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UK Regulator To Lose 20% Of Staff In Post-Brexit Cost-Cutting Plans

by Vibha Sharma

The MHRA intends to drop around 300 roles as it faces a financial crunch after leaving the EU and other pressures.

The UK's Medicines and Healthcare products Regulatory Agency could lose around 20% of its 1,200-strong workforce under cost-cutting plans being drawn up to address post-Brexit revenue losses and other challenges.

The *Pink Sheet* understands that the plan to "transform" how the MHRA operates will lead to a reduction of approximately 300 roles and will take into account different functions across the agency. The MHRA intends to make savings in its operating costs, as well as redeploying and retraining its staff in new areas of regulation and science. The transformation plan, which was conveyed to the MHRA staff in February, is in response to four challenges:

- The UK's exit from the EU with a consequent reduction in the fee income that the MHRA receives from the EU medicines regulatory network.
- The MHRA's role in enabling the Life Sciences strategy.
- The recent Cumberlege review, which recommended that the MHRA should focus on patients in all its activities. (Also see "*England To Get 'First Ever' Patient Safety Commissioner Next Year*" - Pink Sheet, 27 Jul, 2021.)
- Financial pressures.

Despite the cost-cutting plans, the MHRA has indicated that it wants to continue being a world-class regulator that delivers the right outcomes for patients while it modernizes the services it provides to industry, and remains financially stable.

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Voluntary Exit Scheme For MHRA Staff?

It is not clear how exactly the MHRA intends to achieve the 20% target in reduction of roles – for example, whether it would result in forced layoffs. The agency is currently in discussion with staff and unions and plans to conclude a formal consultation process in the late autumn.

The *BMJ* reported in an article published on 30 July that it had seen "leaked documents" that provided details of a "voluntary exit scheme" that the MHRA was offering to staff from its divisions on vigilance and risk management of medicines, licensing, devices, inspection enforcement and standards, as well as its committee secretariat.

The documents also showed that the MHRA's income could fall by 15-20% in the next financial year and beyond, while its operating costs would rise by £7-9m per year.

These developments could be of major concern for drug and device companies given the MHRA's ambition to become a world-class regulator after leaving the EU. In support of its ambition, the MHRA has announced new pathways to attract sponsors of innovative medicines, has joined international work-sharing schemes to speed up drug approvals, and is making changes to streamline the evaluation of clinical trials. (Also see "*Brexit: MHRA Joins Second International Work-Sharing Scheme To Speed Up Drug Approvals*" - Pink Sheet, 15 Oct, 2020.)

The UK BioIndustry Association (BIA) said it was critical that the MHRA should have the required funding to "implement its international strategy and undertake the new processes they're putting in place to continue to be a world leading regulator."

"Ensuring that the MHRA has the necessary resources to be a sovereign regulator… must be a key priority for the Government in the upcoming comprehensive spending review," the BIA added.

New Fee Structure

Ensuring financial sustainability is a key priority for the MHRA and an update on this front was provided by agency chief June Raine at the MHRA's board meeting held in public on 15 June.

Raine said that work was under way to define a new fee structure for the MHRA for which a cross-agency group had been formed.

According to the MHRA's 2020/21 annual report, the agency's funding is structured as follows:

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  - Medicines regulation is funded entirely from fees. In setting its fees the agency takes account of full cost recovery rules as set out in the Treasury's "Managing Public Money" document.

- Devices regulation is primarily funded by the Department of Health and Social Care (DHSC), with approximately 10% of its revenue generated from fees charged for services.
- The National Institute for Biological Standards and Control (NIBSC) derives about half of its revenue from fees charged for services, including the sale of biological standards, and from research funding. The DHSC provides the remaining funding to finance its public health functions.
- The Clinical Practice Research Datalink (CPRD) is jointly funded by the MHRA and the DHSC's National Institute for Health Research. It is managed and operated by the MHRA with the DHSC having oversight through membership of the CPRD Executive Committee.

Raine said it would take around 12 months to define, consult, legislate and implement a new fee structure for the MHRA.