BIVDA
British In Vitro Diagnostics Association

Consultation on proposals for changes to the Medicines and Healthcare products Regulatory Agency's statutory fees

https://www.gov.uk/government/consultations/consultation-on-proposals-for-changes-to-the-medicines-and-healthcare-products-regulatory-agencys-statutory-fees

*Closes **23 November 11.45pm***

BIVDA is the National Trade Association representing over 200 In Vitro Diagnostics suppliers in the United Kingdom. Our members are producers of electrical and/or electronic equipment, waste management companies, distributors (retailer or distance seller), and in some cases end users of electrical and/or electronic equipment.

Question 1: Do you support proposal 1, to apply a 10% indexation uplift across Agency statutory fees to match the increased pay costs national average since the last MHRA fees review?

Yes – BIVDA agrees with the implementation of these fee increases to allow MHRA to become self-sufficient on fees and recoup the cost of these services, assuming the new cost accurately reflects the cost inferred to MHRA.

The fees should be reinvested to the benefit of the UK regulatory infrastructure for the long term with resource and efficiency at the head of it. As well as this, it is notable that increased fees will come with an obligation and expectation that the service that industry receives is an appropriate standard for a fee charging service provider.

Details cannot be located on how these new fees have been calculated. Transparency would be appreciated to demonstrate how these new fees would allow renumeration for MHRA (i.e. breakdown of staff time expected and other associated costs for MHRA).

Question 2: Do you support proposal 2, to place a cost-based uplift for 61 significantly under recovering fees to achieve full cost recovery?

Yes – Generally, BIVDA agrees with the implementation of these fee increases to allow MHRA to become self-sufficient on fees and recoup the cost of these services, assuming the new cost accurately reflects the cost inferred to MHRA.

The fees should be reinvested to the benefit of the UK regulatory infrastructure for the long term with resource and efficiency at the head of it. As well as this, it is notable that increased fees will come with an obligation and expectation that the service that industry receives is an appropriate standard for a fee charging service provider.

Details cannot be located on how these new fees have been calculated. Transparency would be appreciated to demonstrate how these new fees would allow renumeration for MHRA (i.e. breakdown of staff time expected and other associated costs for MHRA).

Notably, some of these fees are increasing substantially (from £15,904 to £58,341 for an initial designation audit of an approved body), and for these fees this transparency is especially requested. It is possible that in a time where there is insufficient approved body capacity, having such a substantial fee could deter organisations from undergoing designation in the UK. This puts the medical device and IVD market at risk in the UK, and could result in a lack of products for patients.

Question 3: Do you support proposal 3 to introduce 22 new fees for services offered by the MHRA?

Yes – Generally, BIVDA agrees with the implementation of these fee increases to allow MHRA to become self-sufficient on fees and recoup the cost of these services, assuming the new cost accurately reflects the cost inferred to MHRA.

The fees should be reinvested to the benefit of the UK regulatory infrastructure for the long term with resource and efficiency at the head of it. As well as this, it is notable that increased fees will come with an obligation and expectation that the service that industry receives is an appropriate standard for a fee charging service provider.

*Some of these fees indicate new services that MHRA have previously not conducted, which will come as reassurance to the industry, for example, the ability to undergo a regulatory advice meeting in relation to clinical investigations. The fee labelled as "*In Vitro Diagnostic (IVD) Performance Report (also known as IVD performance evaluation report)*" is not defined, and therefore BIVDA have assumed this is comparable to the notification fee for submission of a clinical investigation for "*Class I, IIa, or IIb other than implantable or long-term invasive devices*" as these are the same cost. BIVDA would agree that pricing of this notification is justifiable against Class I, IIa, or IIb other than implantable or long-term invasive medical devices.*

*Clarity would be appreciated on whether "*Clinical investigations consultation fee (optional) – Device Regulatory Advice meeting*" and "*Clinical Investigations consultation fee optional service – Clinical Investigations statistical review*" are also applicable to performance studies conducted for IVDs. These types of meetings and services would also be beneficial for IVDs.*

Question 4: Would you consider these proposals to impact certain types of business disproportionately? e.g. small businesses?

*Yes - These proposals will impact certain businesses disproportionately. For example, a fee of £7,472 for "*In Vitro Diagnostic (IVD) Performance Report (also known as IVD performance evaluation report)*" is incredibly expensive for a SME, whereas it is relatively insignificant for a multi-national organisation. This is likely to dissuade SMEs and newer organisations, or prevent them from generating clinical evidence at all, potentially forcing such organisations to merge with larger organisations.*

A more suitable proposal may be a scaled cost determined by a) the revenue of the organisation, b) the volume of funding already gained by an organisation, or c) the headcount of the organisation. All of these metrics would give an indication of the feasibility of these fees and help prevent monopolisation within the medical device and IVD sector.

These smaller organisations are also those who are most likely to benefit from regulatory advice meetings as they may be utilising consultants or not have a great deal of experience or expertise within the regulatory field. Therefore, MHRA may wish to take a scale-approach to these fees also, or consider lowering them completely to enable innovation within SMEs.

Question 5: Do you think any of the proposals in this consultation could have an impact on the development and access to medicines or devices for (1) rare conditions or (2) minority groups with smaller patient populations?

Yes - In order to conduct a performance study for an IVD, these proposed MHRA fees indicate it could cost approximately £9,160 (£906+£782+£7,472). This is not including the costs to actually conduct the study itself which would also fall on the manufacturer.

Such a fee is understandable to organisations who are making a high revenue, but for organisations who have lower revenue or who focus on rare conditions or minority groups, these fees may be unmanageable. It is likely that organisations working in these areas may look to conduct clinical studies in other geographic regions with lower costs associated, or rely more heavily on equivalent clinical evidence (where possible).

The risks associated with this, is that innovative or new devices may not be available for patients in the UK, and the health service in the UK may not be as attractive to industry.

Question 6: Do you think any of the proposals in this consultation pose a risk to existing products being withdrawn from the UK market?

Yes - These fee increases alone could pose a risk to products already within the UK market. However, as most of these fee increases are in relation to clinical studies, they are more likely to have an impact on future devices.

The increased cost to approved bodies is likely to have a downstream effect on the cost of industry accessing approved bodies and may mean that reassessment under existing certificates are no longer feasible from a commercial stand point. In a similar vein to the above point, this is more likely to have an impact on future products and the affordability of bringing a new product to the UK market.

BIVDA believes that the increased registration fee is unlikely to pose a risk to products already on the UK market, assuming the same criteria remains for how many devices can be included in a single registration.

Question 7: Do you think any of the proposals in this consultation could have an impact on research, clinical trials or clinical investigations in the UK?

Yes – the increased fees for clinical investigation application are likely to drive industry to conduct their clinical studies outside of the UK in order to avoid this fee. However, it is notable that other competent authorities do charge for these services (as a guide, a notification of an IVD performance study costs 7,223.36€ in Belgium).

BIVDA would request MHRA to review costs for other competent authorities and regulatory authorities and ensure this cost is proportional to the market size of the UK.

Question 8: With reference to the protected characteristics covered by the Public Sector Equality Duty set out in section 149 of the Equality Act 2010 or by section 75 of the Northern Ireland Act 1998, we do not consider that our proposals risk impacting different people differently with reference to their protected characteristics. Do you agree?

Yes – BIVDA agrees that these proposals do not risk impacting different people differently with reference to their protected characteristics.

Question 9: In Northern Ireland new policies must be screened under Section 75 of the Northern Ireland Act 1998 which requires public authorities to have due regard to rural needs. We do not consider that our proposals risk impacting different people differently with reference to their protected characteristics or where they live in Northern Ireland. Do you agree? Yes/No.

Yes – BIVDA agrees that these proposals do not risk impacting different people differently with reference to their protected characteristics or where they live in Northern Ireland.