BIA response to MHRA consultation on statutory fees

Overview

The MHRA has consulted on proposals to update statutory fees charged from 1 April 2027. The consultation ran until Friday 25 September.

Summary of BIA response:

- BIA strongly supports the MHRA's leadership in providing enhanced support to UK SMEs and welcomes the improvements to scientific advice services. We recognise the need to increase fees for some foundational and high value services in order to sustain and build the MHRA's notable national and international momentum.
- However, the proposal for a 27% increase in some fees for high-value and frequently used services, and some fee adjustments which amount to increases of more than 100%, are not accompanied by clarity on the MHRA's plans for the improvement of these services. We therefore ask that these proposals be accompanied by clear and transparent service standards and key performance indicators (KPIs). MHRA should engage with industry and other stakeholders on these standards and its plans to deliver its services to these standards.

Consultation questions

1. **Do you agree with Proposal 1: increasing most fees by indexation only?**
   Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

   Please explain why.

We recognise the need for the MHRA to operate on a sustainable cost-recovery basis and do not have significant concerns regarding the proposed 8.93% uplift.

The fee increase should be accompanied by continued improvements in service performance, predictability and reliability.

2. **Do you agree with Proposal 2: targeted increases for higher-value services?**
   Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

   Please explain why, including whether the proposed fee lines are the right services to include in this category.

   BIA understands the need for targeted fee increases where these are directly linked to meaningful improvements in service delivery, including greater predictability, timeliness and transparency.

   However, the consultation document does not include sufficient detail on why these have been classified as "higher-value services", the planned service improvements associated with these targeted fee increases, and the KPIs which will be used to measure service improvements. While we broadly agree that targeted fee increases will be acceptable where they are linked to faster, more predictable service performance, the fee increases must be proportional to the service improvement. We recognise that MHRA is planning to publish this detail on planned improvements and expected performance in due course, and encourage the agency to engage with industry when this detail is available.

3. **Do you agree with Proposal 3: introducing enhanced service standards, guaranteed timelines and rebates for selected services?**

Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

Please explain why, including: (a) whether the proposed offer would provide value to your organisation, (b) how performance should be measured and reported, (c) what information should be included in the detailed guidance we provide, and (d) any issues, risks, or points that would need to be clarified before implementation.

BIA welcomes the MHRA's plans to introduce enhanced service standards and rebate mechanisms for selected services, as these strengthen accountability, transparency and confidence.

However, it is of paramount importance that the enhanced service standards for selected services do not reduce the quality or reliability of standard services for all users, and encourage the MHRA to set out in more detail how it will ensure that this does not happen. Maintaining consistently strong performance across standard routes should be the primary objective so that all applicants receive a high quality and timely service.

As recognised in the consultation document, predictable and reliable timelines are generally of greater value to companies than financial rebates. We therefore welcome the intention for the increased fees to accompanied by meaningful service standards and KPIs.

To ensure these service standards and KPIs are meaningful, MHRA should clarify exactly when the review timeline begins, what events pause or restart the clock, and how Requests for Further Information (RFIs) will be treated. This should be clarified for both the enhanced service standards, and the standard services, so that applicants can make decisions based on accurate information about all services.

MHRA should also provide more detail about how the rebate mechanism will work, including any circumstances where MHRA can exclude a delay from the guarantee,

whether the rebates will be automatic or need to be claimed by the applicant, and when rebates will be paid.

We also have some comments and questions regarding the specific plans for the enhanced service standards:

- **NAS licensing assessments:** We welcome the introduction of guaranteed timelines for NAS licensing assessment. More detail is needed on how the proposed 90-day first assessment timeline compares to current performance expectations, or how the rebate mechanism would operate in practice if the 90-day first assessment is not met.
- **NAS Priority Pathway:** The value proposition for the proposed NAS Priority Pathway is unclear, as the latest published MHRA performance metrics for July 2026 show the reported median assessment timeline for national procedures is 185 days. In this context, the proposed priority pathway fee of £100,000 appears very high relative to the level of acceleration being offered through a 180-day assessment timeline. MHRA should provide further detail regarding the benefits of this pathway, as well as reassurance that investment into the priority route will not adversely affect the performance of the standard route. MHRA should also specify how the 10 priority slots will be allocated to ensure fair access across applicants, and whether SME applicants would be able to access the route using the voucher/waiver scheme set out in Proposal 4.
- **Phase I first-in-human clinical trials:** We welcome this commitment to 14-day initial assessment to deliver faster approvals and improved UK attractiveness for early phase R&D investment, building on the pilot programme launched earlier this year.
- **Scientific advice:** We understand the potential benefits of an accelerated route for scientific advice, but more detail is needed on how the end-to-end timelines for scientific advice are calculated. Moreover, it is crucial that the introduction of an

accelerated route does not impact the quality, timeliness or accessibility of the standard scientific advice offering. Please see further detail in our response to question 5.

4. **Do you agree with Proposal 4: enhanced support for eligible small and medium-sized enterprises?**
   Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

   Please explain why, including (a) whether the proposed eligibility criteria and overall design of the scheme would target support appropriately and (b) what information should be included in the detailed guidance for this proposal, including any points that would need to be clarified before implementation.

   BIA strongly supports the introduction of a voucher/waiver mechanism for UK SMEs. This is an important step forward in delivering a UK life sciences infrastructure which supports UK companies to scale and deliver innovation for the benefit of UK patients, and ensures public investment delivers greater value for UK growth.

   In order to ensure that the support which the voucher/waiver scheme provides is additive to the existing offer, UK SMEs should continue to have access to free scientific advice from the MHRA, and this scheme should not be used to replace free scientific advice. The voucher/waiver scheme could potentially be used to enable SMEs to cover the additional cost associated with the accelerated route for scientific advice.

   We support the rationale for the requirement for companies to have a “substantive UK economic presence” in order to ensure support is directed towards companies which are genuinely contributing to the UK economy and driving UK innovation. We encourage the MHRA to work further with BIA to develop clear criteria for this which are easy for

companies to understand and substantiate, and which avoid inadvertently excluding companies which should benefit.

In designing the criteria, it is important to recognise the different operating models which UK biotech companies may have, including using outsourced R&D and manufacturing. Outsourcing is a very common practice in biotech due to the prohibitive costs involved in having all skills and equipment in-house. A survey of BIA members carried out in September 2026 found that 75% of respondents had outsourced R&D activity taking place in the UK, and 31% of respondents had outsourced manufacturing activity taking place in the UK. We would encourage these UK-based outsourced activities to be recognised as part of a company's UK economic presence.

Other elements of the standard SME definition also cause unintended consequences for biotechs. It should be recognised that very early-stage companies and some others will not pass the control test (whereby a single investor must have no more than 50% issued share capital), due to having limited investors, despite being independent companies. Moreover, scaling UK biotech companies will often exceed the standard UK SME criteria on the basis of employee numbers and/or annual turnover, especially as they reach late-stage clinical and commercial stages. These companies are strategically important to the UK life sciences sector and it should be recognised that, while these companies may be successful and scaling, they do not have the same resources as most global pharmaceutical companies. We urge the MHRA and other parts of Government to consider how it can provide targeted support for these companies to enable their continued success. The R&D tax relief regime delivered by HMRC sets the SME employment threshold at 500, for example.

BIA would welcome the opportunity to work closely with MHRA on determining the exact definition.

The process for confirming eligibility and obtaining a voucher/waiver should be as simple, short and predictable as possible, to avoid creating unnecessary bureaucracy and delays for companies. MHRA should set out how it will resource this process to ensure it can deliver timely decisions.

MHRA should clarify how the £2 million annual scheme cap will operate in practice if demand exceeds the available funding, including whether support will be allocated on a first-come-first-served basis or according to defined prioritisation criteria.

5. **Do you agree with Proposal 5: improvements to the MHRA's scientific advice service?**
   Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

   Please explain why, including (a). whether the proposed changes would meet your needs or if additional elements could be added to improve them, and (b) what information and clarifications should be included in the subsequent detailed guidance.

   BIA welcomes MHRA intention to improve its scientific advice service to give companies clearer choices with better transparency.

   Clearer guidance on the current tiered scientific advice options is particularly welcome, as members have previously reported that it can be difficult to know which level of complexity their request will fall into, which presents challenges in forecasting costs. We encourage MHRA to engage with industry as it develops this guidance to ensure it is clear and helpful.

   The proposed new Customer Relationship Service has the potential to provide a more efficient mechanism for non-scientific regulatory queries. However, more detail is

needed on how this service will operate in practice, including how block purchasing arrangements will function, and any usage limitations. MHRA should also clarify if the new SME voucher/waiver scheme could be used for this service, or if other mechanisms will be introduced to ensure equitable access for all users. MHRA should also set out how this service will be distinguished from the Innovation Office which provides free regulatory guidance to developers of innovative medicines and novel manufacturing processes.

BIA welcomes the introduction of accelerated scientific advice service with guaranteed service standards, however we are unsure whether the proposals as they stand will deliver value for money for companies. The proposed fees for the fast-track service (£45,111 for high complexity and £33,833 for medium complexity) are very high, at double the cost of the standard service. MHRA performance data for July 2026 shows that the current end-to-end scientific advice turnaround is 67 days so it may not be value for money for companies to pay such a high fee for a slightly faster service. Moreover, the proposals do not seem to be competitive compared to peer regulators, including the EMA where the standard scientific advice has predictable timelines of around 10 weeks from submission of the briefing package, so only one week slower than the MHRA's accelerated route.

It is imperative to ensure that the introduction of an accelerated service does not adversely impact the quality, timeliness or accessibility of the standard scientific advice offering. Regardless of service tier, companies should continue to receive advice that is scientifically robust, delivered within expected timelines, and supported by clear and transparent service standards.

MHRA should set out clear KPIs for both the accelerated and standard route to enhance transparency and enable applicants to make informed decisions about which route to apply to. We propose that the MHRA publishes the following KPIs on a monthly or quarterly basis, providing the median, range and total numbers for each:

1. Average time (with range) from meeting request submission to formal written advice being issued
2. Average time (with range) from meeting request submission to meeting* taking place (when meeting* is granted)
3. Average variation (with range) between sponsor's requested meeting* date and actual meeting* date
4. Total number of SA requests received per year
5. Proportion of SA delivered via meeting* + advice letter vs written advice only
6. % of meetings* requested vs granted
7. Proportion of scientific advice requests where the applicant requested follow-on advice
8. % of meetings held as joint scientific advice including NICE

This data should be separated by clearly defined categories including CMC, non-clinical, clinical and multi-disciplinary advice. MHRA could also provide breakdown by type of product (e.g. ATMPs) and therapeutic area.

Please also refer to the **BIA Regulatory Affairs Advisory Committee (RAAC)'s position paper on MHRA's scientific advice service**, which has been submitted to the MHRA as an annex to this response. The paper includes additional feedback and suggestions, including a preferred model for the future service.

6. **Do you agree with Proposal 6: a phased approach to the medical devices post-market surveillance registration fee?**

Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

Please explain why, including what you see as the most beneficial activities for post-market surveillance and if you have any feedback on how the fee is currently operating? (optional)

7. **Do you agree with Proposal 7: adjustments to some existing fees?**
   Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

   Please explain why, including whether you have concerns about any specific fees.

   BIA recognises the need to ensure fees appropriately reflect the resources required to deliver regulatory services, and understand that adjustments may be needed to some fees where they are lower than the cost of delivering the service.

   However, we are concerned that this applies to a significant number of fees (24% of MHRA's statutory fees), and some of the proposed fee increases are very high, with some increases exceeding 100%. MHRA should provide greater transparency on the underlying cost modelling to justify these increases, and explain what service standard will be delivered for the higher fee. In particular:

   - The proposed increased for fees associated with National Type IB variations and Type II variations are particularly high, and given the volume at which these procedures may be submitted by companies with portfolios of established products, the cumulative financial impact could be very high. This may discourage companies for submitting for national assessment and increase the number of IRP variations.

- The proposed 100% increase for Complex IRP Type A applications appears very high, and would also make the fee almost three times higher than the Standard IRP Type A applications.

8. **We expect that the proposed increases in fees will not have a significant negative impact on market activity, innovation, or production. To what extent do you agree or disagree?**
   Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

   Please share any evidence to support your view.

   We do not expect that the proposed increases in fees will have a significant negative impact on market activity, innovation or production. Regulatory fees represent only one component of overall development and lifecycle costs, and we believe most organisations will continue to invest in bringing and maintaining medicines on the UK market despite the proposed changes.

   However, industry acceptance of these increases and the reputation of the UK as a place to invest in innovation will depend on the delivery of meaningful improvements in MHRA performance and service quality. The impact of the fee increases should be monitored following implementation, including tracking application volumes and use of regulatory pathways and services.

9. **The MHRA's services should be funded at a level that supports effective and efficient regulation and avoids a decline in service performance. To what extent do you agree or disagree?**

Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

Please share any evidence to support your view.

We strongly agree that the MHRA should be funded at a level that supports effective and efficient regulation and avoids any decline in service performance. It is important that this is delivered in a way which ensures that MHRA services remain accessible to small and scaling UK companies, and the proposed SME voucher/waiver scheme is an important step forward in enabling this.

Industry places significant value on predictable timelines, high-quality scientific assessment, effective stakeholder engagement and efficient regulatory processes. Sustaining and further improving these capabilities requires continued investment in both people and infrastructure.

We welcome investment not only in scientific and assessment capacity, but also in digital transformation, regulatory systems and modern applicant-facing tools that improve transparency, streamline submissions, reduce administrative burden and increase operational efficiency. AI should be used to enhance capability but should not replace human involvement in assessments.

Increased fees should be accompanied by transparent performance measures that demonstrate how the additional revenue is contributing to sustained improvements in capacity, timelines, predictability and applicant experience.

10. **The MHRA does not consider that these proposals risk impacting different people differently with reference to their protected characteristics as covered by the Public Sector Equality Duty set out in section 149 of the Equality Act 2010 and by**

section 75 of the Northern Ireland Act 1998. To what extent do you agree or disagree?

Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

Please share any evidence to support your view.

11. **The MHRA does not consider that these proposals risk impacting people differently with reference to their protected characteristics or where they live in Northern Ireland. In Northern Ireland new policies must be screened under Section 75 of the Northern Ireland Act 1998, which places a statutory duty on public authorities to mainstream equality in all its functions – so that equality of opportunity and good relations are central to policy making and service delivery. In addition, new or revised policies must be rural proofed in line with the Rural Needs Act (NI) 2016 which requires public authorities to have due regard to rural needs. To what extent do you agree or disagree?**

    Strongly agree/Agree/Neither agree or disagree/Disagree/Strongly disagree/No view

    Please share any evidence to support your view.

About the BIA

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. We have over 600 members spanning human health and non -health biotech, including start-ups, scale-ups and established global companies. Our membership also encompasses the full UK ecosystem, including non -commercial research institutions and service providers.