BIA response to MHRA consultation on proposals to increase statutory fees to recover costs November 2022

UK BioIndustry Association

The consolidated BIA response was developed with input from our Regulatory Affairs Advisory Committee and submitted using the online consultation survey providing our responses to questions raised in the Medicines and Healthcare products Regulatory Agency (MHRA) consultation on proposals to increase statutory fees.

We provided BIA members' feedback on the following proposals and the impact of these proposed changes on the innovative life sciences industry including SMEs, which would apply from 1 April 2023:

1. **A 10% indexation uplift across the Agency's statutory fees.**
2. **A further uplift for 61 significantly under recovering fees, on top of the indexation uplift, to achieve cost recovery.**
3. **The introduction of 22 new fees for services that require cost-recovery since the last fee changes for medicines and medical devices.**

General questions

Please tick the box which best applies to you:

- I am responding as an individual (such as a patient, carer or member of the public)
- I am responding as an individual sharing my professional views
- ✓ I am responding on behalf of an organisation

What type of organisation, group or profession do you represent?

- Academia or a research organisation
- Healthcare professionals
- Healthcare scientists
- Medical device developers or manufacturers
- ✓ Pharmaceutical developers or manufacturers
- Research funding bodies
- Charity

What geographical area does your organisation cover or do you operate in?

- ✓ United Kingdom
- Great Britain

- England
- Northern Ireland
- Scotland
- Wales

What is the area of your expertise or your organisation's main activities?

The BioIndustry Association (BIA) is the voice of the innovative life sciences and biotech industry, enabling and connecting the UK ecosystem so that businesses can start, grow and deliver world-changing innovation.

The BIA represents over 500 members, including start-ups, biotech and innovative life science companies; pharmaceutical and technological companies; universities, research centres, tech transfer offices, incubators and accelerators; and a wide range of life science service providers and Contract Research Organisations.

Name of organisation:

UK BioIndustry Association (BIA)

Consultation questions

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?

Response:

Yes

If you have any concerns about this proposal, please provide them below

Generally, BIA member organisations are in support of this proposal. An uplift across all statutory fees seems reasonable. This will ensure the MHRA is adequately resourced with talented and experienced staff and financially sustainable in the long-term, benefiting both the life sciences industry and UK patients while protecting public health. It is of paramount importance that a world leading regulatory agency can fulfil its regulatory functions and deliver responsive and efficient services in order for the UK to retain and grow its reputation as a global base for life sciences, in line with the ambitions of the Life Sciences Vision.

The ability of the MHRA to provide timely scientific advice and deliver quality regulatory assessments and decisions are important to companies planning their product development strategy. BIA members are concerned about the impact of recent staff departures from the Agency

and would therefore need some assurance that the increase in fees be matched with a commitment to deliver a high level of service against published timelines.

In addition, there are some efficiencies that the MHRA could consider with respect to reliance by acting as a point of reference for the regulatory decision-making of other regulators and by leveraging outcomes from trusted global regulatory agencies to deliver regulatory decisions and facilitate access to new medicines for UK patients. This would enable the MHRA to charge lower fees in certain areas, which would be helpful to support and encourage innovation in the UK.

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

Response:

Yes

If you have any concerns about this proposal, please provide them below

Feedback from BIA member organisations indicated that they would support this proposal. It would be helpful to understand if increases in fees for certain activities such as inspections are planned to be implemented with increased frequencies of such activities in the future.

Fee increases for variations are significant, but the fees proposed are in line with or lower than many other EU countries, so this seems reasonable. Assessment timelines for variations have significantly increased during 2022, and BIA member companies are expecting that the increased fees will result in increased resources and improved performance.

Given that devices development and registration budgets are often very tight, the large increase in medical device fees is concerning to BIA member organisations. It would be helpful to provide clarity if the fee is per device, or per group of similar devices.

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

Response:

Yes

If you have any concerns about this proposal, please provide them below

BIA member organisations support this proposal except for the fees proposed for the Innovative Licensing and Access Pathway (ILAP), the flagship initiative to support the development of innovative products in the UK post-Brexit, and Clinical Trials - Complex amendments.

The proposed large increase to the fees for the ILAP Innovation Passport designation and the Target Development Profile (TDP) are significantly high for SMEs where there can be limited funds and milestones to meet in development. Moreover, SMEs indicated that it would be difficult for them to convince investors that this is a worthwhile cost early in development for one market. It should be noted that similar schemes exist such as PRIME and breakthrough designation which are free of charge and cover larger markets. If a TDP meeting is held early in development there may not be a very detailed plan and the associated fee seems high, particularly as the plan could change numerous times over development and more than one meeting may be required.

The Innovation Passport meeting is currently charged as a standard scientific advice fee, and it is not clear why this meeting would cost three times more to arrange than any other scientific advice meeting as per the fees proposals. This is regrettable and may discourage use of the ILAP by innovative life sciences companies.

The UK has become an important centre for advanced therapy medicinal product (ATMP) development with a vibrant biotech startup and academic ecosystem, and ILAP has the potential to accelerate the time to market and patient access to innovative medicines. Considering the profile of companies likely to undertake such procedures, the early engagement required and the less formal nature of interactions (in comparison to formal scientific advice from MHRA, EMA or FDA), which is a key strength and must be maintained, it is imperative that fees are kept to a minimum so that SMEs can easily access this valuable pathway.

Our member companies, in particular SMEs developing ATMPs, are concerned about the new fee for “Clinical Trials - Complex amendments”. ATMPs are already subject to extended assessment under the EU Clinical Trials Regulation (regardless of the nature of the product) and there is concern that MHRA might take a similar approach. If this fee were to be applied frequently, it could dissuade small companies from conducting phase I clinical research in the UK – phase 1 studies are subject to frequent amendments as the safety profile is emerging and clinical trials are amended to take account of new data. We would require guidance for the circumstances such fee would be charged by the Agency.

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

Response:

Yes

If yes, in what ways? e.g. costs/time etc. Please provide more details below

These proposals are likely to have a disproportionate impact on SMEs that are developing innovative therapies. ILAP and the Early Access to Medicines Scheme (EAMS) would be particularly

helpful to small biotech companies that could greatly benefit from additional support from the Agency.

We are therefore advocating for fee reductions and waivers for ILAP and EAMS for SMEs to avoid stifling innovation in the UK. The new costs of entering ILAP early in the development far outweigh the benefits of using the pathway and the TDP toolkit. The benefits of ILAP are skewed toward later clinical development and pre-commercialisation.

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?

Response:

Yes

If yes, please provide more detail below

We believe that the proposals could have an impact on the development and access to medicines for rare conditions, as described in our responses above. The increasing costs for scientific advice mechanisms and medical device assessment may discourage some companies developing products for smaller patient populations from making marketing authorisation applications or device submissions in Great Britain.

It is worth adding that UK based affiliates of medium and large biopharmaceutical companies need to convince global teams to consider placing regulatory activities in the UK alongside other global regions. Increased costs without the associated performance will decrease the UK attractiveness for R&D within this global context.

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

Response:

Yes

If yes, please provide more detail below

The proposals do not pose a risk for companies which have a small, licenced product portfolio or no products currently on the market in the UK.

Increasing inspection fees and variation fees will raise the revenue threshold that products need to achieve to remain profitable. It should be noted that products with niche markets or older products with low sales and low reimbursement may not reach the threshold and could be withdrawn.

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?

Response:

Yes

If yes, what could be the impact? Please provide more details below

As per our responses to the questions above, the proposed fee increases alone are unlikely to have an impact immediately on research and clinical trials in the UK, provided the increased revenue is used to increase the capacity and efficiency of the MHRA in supporting these areas. It is currently evident that the Agency is struggling to fully resource areas like clinical trial support, scientific advice and ILAP.

However, there may be an impact more generally on the life sciences sector. The decision to invest in the UK and conduct clinical trials is multifactorial. At a time when the percentage of clinical trials is falling in the UK compared to other major EU countries, any proposal that could increase the costs of bringing a medicine to the UK market is a cause for concern.

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?

Response:

Yes

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?

Response:

Yes

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