Proposal 1 - increase the statutory fees (CI, AB) to ensure continued cost-recovery

We do not support this proposal.

Companies need clear, consistent and predictable fees to support planning. The proposals are counter to this and businesses do not see what benefits would arise from the increased costs.

The proposals will make the UK significantly more expensive than other jurisdictions including EU and US. This makes the UK much less attractive to businesses.

Members who run clinical investigations in the UK noted that MHRA is already more expensive than EU countries and additional costs will discourage clinical research happening in the UK.

The rises are out of step with inflation and far higher than would be allowed under NHS contracts. In some cases, MHRA fee increases may make it unviable to supply the NHS.

The proposals do not make clear the MHRA services that will be included or improved because of increased funding, likewise, the mechanisms to be used to demonstrate accountability.

New MHRA fees come on top of existing cost pressures such as those associated with NICE assessments, REACH compliance, new packaging, sustainability costs, extended producer responsibilities, and minimum wage. Collectively, the proposals fail the test enshrined in the Medicines and Medical Devices Act 2022 requiring that the UK be seen as a favourable place to develop and supply medical devices.

Proposal 2 - amend existing registration fee to include the costs for post-market work (£210 per GMDN code).

We do not support this proposal. Key points are grouped below under relevant headings.

An adverse impact on HealthTech industry in the UK.

The proposed costs will have an adverse impact on the UK HealthTech industry. Members are concerned that the proposed costs will be prohibitive, limiting the number of devices available to UK patients. Additionally, the future post market system in the UK remains unclear, and the potential impact of MHRA's proposal on international recognition and reliance has not been addressed in the proposal.

After close analysis, companies have reported that fee increases would result in a rise of thousands of percent. This would lead to increased administrative costs, forcing companies to review their portfolios and, in some cases, remove products from the market due to higher maintenance costs. This could be further compounded by the reluctance of the NHS to accept cost increases from its suppliers.

It is not clear if MHRA has assessed the impact of different fee models on product or company viability, particularly regarding the GMDN model compared to other models. MHRA fees are already comparably much higher than others, including the EU and US, and the proposal is not compatible with the MHRA's ambition to be an 'enabling regulator'.

Unintended impact on patient safety

Although no concerns have been expressed about the GMDN system itself, some members are worried that this approach may incentivise companies to reducing the number of codes used. It is a concern that adoption of this model, akin to a "windows tax", will lead to the misuse of GMDN codes, which could have an impact on patient safety. Furthermore, product SKU rationalisation programmes could also reduce the availability of products for patients.

Uneven distribution of costs across products

Many members expressed dissatisfaction with the use of GMDN codes as a basis for fees, as this disproportionately impacts companies across different product categories. For example, manufacturers of IVDs, surgical instruments, woundcare devices, single-use instruments, procedure packs, low-margin devices and custom-made devices may be particularly affected. It is likely that other sectors would be adversely affected, but this could only be discovered through modelling using the decades of post-market data available to MHRA.

Uneven distribution of costs across businesses

It appears that MHRA's modelling was based on names of suppliers in the PARD system. No thought was given to the fact that some suppliers fall under a single Corporation umbrella. This puts an unfair burden on some corporations that have multiple Legal Manufacturers within their scope. Explanations should be provided that clarify the process used to develop the GMDN model in all instances.

Small and medium sized enterprises (SMEs) may have fewer products and codes, and will likely have fewer products per code. The SME cost increase is therefore disproportionately high. MHRA has assumed that each registered business is an individual company and have therefore

miscalculated the number of SMEs registered with them by a significant margin. This should have been clear from the modelling done by MHRA.

No provision was given to SMEs, and any subsequent provision will not, therefore, have been subject to consultation. This was obvious as soon as the consultation was published, but MHRA does not seem to have noticed this. By comparison, NICE fees include a significant discount for SMEs.

Innovation gap

There will be a disproportionate impact on start-up and micro businesses and this will discourage innovation in the UK. Innovative products will be registered prior to adoption in the health system, placing an undue burden on smaller companies and stifling the introduction of innovative solutions.

In addition, basing the charges on the number of GMDN codes does not capture how much future work a supplier is creating for the MHRA.

MHRA will overcharge

Although there is a mass upload system, the process to remove GMDN codes no longer needing to be registered is very difficult. Items must be removed one by one at product code level. This uses massive resource. Until MHRA has a usable mass-upload system, companies will be over-charged because they have not been able to update the database.

If manufacturers, or their UK Responsible Person (UKRP), are unable to rationalise their registered codes by the cut-off date, they will be charged for the full year without any post-market service from MHRA.

There are also concerns that the charge is duplicative (triplicative if carried out by both UK Approved Bodies [ABs] and EU Notified Bodies [NBs]) as ABs and NBs already charge for auditing the effectiveness, appropriateness and output of post-market work. If substantial fees are introduced by MHRA for post-market surveillance, then any future regulatory system (including recognition/reliance) must ensure that fees cover all post-market surveillance activity whether performed by MHRA or by third party assessment bodies.

IVDs for performance evaluation are ‘registered’ with MHRA and will be liable to the same post-market surveillance fee without the same post-market service from MHRA.

Many products are still transitioning to new regulations, which means the same product may be registered under multiple systems (UK MDR, IVDD, MDD, IVDR, MDR), resulting in the MHRA charging multiple times for the same product.

UKRPs are responsible for the costs of the manufacturers that they represent and must pass these costs on. For some, once the legislation is in place, this will require an update to the contractual terms which could take time – especially where multiple manufacturers work with the same UKRP. If these terms are not updated in time, then UKRPs may not be able to pass on costs.

Billing and payment concerns

A single bill due on 1st April will be impossible for some businesses. Quarterly billing with long payment terms will be essential. Additionally, invoicing will be a helpful addition to credit card payments.

Manufacturers, corporate partners, legal entities, distributors and RPs that form part of the same group, each placing the same product on the market and registering it separately, should not face duplicative charges for the same GMDN codes.

MHRA modelling is flawed

Our response has highlighted several flaws in MHRA modelling which has led to an uneven distribution of costs across products and businesses. We have been told that the modelling will not be available publicly. We do not have any information on what, if any, alternative models were considered or why they were rejected.

We also believe that the modelling is driven by HMT's "Managing Public Money" and not on the requirements of the Medicines and Medical Devices Act 2021. As such, MHRA's proposed fee structure does not, in any way, take into account the safety and availability of HealthTech in the UK. Nor does it take into account the favourability of the UK as a place to research, develop, manufacture and supply HealthTech.

MHRA is developing a barrier to innovation

The additional costs for clinical research outlined in proposal 1, combined with the disproportionate impact on small businesses and unintended costs for IVD performance evaluations, will make the UK a less attractive place for research and innovation.

ABHI response: NO

Proposal 3 - create new regulatory advice meetings for medical devices (£987/hour)

Members were cautiously in favour of advice meetings, although many pointed out that that the same service is free from the FDA. There is also a need to improve the quality of service and MHRA expertise in device regulations before justifying such fees.

Members highlighted that, without knowing the future regulatory system, it is not possible to respond to the consultation. For example, what mechanisms will ensure that subsequent regulatory decisions (e.g. by ABs) align with MHRA's advice provided in these meetings?

There is a lack of clarity on what defines a 'complex query'. Members questioned whether less complex requests will still be answered without charge and whether responses will be personalised, rather than just generic directions to check the MHRA website.

Members also noted that different advice routes may be available (e.g. legal firms, ABs, consultancies) and would be compared with the MHRA offering. It is unclear what benefits MHRA's service would provide in comparison - could it potentially fast track approval times?

To maintain consistency and transparency in MHRA's pre-market reviews, it was suggested that any scientific or regulatory advice given during these meetings should be made publicly available through guidance documents, with appropriate anonymisation.

There is also a question about how advice for companion diagnostics would work (i.e. different advice routes for pharmaceutical and IVD partners).

MHRA has since stated that the service will be available only to smaller companies with no in-house regulatory division. However, this was not made clear in the consultation. It is also unclear how many meetings MHRA would be able to offer, which is crucial information for assessing the viability of this service.

ABHI response: NO Not with current level of fees proposed.