

PL-16

Future of the Hungarian Drug Market – Role of the Hungarian Regulatory Authority

MÁTYÁS SZENTIVÁNYI

*National Institute of Pharmacy and Nutrition, H-1051 Budapest, Hungary**Correspondence: szentivanyi.matyas@ogyei.gov.hu***Keywords:** *Regulatory authority, scientific advise, health technology assessment, ATMP, complex products*

1. Introduction

The National Institute of Pharmacy and Nutrition (NIPN) has a long tradition as the safeguard of patient safety and as an institution that is committed to ensure that Hungarian patients have access to good quality, safe and efficacious medicines. During the last few years responsibilities of the Institute has been broaden and now we are also a key player in the regulation of special food and medical devices.

During the past two decades a transition can be seen in the role of medicines agencies. While in the past the role of regulators was mainly acting as a gatekeeper, nowadays we also need to act as enablers. And while ensuring regulatory compliance of new medicines is still a key activity, our role cannot be narrowed down to the review of documents and other authorization tasks.

This is due to the enormous development in the field of biotechnology, precision medicine, the revolution in synthetic biology, just to name a few. On one hand regulators need to be prepared for these new scientific challenges, on the other hand we have to be ready to give the necessary regulatory support to those developers that are coming from various fields and have limited knowledge and experience in regulatory issues.

2. Advanced therapy medicinal products

ATMPs are a very special category, and the group contains gene therapy, cell therapy and tissue replacement medicines. During the last 70 years we could witness a fast development in how much we understand the function of the cells. This led to the current gene therapies, like the CAR-T cell based therapy. Nevertheless, it is also clear that the number of new ATMPs that are readily accessible to patients is not that substantial, currently

there are appr.10 registered products in Europe. It is the task of the future to identify therapies that address unmet medical need and provide the necessary assistance for developers. It is also of utmost importance that creative payment models are developed that ensure affordability and access to ATMPs because we predict a substantial increase in the number of ATMPs during the next 5-10 years. As part of this we have created the „ATMP roundtable” in which many Hungarian experts participate and try to find ways to improve Hungary’s activities in the ATMP field. We have recently created a white paper about the innovative medicine sector development in Hungary that we hope will direct focus on this field.

Assistance to developers is also a key factor for successful authorization of new medicines. The EMA has launched the PRIME scheme in 2016 to provide early and enhanced scientific advice to support medicines that have significant potential to address unmet medical needs. However, it seems that involvement of HTA will be important in the future as successful marketing authorization is not the end of the story – patient access depends heavily on HTAs and reimbursement. NIPN has the Hungarian HTA body within the or-



Figure 1 Are we ready to engage with scientific innovations?

ganisation, which helps us to join forces and advise developers from both regulatory and HTA aspects.

Facilitating ATMP developments, bringing forward the PRIME scheme are tasks for the whole continent. In Hungary one very important thing is that since we are here, we are accessible. Developers can find us, can talk to us. On the other hand we have many connections to colleagues all over Europe, and therefore we can collect knowledge from other countries and from EMA. In 2016 the EU Innovation Network was created in order to have a structured way of interaction between regulators and where difficult products can be discussed, initial opinions can be collected. The idea behind the network is that national competent authorities have a much better knowledge of promising developments in their countries, better personal relationship with key stakeholders and therefore they can facilitate and support early developments in a very efficient way. The Network is there as a background and as forum to do horizon scanning, to find out the needs for new guidances for borderline products and new regulatory tools to support innovation based on best practices from the member states. NIPN is being active in the network and have already organized several consultation with developers.

3. Complex medicinal products

Another important challenge for the future will

be the increasing number of complex products, like medical devices that contain medicinal products. In principle, the regulatory pathway depends on whether the primary action is of the device or the medicine part. However, it is getting evermore difficult to attribute one primary mode of action to these products and therefore integrated competence and expertise are needed. NIPN is again in a good position with this regard given that medical device regulators are part of the organisation, but this is obvious that the level of expertise should be substantially increased. It is also essential to facilitate the regulatory pathway between notified bodies and medicines regulators.

4. Other aspects

There are also other aspects that we will need to consider in the future. One of those is how we can enhance the usage of Patient Recorded Outcomes, or how can we create a sustainable, quality assured, flexible framework to use real-world data in decision making. To find answers to these and other questions it is important to leverage collaborations with academia. We has been active in this but still, we need to build the best expertise around our core activities to be able to respond future challenges. One option for this the so called STARS project that aims to strengthen training of academia in regulatory sciences and by this to improve communication between developers and regulators.