Interview with Catherine Bourrienne-Bautista, Managing Director, GEMME

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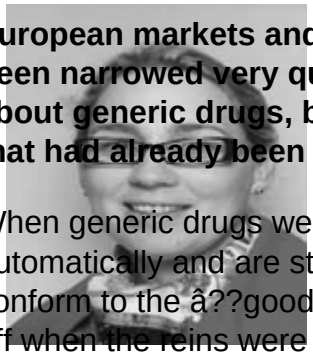

ery late arrival for the French market in comparison with other European markets and healthcare systems on a par with the French one. Today the gap has been narrowed very quickly as highlighted by public opinion and the fact everyone knows about generic drugs, but how can we explain why France was reluctant to accept a model that had already been accepted elsewhere for some time?

When generic drugs were originally introduced in France, doctors were not quick to prescribe them automatically and are still not big subscribers themselves. For doctors, generic drugs didnâ??t conform to the â??good old wayâ?• so inevitably some time was wasted and generic drugs only took off when the reins were in the hands of the pharmacists. As a result I think it was this reluctance of doctors to go for generics which explains Franceâ??s lateness.

In 1999 a law was passed which gave the pharmacists the authorisation for substituting branded products with generic ones. After that generic labs focused their commercial and advising efforts on the pharmacists, and generics started picking up.

How do you explain the reluctance of the French doctors to embrace the generic model, is there something about France in particular?

In France there was and still is a preponderance of laboratories which work closely with doctors enabling sales reps to approach them. Now this process is subject to tighter regulation since there is a law which bans this type of relationship, whereas before there was a clear privileged link between doctors and labs, who worked very closely together in terms of sales. The situation has changed and although a privileged link between labs and doctors still persists, it is more strictly governed and exists only within certain legal frameworks.

However, it is increasingly common for the generic drug houses to belong to big laboratories, does this mean that there could be a new focus from generic manufacturer towards doctors?

In France generic laboratories still do not have relationships with doctors. There are no/very few sales reps from generic drug labs which have close relationships with doctors. Unlike in Italy, in France, generic drug labs focus all their sales on pharmacists as until now they were the best promoter.

It is true that generic drug producers do not usually bother with sales reps approaching doctors as they have to go by pharmacists beforehand to promote the drug.

Until April this year, doctors were not in any way involved in generic drug promotion strategy. There were some incentives but until April 2008 (Loi du Financement de la SÃ©curitÃ© Sociale, LFSS) nothing significant was implemented. Now incentives have been introduced and thus it remains to be seen what happens as a result of this.

You said that today the generic industry had caught up somewhat, what is the significance of this for the French drug market?

In France there is a tendency which has no direct medical explanation: when a drug becomes generic, its sales figures drop immediately and there is a transfer of prescriptions to products which are still patented. In Germany, when a product is released into the public domain, its volume of prescriptions rises whereas in France right from moment a generic product is released, its sales hit a low point. This transfer of prescriptions highlights again this link between doctors and laboratories. Generic drugs only represent 11% of the market in France in terms of value which is not agreater figure when compared with other countries such as Germany. In terms of volume in Germany this represents 24% with a dynamic growth rate notable until 2007. This encountered some slowing after 2008 and into 2009 when the figure lowered to 10%. 2008 and 2009 were not big years in terms of patents expiration, and didnâ??t witness significant introductions into the market. The impact of the new products from 2009 will be visible in 2010.

A large part of the incentives for implementing generics policies obviously entail the costs in France for social security and health insurance. Are there estimations of benefits for health insurance from these generic drugs?

The CNAM (caisse nationale dâ??assurance maladie) made an estimation of 1.2 billion Euros per year worth of savings from generics, which is not negligible in a market which represents 2 billion in terms of the off patent drug market. I think this is not negligible, and when people compare France and Germany for example, they should not only take the bulk figure, but relate it to the gross market concerned.

The situation is difficult to surmise as where it seems one model works better in Germany for example, they have 25 years of experience in generics whereas we have 10. To say a sum of 1.2 billion out of a market of 2 billion is insignificant would be false. Itâ??s difficult to compare to the models. Thanks to Mr Renaudinâ??s pricing model we have an effective system here in France which of course, we support.

There are other ways of reducing costs of social security, as implemented in other countries, such as not selling whole packs of drugs but instead just sell what is necessary in terms of the dose. What is your position on this?

The packaging issue has been addressed in France and reviewed to adapt to prescriptions. You can buy drugs in packs of 7, 14, 28, 30, 84, or 90. As you can see, we have truly adapted to fit with requirements of customers.

What are the risks of counterfeit drugs coming from emerging markets such as India or China threatening the generic drug market in France and of other developed countries such as Germany or the US?

When a drug is authorised to enter the French market, it has to pass a series of extremely rigorous tests. Therefore the very arrival of a drug on the French market should denote its security from

counterfeit equivalents. Of course now when you can buy many medications on the internet such as Viagra, and there are some risks associated with this. However, the French distribution system, dominated by pharmacies, has a structure which protects us against the arrival of counterfeit drugs. Anything verified by the meticulous testing of AFFSAPS ensures the quality of the product. The structure of the generic market means that whether labs are well established or small, the tests are rigorous.

You talk about well established laboratories; one of the themes in this report is the industrial attractiveness of France, what is your view on this potential?

It is true that factories no longer needed by labs have had to close not just in France but over Europe, and there is a tendency for these to be used instead for self-mediation and generics to survive. I would say that the new measure introduced that allows manufacturers to start producing drugs before the patent expires should offset some factory closures.

Thanks to the proposition made by CSIS (Conseil strategique des industries de santÃ©), the strategic committee on healthcare industry proposed a measure on Monday which would allow production of specialised generic drugs before the patent expires. This would allow companies to be ready on D-day, and should prevent that the D-day drugs available are all imported. This is to ensure fair competition with countries in the EU who entered later and who donâ??t have the same rules on patenting such as Malta for example.

I would like to stretch out a study that shows that 95% of the generic drugs sold on the French market are manufactured in the EU and 55% in France. So domination by China or India is still a myth and a far cry.

What are your recommendations to the French authorities for heightening the presence of generic drugs and increasing their subsequent penetration into market today?

In terms of the agency (AFFSAPS), we would want to limit outside intervention from multinationals in the procedure of creating a dossier for a generic drug. I would recommend each laboratory appeal to the European Commission requesting that the management of dossiers for generic drugs should be solely a bilateral affair between the generic drug lab and AFFSAPS; this type of intervention from MNC just slows things down.

The process could perhaps be quicker â?? but it does work quite well, now within a guaranteed time period of 60 days. On the other hand, one thing which could speed up the process is the doctors and their incentive to prescribe generic drugs. AFFSAPS can enlarge the list of generic drugs, for example there are not so many patch and spray forms available.

The future for generic drugs in France?

The most important steps have already been taken. There have been important developments and I maintain the future is a bright one. We have to stabilise and re-enforce the model now.

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