“Shocking blow” to UK: EMA Cuts Off Multi-Million Euro MHRA Drug Review Funding

The EMA has cut the UK Medicines and Healthcare Products Regulatory Agency (MHRA) out of its drug approval process seven months earlier than expected in preparation for Brexit, according to media reports. The move will slash the MHRA’s annual budget by approximately EUR 50M ($59M).
The EMA has already stopped giving new marketing authorization application (MAA) review contracts to the MHRA, and existing contracts with the UK regulator are being reallocated to the national regulators of other EMA member countries, reported the UK’s Guardian newspaper.
The MHRA won just two contracts this year, it reported. “We couldn’t even allocate the work now for new drugs because the expert has to be available throughout the evaluation period and sometimes that can take a year,” said a spokesperson.

Martin MacLean, Life Sciences Partner at intellectual property firm Mathys & Squire, said the news that the EMA will discontinue awarding contracts to the MHRA is “a shocking blow to MHRA, which will create a massive [funding] hole that is unlikely to be filled by way of demand from national applications or UK government funding.”

Until now, the UK has performed a disproportionately large number of drug reviews—the annual revenues of the MHRA from the EMA are about EUR 50M ($59M). This represents around two-fifths of the EMA’s review budget, which in 2018 is approximately EUR 127.6M ($150M).
Withdrawal of EMA funding means “[the UK’s] current wealth of regulatory expertise will likely be forced to find new roles, else retrain or migrate,” MacLean told PharmSource.
It is unclear how the UK drug approvals process will work after Brexit. If the UK sets up its own separate system, and if the UK government can fill the funding gap and continue to employ domestic regulatory experts, then the country has every chance of maintaining an excellent parallel regulatory system, MacLean said.

However, in a separate system, there may not be enough work available to re-employ the current number of experts, MacLean said. The obvious response will be some form of downsizing for the MHRA, he said. Instead of trying to fill the gap with money, the UK could change its drug review regulations procedures to make them more user-friendly, quick, and efficient. For instance, this could involve bespoke processes for different types of product, MacLean said. This could have the advantage of giving UK pharma companies a competitive advantage if new provisions were tailored accordingly, he said.

The EMA is responsible for the centralized evaluation of MAAs, awarding contracts to an assessment team and “rapporteur” in EU member states, Switzerland, Iceland, Norway, and Liechtenstein. Their decision is valid throughout the region.

Withdrawal from the EMA will also affect GMP facility inspections in the UK. These inspections are currently made under the EMA umbrella, both for inspections as part of a drug’s application process for marketing approval and for those ongoing inspections to make sure quality standards are maintained. That will probably stop and that role will be taken over by the MHRA, said MacLean. The UK pharma industry is still reeling from the loss of the EMA’s headquarters in London and its 900 jobs. It was announced in November 2017 that the EMA headquarters will move to Amsterdam, Netherlands.