

Europe *Poland*

Fuelling healthcare innovation: Poland creates new Medical Research Agency

In March 2019, the new law creating a Medical Research Agency (“the Agency”) entered into force in Poland. This new entity is intended to play a similar role to institutions like the UK’s Medical Research Council, the National Institutes of Health in the US, the Danish Medicines Agency, and Inserm in France.

Scope Of Agency Responsibilities

The new Agency brings together a specialised body of experts to work on innovation in Polish medicine. With the focus on areas related to oncology, haematology and rare diseases, Agency activities will consist mainly of co-financing scientific research and development (R&D) work, as well as interdisciplinary projects. There’s a special emphasis on clinical, observational and epidemiological research.

The Agency can initiate and carry out its own scientific R&D. It will also work on expanding international cooperation and can provide expert opinions to administrative bodies and other entities within the field of medicine and health science.

Financing scientific R&D

To start with, the Agency will most likely focus on research competitions to identify and select research projects that it will be co-financing. The choice of projects will be based on their:

- scientific value
- impact on improving citizens’ health
- level of innovation
- predicted economic impact
- effectiveness for use in health protection and
- the material and human resources that will be required.

Competitions will be open to various entities. These include Polish organisations that conduct scientific R&D, entrepreneurs with the status of R&D centres, and university healthcare institutions. Large companies are not excluded. The Polish Ministry of Health recognises that it’s often pharmaceutical and medical device companies that can bring the most resources to bear. But the Agency’s primary objective is to promote R&D that might not be profitable.

According to the Ministry of Health, the first research competitions will be announced in the second half of 2019.

Supporting Innovation

The Agency’s aim is to facilitate innovation in Poland. One of its key roles is to support businesses pursuing innovation in the field of medicine and health science. Such support will not require any research competitions. Unfortunately, however, it’s not yet clear what the Agency’s approach will be in this respect.

Clinical Trials

The Agency will focus on clinical trials (commercial and non-commercial). The Ministry of Health wants the Agency to promote clinical trials in Poland by acting as a commercial partner to the firms that conduct them. Over time, it could assume responsibility for all clinical trials in Poland (not just the ones that it’s actually involved with).

According to the Ministry of Health, the Agency’s main area of interest when it first becomes operational will be non-commercial clinical trials of medicinal products and medical devices (in all phases). While these currently constitute only around 1% of the total number of clinical trials in Poland, it’s hoped that the Agency’s involvement will see this rise to 20-30%.

Business Activities

The Agency can create companies in connection with its own research activities. It can also conduct business activities related to, among other things, carrying out research, advisory and expert services, organising conferences and training, as well as commercialisation of scientific R&D.

Agency Budget

Budget in 2019 will amount to approximately PLN 50 million, rising to around PLN 1 billion by 2028. The Agency will be financed by the state budget and a write-off from the National Health Fund (“NFZ”) of 0.3% of its revenues. The money from the NFZ write-off will be used only for non-commercial clinical trials. The Agency may also be financed from other sources, including donations, the EU budget, international research programmes or from its own business activities.

Comment

By providing institutional support for the financing of analysis and scientific research in healthcare, the Agency is expected to contribute to the growth of innovation in Polish medicine. The Ministry of Health hopes that the Agency’s launch later this year will encourage international investors to choose Poland for their research activities. We’ll keep readers updated on developments.



Agnieszka Majka
Senior Associate, Warsaw
T +48 22 529 29 69
agnieszka.majka@hoganlovells.com



Anna Wiktorow
Lawyer, Warsaw
T +48 22 529 29 14
anna.wiktorow@hoganlovells.com

