Interview with Janusz Obukowicz, Managing Director, Pharmaceutical Reearch Institute

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Pharmaceutical Reearch Institute

Would you start by giving our readers a brief outline of the history of the PRI?

In 1952 the institute was established as a research and development (R&D) centre for the Polish pharmaceutical industry. In the 1960s the institute became part of what was known as the state-owned â??Polfaâ?• consortium the last vestiges of which are being sold at the moment. Then through the 1970s and 80s the PRI was the chief coordinator for the national programme for the pharmaceutical industry.

The 1990s represented a challenging time for the PRI and for the Polish industry as a whole. Polish manufacturers were suddenly exposed to the open market with competitors from around the world. In other Eastern-bloc countries similar institutions to the PRI were simply dissolved because they could not compete or taken over by international pharma companies.

The PRI adapted to this change by starting to offer APIs and registered dosage forms, converting some of our laboratories into manufacturing units. The institute also founded the company, Anpharm, and transferred its technologies and formulations to this private company. The PRI then became the major share-holder of Anpharm. In fact, Anpharm was successful and several large European pharmaceutical companies were interested in buying it. Ultimately, Servier was the winning company in bidding for Anpharm and it is now part of the Servier group.
Next year will mark the 60th anniversary of the PRI. It will also see our biannual conference for the whole pharmaceutical industry in Poland which is oriented towards those who are engaged in pharmaceutical research.

Today, what does PRI represent and what are the main competencies of the PRI?

Today, the institute is a state-owned R&D organisation and manufacturing centre for the pharma industry as well as the organisation providing some contract R&D for Polish and European manufacturers. The organisation therefore consists of two main parts: manufacturing and R&D and they mirror each other exactly.

The full range of our capabilities ranges from international patent searches to design non-infringement processes, to organic synthesis of active pharmaceutical ingredients (API) including polymorphic studies to dosage form development and compiling the registration dossier. The PRI can also supply API.

The PRI is very stringent in its patent searches as this is very important for our clients. Although the PRI has both generics and innovator clients the majority are generics because of their dominant share of the Polish market. Non-infringement of patents is therefore a crucial concern to the majority of our clients who are careful not to become embroiled in legal cases by undermining patent law or for any other legal shenanigans. Indeed among the instituteâ??s 220 employees and 80 high-level researchers there are a large number of patent attorneys, including European patent attorney.

In terms of manufacture, we have state of the art facilities able to run up to three independent process at a time. These facilities are capable of obtaining molecules in D-class areas. The PRI uses the most advanced analytical tools to establish the bioequivalence of our products and to perform crystal analysis in polymorphic studies. The most advanced technologies are used at PRI to detect small concentrations of impurities.
These high standards in manufacturing are partly a result of cooperation with the EU. Interestingly such cooperation between Polish institutions and the EU actually predates the accession in 2004. The institute practically joined the EU in 2001 and subsequently adopted all the required quality standards and GMP certifications.

One of the main advantages of the PRI is that our R&D is transferred internally to another division for optimisation and then it can be manufactured in-house. It is often difficult to make the transfer directly from R&D to an external company. In chemistry it is important not to stop a project at the end of the R&D process but to take it on to a bigger scale to confirm that all the results of the research apply on a bigger scale. The unique advantage of the PRI is that it has the capability to make products in-house and when the process is proven, through scaling up, it is then easier to commercialise the project.

We are proud of certain products such as our anti-glaucoma treatments with extremely low concentrations of fewer than 50 micro-grams per millilitre. Indeed, our strategy involves these sophisticated and complex projects which are very demanding. The PRI also has expertise in creating non protected by patent polymorphs in our API projects, giving our customers the chance of early entry into the market. This offers our customers a competitive advantage.

You have worked for the PRI for over 35 years and observed two major shifts in the climate for innovation in Poland. What is the current state of affairs?

Our government is now serious about helping to build the environment for innovation. Innovation is the only way to grow for the pharmaceutical industry.

The Polish patent office is currently very strict in their evaluation of innovation. This is a very good approach. At the moment almost anything is patentable. This is not good for innovation. Too much protection is an inhibitor and discourages the innovation process.

Yet most players in the market are still in generics so is it working?

The trouble is that even for Polish domestic players the pharmaceutical market is too small. To be successful in innovation you have to be a global player. There is a certain critical mass for a company to engage in a truly innovative programme. Only the biggest players within the market are going to be able to run truly innovative projects.

How easy is it to get involved in such innovation projects with these pharma companies?

Actually, the PRI collaborates most actively with institutions such as the Medicinal University of Warsaw as well as other universities. It is now possible to make a consortium with universities and apply for a join grant. We are successful in this and it fits with our business model of connecting

cutting-edge research with commercialisation using our know-how.

Multinationals tend to have vast teams of scientists and huge innovation budgets so the PRI is too small to engage in such projects. However, the PRI is a strong partner especially to the local industry. Being a state organisation we are neutral and can cooperate with several customers who will not view us as a competitor. This is extremely advantageous.

How else do you benefit from being a state-owned institution?

The PRI has opportunities to apply for financial assistance and structural funds from the European Union. The PRI has won 3 major projects on the basis of this funding for oncological, cardiological and ophthalmological drugs. These projects will last until 2013/14 and the question is what will be next.

There is an understanding in government that innovation needs financial support and incubation. European and government funding will therefore be significant sources or assistance to the development of the PRI going forward.

Some people might say that true innovation does not easily spring from a government owned institution, given that it has no need to innovate in order to ensure its survival in the market. What would your response be?

The response would be to look at our record. The institute has had numerous successes in many different fields because the philosophy is not to focus on easy projects but those which are most demanding. Especially in this field of innovative capabilities we are a leader in Poland and have applied for many patents to protect our discoveries.

And why should innovative institutions such as yours need the support of government?

Institutions such as the PRI should be supported. It is a matter of risk. In the pharmaceutical industry the risk of failure of a project is huge. If we compare a new pharma project and the design of a new car, they have more or less the same budget however, a new car will take 2-3 years to produce where a pharmaceutical project will take 10 years. The success rate of a car project is more than 80% whereas for a pharmaceutical project the success rate is less than 5%. This is why innovation must be supported and risk must be shared in the industry.
It would be very difficult to find many industrial organisations that would be willing to invest now and not see the results for 10 years. In the European Union if we want a truly innovative pharma industry we need to compensate this risk. The future lies in European funded projects and the PRI is one of the institutions representing this direction.

What is your personal approach to making the PRI successful and encouraging the recruitment of the best talent?

When I became Managing Director my goal was to bring the PRI to the point where both R&D and Manufacture are self-financing. In 2010 we achieved this.

In terms of recruitment, the PRI organises its biannual conference where we invite many academic and high-school organisations with young people. There is a contest for the best scientific work of young scientists. This type of communication with the new generation of researchers can allow us to expand our organisation. The only limitation is lab space and we are aiming for financial support to enlarge our laboratory space. However, at 220 people the current number of employees is good and taking on more runs the risk of making the organisation unwieldy.

Addressing the future of generics companies in Poland, do you see them as capable of making the transition into innovation within the next 10 years and how will the PRI be involved?

Even now companies such as Adamed, are deciding to engage in innovation and finding genuinely new molecules. There are not many of these companies but good examples for others to follow and PRI sees itself as a partner to these companies.

In terms of our model for the coming years we seek partnerships with the pharma industry and with universities. The universities are engaged in trying to find real scientific results and the PRI is an institute which holds a position in-between this and a commercial organisation. We understand both the scientific approach and the commercial approach with knowledge about how to turn scientific results into industrial process. The PRI is therefore a link between fundamental science and industry.

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