Interview: Zofia Ulz, Main Pharmaceutical Inspector, Main Pharmaceutical Inspectorate, Poland

08.05.2014

Tags: GMP, Government Regulation

Poland's Main Pharmaceutical Inspector discusses the dangers behind falsified medicines and the need to control internet pharmacies. She also showcases the great power Poland holds as a manufacturing country with over 200 manufacturers.

Can you please start by introducing your organization, Main Pharmaceutical Inspectorate, and explain how it fits within the Ministry of Health and other government entities in Poland?

We are an independent central governmental organization, which is supervised by the Ministry of Health, although we do issue independent administrative decisions and we also have an appeals process. In this way the Main Pharmaceutical Inspectorate belongs to the health sector in Poland but we operate somewhat independently.

The Main Pharmaceutical Inspectorate functions as a supervisory authority and deals mostly with pharmaceuticals, in terms of verifying the quality of medicinal products— starting with manufacturing, through import, distribution and retail distribution in hospitals and pharmacies.

Our organizational chart is a little different from the rest of the European Union because we don't have a health agency in Poland. The other Competent Authority – Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL) is responsible for, handling marketing authorization, and we deal with manufacturing authorization and all authorizations that

give rights for stakeholders to manufacture, import, distribute, and sell product to patients. Hence, we cooperate closely with URPL, which is also an independent government organization, and other authorities.

The Main Pharmaceutical Inspectorate functions as a supervisory authority and deals mostly with pharmaceuticals, in terms of verifying the quality of medicinal products—starting with manufacturing, through import, distribution and retail distribution in hospitals and pharmacies."**What have been your priorities for the last two years?**

Priorities actually don't change. I have personally been involved in pharmaceutical inspection since the early 1990s. I was the regional pharmaceutical inspector and was then called to come to Warsaw after a post-grad program in Lexington, Kentucky, to create the Good Manufacturing Practice (GMP) inspection department. Acting as the head of this department, I became the main inspector in 2006.

All of this is to say that we always deal with the same issues; rather we just get more tools and provisions in order to be more effective.

In the last decade, one of the big influences for falsification of medicinal products has been the use of Internet pharmacies. How does the Main Pharmaceutical Inspectorate deal with this challenge?

Falsification of medicinal products has been a huge hurdle for the entire health sector, and we hope that by having more human resources, we can be more efficient in handling it.

The Main Pharmaceutical Inspectorate was strongly against introducing Internet pharmacies into the law because we realized how large of a problem they could become. However, the industry was rapidly changing and our hands were essentially tied. As we only deal with the legal end of the spectrum, we managed to introduce some provisions to help us mitigate the effects.

Now in Poland, Internet sales of medicinal products are allowed, but only for OTC. In addition, certain requirements need to be met in order to trade over the Internet, such as having a real, physical pharmacy, and notifying a regional inspector prior to entering the business.

Given price pressures in the country, parallel trading is another phenomenon that has been increasing over the last few years. How do you think this issue can be contained within Poland?

The aim of all of the players in the Polish pharmaceutical market, including the Main Pharmaceutical Inspectorate and the Polish Pharmaceutical Inspection, is to assure the equal availability of medicinal product to patients. The reimbursement policy has this priority as well, and our obligations have to go in parallel. Our Ministry of Health undertook steps to control parallel trading by, among other things, giving us suitable tools to navigate through these processes. At the same time we are keeping track of European market in this respect.

Poland has a large manufacturing industry known traditionally for high quality coupled with affordable prices. However, since Poland has been using EU standards, manufacturing prices have increased. What can you tell us about this threat to manufacturers and how do you foresee this situation evolving?

Since we have a myriad of manufacturers, their scale varies significantly. Not only classified as big or small, we also have private laboratories, for example, that work for industry, which are also considered manufacturers. Unifying such a large industry is complicated, but we are of course trying to keep all our manufactures on the market, while complying with the law.

It is evident that lifting standards requires more money. Given the dangers of falsification, the European Commission is proposing new provisions that will hike up the cost of production. Taking into account that Poland is a 99% generics country; the Main Pharmaceutical Inspectorate cannot rest in our laurels. Having said that, the time for GMP introduction and implementation has gone many years ago, 10 years have passed since GMP was introduced into pharmaceutical law in Poland.

Looking back, changing the mentality of the manufacturers was the definitely the most difficult part. We have over 200 manufacturers, and even more sites, since one manufacturer can have multiple plants. To be able to control GMP, we needed to establish suitable departments, such as the GMP inspection department. We also introduced inspections every two and half years, both unannounced and follow-up inspections.

In 2006 we became full members of the Pharmaceutical Inspection Co-operation Scheme (PICS) and were also inspected by Mutual Recognition Agreement (MRA) partners. The results were successful since different authorities concluded that our standards were of European level in 2011.

We are very active and I cannot imagine fighting against counterfeit without cooperation."**What is your perspective on the consolidation of the wholesaler sector?**

I think that we have a big market of wholesalers in Poland. The proposition in the new law for Good Distribution Practice (GDP) results that will have the same quality system of inspection as for GMP, and we will have centrally employed GDP inspectors. We will be very strict in implementing the new GDP guidelines, and we hope that these standards will help distributors improve their services. As for those who cannot manage, decisions will be taken.

How do you see the cooperation at the EU level developing over the next five years?

I am really looking forward to our relations evolving, since we are currently engaged in cooperation with many international organizations within the European Union and outside, which deal with falsification of medicinal products as well. We were even asked to train our colleagues from Georgia, Croatia, Ukraine and many other countries. We are very active and I cannot imagine fighting against counterfeit without cooperation.

Back in 2007, we initiated development of a special team to fight against counterfeits. Every year we hold quarterly meetings with URPL, national laboratories, prosecutors, criminal police, agencies for consumer rights and patents, and customs in order to exchange information with all of our members concerning illegal trade and counterfeits. As an example of our collaborative effects, we were the leaders of uncovering a big falsification center in Spain, which was connected with a Polish entrepreneur. This flow of information therefore keeps us all updated and helps us tackle counterfeit nationally and internationally.

To read more articles and interviews from Poland, and to download the latest free report on the country, click here.

See more interviews