). This was presented by Marisol Touraine, the Minister of Health, in March 2015 and consists of eighty-two very good proposals targeting seven main areas including communications, hospitals, prescriptions and trust. The main objective is to increase generic penetration by 5 percent in three years and it will affect prescribers in hospitals, towns and pharmacists. This plan is the result of a lot of work on our part including lobbying and government discussions. The generic industry is very happy with the plan and is now waiting to start to see the effect. The impact of this plan will, of course, be progressive: Rome wasnâ??t built in a day! It is very positive to have this level of political support, the Minister of Health is sending a very strong message about the importance of generics in France.

What are the key points of discussion just now between GEMME and the government?

Our two main objectives are to change public opinion and the opinions of doctors regarding generics. Public opinion of generics is very negative because they are seen as low cost medicines made in India and China without any quality control. As such, we need to explain to them, firstly, that most of the generic drugs consumed in France are not made in India or China and, secondly, any products made in those countries have to meet the same obligations. In July 2013, the European Union set a law whereby the raw materials sourced from foreign countries have to comply with EU standards when they are imported.

It is vital that our communications to the general public go beyond cost saving arguments and raise awareness of the fact that generic medicines are of the same quality as branded products. In other sectors there may be issues in terms of quality when materials are produced abroad but this is not the case for medicines. In the Generic Plan there was a big communication topic, highlighting that generics are of the same quality. Nevertheless, in terms of credibility, we believe this message has to come from the authorities in order to have the trust of the patient. The message should not come from us or from the industry because when we say that the products are of the same quality, the patients are going to think that we are just promoting our own interests. There are already advertisements on the television promoting generic products in France; however, these are institutional communications from the laboratories like Biogaran, Teva and Mylan rather than the government. Next year, we are hoping that government institutions such as INPES (Institut National de PrÃ©vention et dâ??Ã?ducation pour la SantÃ© â?? National Institute of Health Education and Prevention) will run awareness campaigns to tell people that they can trust generic products and, in this way, change the opinion of the patients and also the doctors.

In France, doctors are not promoters of the industry. When the generics model was first introduced in France, the government tried to involve doctors but it did not really work. Therefore, the government turned its attention to the pharmacists and developed a model based on substitution. As such, doctors are not content with the model and, as a result, do not promote generics. In addition, the laboratories are unable to visit the doctors to the same extent as large pharmaceutical companies because they do not have enough resources to invest in the necessary sales representation. Moreover, as the pharmacists can substitute the products for another generic product, if the laboratories go to the doctors they still do not know if their product will be given to the patient.

What are your goals and expectations for the generic market over the coming years?

In terms of volume, our objective is to reach one box in two for generics by 2017. We are ambitious but also realistic. Regarding value, the generics market currently represents around 18.5 percent which is in-keeping with the volume so we hope that the progression of value will continue to correspond with the increase in volume. In France, as is the case elsewhere, medicine in general, and generics in particular, are the target for social security savings and the last two years have been very hard as the savings made on medicine reached more than one billion euros.

The situation is different for every laboratory and group but the average profit margin is between three to four percent so the situation is critical. This may change if the industry is able to increase volume but we need to have the volume before changing the economic model. The new PLFSS (Projet de loi de financement de la securitÃ© sociale â?? Social Security Financing Bill) will take effect in January 2016. We hope that the regulations are not going to be too harsh because, over the last two years in particular, they have been very harsh and the multiple price cuts have had a negative impact on generic laboratories. As such, we are hoping that the Generic Plan will breathe new life into laboratories before the new price cut demands are made in 2016.

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