Interview: Marcin Czech â?? Deputy Minister of Health, Undersecretary of State, Poland

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13.11.2017

Tags:

Poland, Ministry of Health, Minister of Health, Healthcare, Pricing, Regulatory Reform, Patient Access

Marcin Czech, deputy minister and undersecretary of state at the Polish Ministry of Health, provides an in-depth perspective on Polandâ??s drug policy framework and the new medicines policy that aims to integrate pharmacoecomonics to ensure Poland can find an efficient balance between innovative and generic treatments for long-term stability. Furthermore, he discusses the implications of the new Reimbursement Act and his unique journey into his newly appointed role.

You have just been recently appointed as the Deputy Minister of Health and Undersecretary of State. What is your mandate?

My area of responsibility is drug policy and to overlook the entire pharmaceutical sector. This encompasses pricing, reimbursement, pharmaceutical law, and all the regulations related to pharmacies, distribution of drugs and medicines and wholesalers. Furthermore, the National Institute of Drugs, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products responsible for registration, and the National Pharmaceutical Inspectorate are under my supervision.

My role, although being the smallest among the other undersecretaries, entails the most decisions, flow of documents and the largest numbers of commercial entities. We have in Poland around 500 laboratories and over 1000 medical device companies with different level of activities. Thus far, managing this great expanse of organizations has been an exciting challenge.

You have been in the role since July 31st, what is your diagnosis of Polish drug policy?

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In terms of strategy, my ambition is to design the medicines policy, a strategic document that was initially drafted by my colleagues. This medicines policy will follow the global methodology of the World Health Organization (WHO) and will be constructed with all the key stakeholders in the public sector, academia, scientific associations, NGOs, analytical companies, industry, aiming to portray a helicopter perspective of decision making for drug policy by taking into consideration both a medical and economic aspect: pharmacoecomonics.

Medically, we need to deliver effective and safe treatments to patients, while being cost effective. We must provide the maximum health benefits for the Polish population within our budgetary restraints, and we believe this strategic policy will be completed between 2018 and 2022, with adjustments being made every two to three years.

Does Poland have the required infrastructure to put in place this system?

Absolutely! In recent years I have worked in the private sector across the continent in large multinational organizations, most recently with QuintilesIMS, now IQVIA, looking at real world evidence in 31 nations. This international perspective has allowed me to understand what is present at a European level and I can say Poland has a very mature system in regard to regulations, procedures, communications and transparency.

From a decision making perceptive, we have a lot in common with the UK, through our evaluation of areas such as drug cost effectiveness and health technology assessment (HTA). Overall Poland has very well-defined criteria for reimbursement, while on the process side, we have a French style system, with a commission of transparency and commission of economics.

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How is Poland rewarding innovative treatments entering the market?

You can divide the market into two groups, generics and innovative drugs. The completion of the medicines policy will help solve the latter, while helping to foster research in the pharmaceutical sector, and biotechnology in a broader sense. Nevertheless, we have to increase the usage of innovative treatments, and in this regard, we have put in place financial risk sharing agreements, which we are utilizing more and more extensively; meaning, companies will be reimbursed when efficacy has been proven on the patients.

Furthermore, we would like to drive forward this mechanism by establishing a large abundance of registries to monitor treatment outcomes, allowing improved tracking of a drugs to understand the medicines with the greatest benefits. The challenge is to determine the patients that should receive the advanced treatments; therefore, we have constructed a team of national consultants to address this challenge.

Generic drugs in Poland are some of the cheapest in Europe. Are you afraid the pricing system will push companies away from entering the market?

I do not see a risk. The Polish generics market has such strong competition and so many players. Our concerns are around the functioning of the jumbo groups and reference pricing â?? although â?? if you have a reference system that rewards reduced prices, it allows more and more generic companies to enter the market; therefore, we are happy with the current model. We are always monitoring products to see when they reach patent cliffs, so we can reduce prices through generics and biosimilars, ensuring on the other end the introduction of innovative medicines.

Equally, we should be creating incentives for the generics industry to further flourish in Poland, as they have a strong impact through large scale production. Moreover, the generics players have the possibility to bring smaller innovations to the market, such as improved indications, formulations or administrations. Hopefully, one day the Polish industry can be the home to more medical advances in generics and biosimilars, or even something completely new!

What plans are there in place to drive forward innovation?

The â??Morawiecki* planâ?• (designed by Mateusz Morawiecki, Polish Deputy Prime Minister, Minister of Finance and Development) aims to boost innovation and biotechnology. This area is very important for the Polish economy as it is a sector strongly related to human capital, not only a huge financial investment. The government must catalyse this movement by establishing the correct conditions and promoting an innovative mindset. This environment must be fair for both Polish and international entities.

How will the spending on healthcare evolve as prices rise?

Our objective is to keep budgets quite stable. If you exclude the drugs for elderly patients budget *[i.e. free drugs for patient 75 years and older],* vaccines and drugs in hospitals that are not on therapeutic programs, pharmaceutical spending hovers around 16 percent. This incorporates the open pharmacy reimbursement system and drug program in hospitals â?? in fact â?? it is written in law that this amount is up to 17 percent. Nevertheless, we hope that this will change to be a flat rate at 16.5-17 percent, rather than a rate up to 17 percent.

This will be possible via the aforementioned risk sharing agreements that are in place. However, we want to see this system used to finance the market entry of innovative drugs, rather than the current model that pushes the generated funds into the general healthcare budget.

The new reimbursement act is being slowly rolled out. What does this policy entail?

Overall, we want to create a more stable system that does not fluctuate so rapidly; therefore, the reimbursement list will be launched each quarter, rather than the current bimonthly release. This does not make our job any easier, but ensures less work for Polish patients. Additionally, we will ensure a longer period of time between the draft reimbursement list and the official announcement, allowing the industry to be able to react if they disagree and want to discuss potential amendments.

Secondly, if a company launches a product that costs less than any drug in its reference group, the economic commission will automatically authorize its market entry approval. Naturally, we are pushing for the use of the cheapest drugs across the board, and are in discussions to determine where to apply certain margins.

Thirdly, we need to take full control of the drug programs. At present, the program is agreed with the companies, and if we wish to make changes, such as add a new treatment, we need their approval. Of course, their competitive behaviour results in them disagreeing at times; therefore, in the new version we can make changes without their permission, and if a company disagrees we will not be interested to have their drugs in that particular program.

Another interesting challenge is parallel imports, in which drugs are imported at a very low price and have no distribution. Their low prices then freeze the reference pricing level of the jumbo group and do not allow other drugs to enter that group; therefore, we want to stop parallel importers without sufficient distribution power from entering the jumbo group pricing model.

Other changes include shortening the time in which HTA analysis is valid and regulating more the medical device sector, around margins and co-payment of high quality devices. Also, we want to move haemophilia and HIV treatments out of national programs and into the standard reimbursement system as they now act as chronic conditions.

Lastly, we are in active talks about the payback system for overspending, that encompasses both the National Health Fund and pharmaceutical companies. Nobody is certain on the preferred model to approach this area as it is a complicated task to find a fair balance for the generic and innovative industries as well as the government.

When is the planned implementation date?

We have started already. We hope to launch the act next year; although, legislative changes generally are very time consuming.

In what areas do you conduct discussions with the retail sector to obtain their perspective?

Everywhere! It is a diplomatic process, and in Poland we deserve this open communication, despite it lengthening out the process. I am completely against out of the blue regulation changes that do not give the industry enough time to adjust or have their say. Therefore, I am always in dialogue with the main stakeholders and I spend a lot of time explaining our actions with the media, and this is no different with the new reimbursement act and medicines policy.

You have a long track record working in the private sector and academia. What attracted you to taking up a role in the public field of healthcare?

During my time lecturing at the Warsaw University of Technology, I was always able to give my students a view of the private sector, but I lacked the piece of the puzzle that gave me the ability to give a public angle. One day, an ex-student of mine, working at the Ministry of Health approached me and asked if I would consider a job with them. When I was told about the Vice Minister position I had to sit down in pleasant shock, though after talking with the Minster of Health it really appealed to me.

It is an uncommon pathway to reach this point, though it has been very exciting so far, and I am grateful to be in a position I can make important decisions to improve the health of the Polish population and establish policies for a sustainable healthcare system moving forward.

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