Interview: Bogna Cichowska – Duma General Director, Employers' Association of Innovative Pharmaceutical Companies (INFARMA), Poland



"Poland remains the largest clinical trials market in CEE – however - both patient participation and site penetration rates indicate a potential for growth."

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Bogna Cichowska-Duma, general director of the Employers' Association of Innovative Pharmaceutical Companies (INFARMA), the voice of 28 leading innovative companies in Poland, discusses the challenges and opportunities for doing research and business in Poland. Furthermore, she points out the importance of seeing healthcare expenses as investments not solely costs and the country's amazing potential, especially in the area of clinical trials.

As general director, could you introduce to our international readers the Employers' Association of Innovative Pharmaceutical Companies (INFARMA)?

I joined INFARMA last year. Being a doctor myself, I am aware of the positive impact of innovative technologies on health care and on patients in particular. My role involves working with member companies and our external stakeholders to create the best possible environment for research and development and patients' access to innovative pharmaceuticals. INFARMA represents in Poland 28 leading pharmaceutical companies engaged in research and development activities and the production of innovative medicines.

On behalf of them we hold active dialogue with decision-makers and other stakeholders, which is focused on key issues for the whole industry. We are a partner for many discussions and projects, not only relating to healthcare but also aimed at enhancing the competitiveness of Polish economy.

Recently, we have been cooperating with the Ministry of Economic Development in regard to an initiative, with the overriding objective to develop the biotechnological industry in Poland.

What are the main challenges that innovators are facing in Poland today?

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Poland spends 4.16 percent of GDP on healthcare, which is one of the lowest percentages across OECD countries. Given the current levels of health care spending, the only way we can create headroom for innovation is to concentrate on delivering health outcomes rather than interventions. Healthcare spending should be viewed as an investment not a cost. To be sustainable the Polish economy needs a healthy and dynamic workforce.

I represent companies which provide patients with new, more effective and safer drugs that improve health outcomes. INFARMA is advocating that successful uptake and diffusion of new drugs is crucial for patients and the healthcare system in general.

The Ministry of Health is planning to roll out a new medicines policy over the coming years to incorporate further pharmacoecomonics. What impact do you perceive this having on innovative medicines?

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The Polish health technology assessment (HTA) agency, AOTMiT, assesses new drugs on the basis of clinical and cost effectiveness. The Agency’s assessments inform the pricing and reimbursement decisions of the Ministry of Health. We would welcome a more holistic approach of the Agency where price is not the crucial decisive factor, with health outcomes and reductions of indirect costs always being considered.

What methods is the government implementing to ensure these more-costly medicines do reach patients?

INFARMA strongly supports all efforts by the public administration to make innovative drugs available to patients. Thanks to the implementation of the EU transparency directive, the pricing and reimbursement process is more transparent and effective. Moreover, through cooperation with the Ministry of Health, we have managed to develop non-discriminative solutions with respect to reimbursement budget controls (e.g. payback) and to introduce modern reimbursement tools such as risk sharing schemes (RSS) or emergency access.

Undoubtedly, the reduction of some fees paid under national authorisation procedures was a milestone. However, we should have no illusions about the work ahead of us. This relates to putting the patient at the centre of the system, improving access to new technologies and improving health outcomes to name a few.

How attractive is Poland for pharmaceutical investments?

Poland is an attractive market for investments in the area of pharmaceuticals. Poland is the largest and strongest economy of the CEE and was the only country in the EU that managed to avoid recession during the financial crisis. With a population of around 40 million people, the nation offers a large internal market and equally makes available a talent pool of highly educated and skilled workers. Our member companies have R&D centres and manufacturing sites here and are constantly expanding.

Moreover, Poland has great potential for research – with a large and mature research market, qualified personnel, specialist and well-organised research centres, a strong market of sponsors, CRO companies, monitors and researchers. Poland aspires to become a country where both basic and implementation research is developed. The government plans to consider a company’s overall investment in Poland in the reimbursement decision-making process; although, this requires further thought and examination.

Nevertheless, there is still vast room for improvement. We hope that the government will continue to put the pharmaceutical industry as one of the driving forces of the Polish economy’s development strategy. Poland has the potential to achieve the European level within the scope of R&D investments. This requires the engagement of stakeholders from across different platforms, such as the government, business, academia and patients.

Why has Poland not reached its full potential in the field of clinical trials?

Poland remains the largest clinical trials market in CEE – however – both patient participation and site penetration rates indicate a potential for growth. Clinical trials entail numerous benefits to both the Polish health care system and its economy. Poland needs to improve and streamline its administrative, regulatory and transparency processes. Incentives should be given to attract further clinical trials. The EU Clinical Trials Regulation which establishes a uniform procedure for clinical trial authorization, is an opportunity for Poland if implemented in a holistic manner by the Polish government through the removal of key barriers.

How does the association view biosimilars, the new wave of generics?

Many of our members are major contributors towards this new therapeutic area, and we completely understand the great overall benefit that these biologic generics offer to patients. INFARMA has an educational role in stressing to all stakeholders that biosimilars carry the same efficacy and safety as originator biologics, and they are not pure generics. The pharmaceutical community must work together to teach medical personnel that prescribing biosimilars is not a concern, and in turn their penetration will allow savings in the market so more innovative drugs can enter. The entire value chain of drugs is interconnected.

INFARMA members contribute 6.76 billion PLN per year to the polish economy. What is the overall impact of a flourishing innovative sector for country?

In Poland our members are not only selling and marketing products. Four of our members have productions sites, and many have positioned their shared services centers, clinical and pre-clinical trial centers as well as regional operations in Poland.

Additionally, our industry is attracting a well-qualified workforce, that has a higher average salary compared to most sectors. Also, statistically our members have a broader influence, with every job position indirectly creating 3.5 more down the line.

Where do you see the market evolving in the upcoming year and what are the key factors for pharmaceutical sector´s success?

Definitely, we want a more transparent reimbursement process oriented towards health outcomes and predictable incentives for companies that are willing to invest.

Poland should build on the momentum created by economic growth, rising life expectancy and increased patients' awareness. Healthcare should be perceived as an investment not a cost. INFARMA will continue to work with the public administration and other stakeholders to increase access to innovation and improve patient health outcomes in Poland. I am convinced that Poland is moving in the right direction and has a promising future ahead.

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