Commentary: Johan Strömquist and Thomas Lönngren

Assessing the consequences of the EMA’s relocation

With the long-awaited decision to relocate the European Medicines Agency, many questions have finally been answered. Out of all the competing options, Amsterdam was the one preferred by the clear majority of agency staff and this bodes well for the stability and continuity of its activities. From this perspective, the decision has provided a very good basis for the execution of the EMA’s public health responsibilities following the departure of the UK from the European Union, otherwise known as Brexit.

As the decision is ratified and put into law, the EMA and the Netherlands can now start to plan and put into effect the activities necessary for the EMA’s transition. This is a huge relief for all stakeholders and will ease the whole relocation process.

Despite the relatively favourable circumstances, the agency is facing a massive challenge – the relocation of close to 900 staff and experts with all the logistics that this requires is an enormous undertaking and will consume time and bleed resources from other activities. For this reason, there will be an impact on the daily operation of the agency and hence on the support and responsiveness companies can expect during the transition period.

It can be expected that the transition process will begin very promptly. The EMA now has 16 months to relocate and to make the best of this narrow time frame, this process must start urgently. Therefore, the impact on the agency’s other activities can be expected within a relatively short time period.

How will the EMA prioritise its efforts outside of the transition activities? Based on the Brexit Preparedness Business Continuity Plan that the agency has created, it is possible to identify some clear priority areas that will never be allowed to fail, and some areas where timelines and development will take a back seat during the transition. The key priority will be to ensure the continued functioning of the EMA’s core business. This includes core scientific activities to safeguard the EU population from significant health threats, with an emphasis on pharmacovigilance and the integrity of the Agency’s IT infrastructure that underpins these activities. It also covers the assessment and management of applications for marketing authorisations and the work of the agency’s scientific committees and working parties.

It can therefore be expected that the EMA will be able to manage the application process for new products well, given appropriate planning, in addition to maintaining its mission to protect the health of the European population.

On the flip side, it is also clear that there will be several activities that will be deprioritised, should the need arise, during the transition. These have been placed into two categories, both within the ‘medium priority’ class. Based on an assessment of the long list of activities within these two categories, it seems likely that the development of new guidelines and regulatory science, exploring and developing a deeper understanding of emerging science, the publication of clinical data and other transparency activities, institutional collaborations as well as the timely provision of scientific advice are at risk of being affected during the transition period.

Impact on industry

It should also be recalled that Brexit places a special burden on companies currently located in the UK. Companies holding centrally authorised medicine approvals and based in the UK, will need to transfer these authorisations to a legal entity in the EU. Similarly, any UK-based personnel responsible for pharmacovigilance will be required, under EU law, to move to a location within the union.

Given the pressure on the agency’s resources in the coming 16 months, companies working in novel scientific areas, particularly smaller companies in need of additional scientific guidance, should start considering their options. There may be fewer opportunities both to receive advice and to support the agency’s knowledge-building processes around emerging science. This could well create challenges both with selecting the right development strategy, and, later, with gaining acceptance of strategy, development approach and data, with the agency.

For companies finding themselves in this situation, it may be pertinent to explore options such as gaining external advice from specialised experts in the European regulatory system, but also to look deeper into the capabilities of the national regulators around Europe. Not only will the move from London create a potential competency vacuum in the agency, but the rush to fill this vacuum from the national agencies has already started. Being in tune with the national agencies, having the right intelligence on where to seek the best advice and where the key regulatory experts are located, will be critical both to build the right programme, and to educate the right regulatory stakeholders on the science around your product.

In conclusion, the regulatory system in Europe has let out a sigh of relief with the selection of Amsterdam as the EMA’s new home, but the problems are far from over. The challenges to transition to the new location are likely to cause stress and delays in the areas that are not explicitly prioritised by the agency. If you are a developer of novel drugs, engaged in emerging science, it is wise to take stock of your options as soon as possible and learn where you can find reliable sources of expertise to assist you during the transition period.

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