Medicines & Healthcare products Regulatory Agency

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

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1. Executive summary

The MHRA led on a joint consultation on proposed amendments to the MHRA's statutory fees with the Department of Health in Northern Ireland, in accordance with Section 45(1) of the Medicines and Medical Devices Act 2021.

The consultation ran between 31 August and 23 November 2022 to seek views on proposals to update the statutory fees charged for the MHRA's regulatory services. The fees are set on a cost recovery basis, in accordance with Managing Public Money guidelines, however they have not been updated for several years and are not fully recovering costs.

This document provides our response to the consultation and outlines next steps. We received a total of 99 responses. There was general acceptance of the need to ensure cost recovery for regulatory activities, and that this was important for ensuring a consistent level of service.

One of the main themes raised by respondents was the need for more consistent and improved services, and that any increase in fees should be met with improvements in Agency performance. By ensuring the Agency is sufficiently resourced and operating a sustainable cost recovery fee model, this will help us deliver the required service standards more consistently. There was also general concern about increasing fees in the current economic climate, particularly for small to medium sized businesses (SMEs).

We have analysed all responses and considered the feedback received alongside the necessity of actions that must be taken to operate on a cost recovery basis. We will now be taking forwards the fee amendments outlined in the table below. The fee updates are necessary to ensure the Agency's long-term financial sustainability and enable the Agency to deliver a responsive, innovative and efficient regulatory service that protects and improves patient and public health by facilitating access to high-quality, safe, effective and innovative medical products.

The Agency plans to develop a new Fees and Charges Plan to inform how fees are set in future and is committed to engaging with stakeholders during its development. We will be carefully considering all suggestions and feedback that we have received in response to this consultation to help us shape the direction of the future fee charging mechanism.

Consultation Proposal	**Outcome**
Proposal 1: Apply a 10% indexation across Agency statutory fees to match the increased pay costs national average since	Introduce legislation to amend Agency statutory fees, applying a 10% indexation uplift across all fees, as set out in Annex A

Consultation Proposal	Outcome
the last MHRA fees review	(Table 1)
Proposal 2: Place a further cost-based uplift for 61 significantly under recovering fees to achieve full cost recovery	Introduce legislation to amend Agency statutory fees, applying a cost-based uplift, as set out in Annex A (Table 2)
Proposal 3: Introduce 22 new fees for services offered by the MHRA	Introduce legislation to make provision for 18 new fees set out in Annex A (Table 3). (Four of the new fees proposed were reconsidered independently of the consultation response and will not be introduced at this time – see section 4.3)

2. Introduction

The MHRA regulates medicines, medical devices and blood components for transfusion in the United Kingdom (UK). Generally, whenever the MHRA provides a direct service for medicines or blood components for transfusion regulatory work, a fee is charged to recover the costs. Although medical devices work is primarily funded through grant-in-aid from the Department of Health and Social Care, there are aspects of the MHRA's medical devices work that are also fee dependent. As the fees are set in statute, legislative change is required to amend them.

The principles for how the Agency charges fees are set by HM Treasury in "Managing Public Money". The basic principle is "the standard approach is to set charges to recover full costs". This means that the regulated (rather than the taxpayer more generally) bear the cost of regulation. Another principle is to ensure that the MHRA does not profit from fees or make a loss which must then be subsidised by the Department of Health and Social Care or wider Government.

When setting the cost of fees, the Agency takes numerous factors into account to ensure costs are covered, including identifying activities involved in delivering a service (this can involve anything from processing and registration to technical assessment and specialist evaluation of data), the time these activities take, and the staff grade and seniority required to complete the task. In addition, the Agency is also required to factor in corporate overhead costs and system investments.

The MHRA's statutory fees have been adjusted several times in the past to ensure they remain accurate; this is standard practice for government bodies that charge fees. However, more recently the fees have not been updated since financial year 2016/17 for medicines, financial year 2017/18 for medical devices, and financial year 2010/11 for blood components for transfusion. The MHRA has undertaken a review of our statutory fees and identified that numerous activities are no longer fully recovering costs. There are also services being offered, for which the introduction of new statutory fees is required.

Decisions to not adjust fees in recent years were made to provide certainty and stability for industry throughout the EU Exit period, and while the Agency and wider healthcare system responded to the COVID-19 pandemic. However, it is not sustainable for the Agency to continue charging fees at their current level as they do not adequately cover costs.

Therefore, the proposed amendments to the statutory fees were designed to achieve full cost recovery in line with HM Treasury's principles. The fee updates are necessary to ensure the Agency's long-term financial sustainability and enable the Agency to deliver a responsive, innovative and efficient regulatory service that protects and improves patient and

public health by facilitating access to high-quality, safe, effective and innovative medical products.

3. Summary of responses

The consultation contained proposals to amend the statutory fees charged by the MHRA and questions on the potential impacts of doing so. It ran from 31 August 2022 to 23 November 2022.

We received a total of 99 responses. The majority were sent on behalf of an organisation (59%) or from individuals working in the sector and sharing professional views (35%); and the remainder (6%) were from individuals (such as a patient, carer or member of the public). Organisational responses were received from across a range of trade associations, research organisations, pharmaceutical companies, medical device manufacturers, blood banks and transfusion services, charities, and conformity assessment bodies. Almost all respondents were based in the UK.

We have analysed the responses to the consultation and considered the feedback alongside the necessity of the action that we must take to operate on a cost recovery basis. We have set out our next steps and reasoning in what we hope is a transparent and clear manner. Below is a summary of responses:

Question	**Yes**	**No**	**Total**	**Yes (%)**
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?	59	37	96	**61%**
2. Do you support proposal 2, to place a cost-based uplift for 61 significantly under recovering fees to achieve full cost recovery?	41	52	93	**44%**
3. Do you support proposal 3 to introduce 22 new fees for services offered by the MHRA?	53	43	96	**55%**
4. Would you consider these proposals to impact certain types of business disproportionately?	85	11	96	**89%**
5. Do you think any of the proposals in this consultation could have an impact on the development and access to medicines or medical devices for rare conditions or minority groups with smaller patient populations?	70	25	95	**74%**
6. Do you think any of the proposals in this consultation pose a risk to existing products being withdrawn from the UK market?	55	40	95	**58%**
7. Do you think any of the proposals in this consultation could	63	31	94	**67%**

Question	Yes	No	Total	Yes (%)
have an impact on research, clinical trials or clinical investigations in the UK?				
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?	79	15	94	**84%**
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?	74	18	92	**80%**

4. Summary of the government response

A significant number of respondents recognised that the Agency must be sufficiently resourced to provide consistent service levels. The fee amendments are designed to achieve cost recovery for their respective services, in line with HM Treasury's principles for Managing Public Money. They are necessary to ensure the Agency's long-term financial sustainability and enable the Agency to deliver a responsive, innovative and efficient regulatory service that protects and improves patient and public health by facilitating access to high-quality, safe, effective and innovative medical products.

The MHRA has not updated its statutory fees for a number of years, following decisions to provide more certainty and stability for industry throughout the EU-exit period and the COVID-19 pandemic. It is standard practice for any regulatory agency to periodically update fees to reflect the costs of their regulatory activities.

A common theme raised by respondents was the need for more consistent and improved services, and that any increase in fees should be met with improvements in Agency performance. By ensuring the Agency is sufficiently resourced and operating a sustainable cost recovery fee model, this will help us deliver the required service standards more consistently.

The Agency is also delivering an ambitious Transformation Programme which is driving change right across the organisation. We have now put in place a new, integrated organisational structure with a clear mission for oversight of healthcare products from first discovery and development through to deployment.

Work is now under way on optimising the services we offer and developing new services. This is being supported by a substantial technology investment programme which includes upgrading our support systems, replacing legacy systems and investing in new technology - which will all enable improvements in regulatory processes and provide a more efficient and streamlined service. In addition, our investments will:

1. Deliver significant cost reductions and increase efficiencies within the Agency's technology estate.

2. Enable our staff to work effectively by providing underpinning platforms and enhancing collaborative opportunities across the new Agency structure.

3. Improve access to the Agency's services for patients, the public, industry and our many other stakeholders, ensuring information is provided in a user-friendly way.

We recognise that some respondents felt that the increased fees may affect small to medium sized businesses (SMEs) to a greater extent than larger organisations. The Agency's fees

legislation has provision for certain payment easements for small companies and payment waivers for SMEs. More information on financial support offered to SMEs and how to apply for SME status can be found on our website.

The table below summarises the three proposals in the consultation and the fee amendments we will now be taking forwards. The following sections summarise and evaluate the responses received to the specific questions asked.

The Agency also plans to develop a new Fee and Charges Plan to inform how fees are set in future and is committed to engaging with stakeholders during its development. We will be carefully considering all suggestions and feedback that we have received in response to this consultation to help us shape the direction of the future fee charging mechanism.

Consultation Proposal	**Outcome**
Proposal 1: Apply a 10% indexation across Agency statutory fees to match the increased pay costs national average since the last MHRA fees review	Introduce legislation to amend Agency statutory fees, applying a 10% indexation uplift across all fees, as set out in Annex A (Table 1)
Proposal 2: Place a further cost-based uplift for 61 significantly under recovering fees to achieve full cost recovery	Introduce legislation to amend Agency statutory fees, applying a cost-based uplift, as set out in Annex A (Table 2)
Proposal 3: Introduce 22 new fees for services offered by the MHRA	Introduce legislation to make provision for 18 new fees set out in Annex A (Table 3). (Four of the new fees proposed were reconsidered independently of the consultation response and will not be introduced at this time – see section 4.3)

5. Consideration of responses to individual consultation questions

5.1. Proposal 1: Apply a 10% indexation across Agency statutory fees to match the increased pay costs national average since the last MHRA fees review

The first proposal was to apply a 10% increase or “indexation uplift” to all Agency statutory fees. This increase is based on the need to cover increased staff costs which, in line with the wider Civil Service pay award, have risen by 10% since the last fees review in 2016. Staff costs account for over half of the MHRA’s total expenditure and therefore have an impact on the fees we charge. Non-staff costs including items such as IT, laboratories, and accommodation have risen in line with inflation (and the Consumer Prices Index (CPI) is 21% since 2016) but the Transformation Programme implementation means the Agency is able to absorb these costs within the proposed 10% indexation fee increase.

Summary of consultation responses

1. **Most respondents supported the proposal for a 10% increase in fees**.

2. There were 96 responses, of which, **59 (61%) supported** and **37 (39%) did not**.

The main theme from those supporting the proposal was an acceptance that it was necessary for the Agency to cover rising costs to deliver service standards but also an expectation that increased fees should be accompanied with customer service improvements for those paying them; notably, greater consistency, shorter timelines, and greater transparency and accountability for service performance.

The main themes from those who did not support the proposal were concerns about the impact of increased costs (particularly on small businesses) in the current economic climate; and / or that they disagreed with the extent of the 10% increase, with some responders suggesting a smaller increase. Another common theme was that current service standards were not consistent enough to justify the fee increase, and that these should be improved before fee increases.

Government response

Most respondents were supportive of this proposal and recognised the importance of ensuring the Agency is sufficiently resourced to provide the required level of service.

The fee increases outlined in this proposal are necessary to ensure the Agency is recovering its costs in accordance with Managing Public Money guidelines. Therefore, we will be introducing legislation to amend Agency statutory fees, applying a 10% uplift across the fees set out in Annex A (Table 1). Three fees that were identified as duplicates in the consultation have been removed.

Many respondents talked about the importance of more consistent service standards. We recognise this and have considered the responses. By ensuring the Agency is sufficiently resourced and operating a sustainable cost recovery fee model, this will help us deliver the required service standards more consistently.

Another common theme from respondents were concerns around the impact of increased costs on small businesses in the current economic climate. The Agency already has provision for payment easements for small companies and payment waivers for Small and Medium-sized Enterprises (SMEs). More information and how to apply can be found on our website.

5.2. Proposal 2: Place a cost-based uplift for 61 significantly under recovering fees to achieve full cost recovery

The second proposal was to apply a further uplift for 61 fees for services that are significantly under recovering costs. Through a review of its fees, the MHRA identified these 61 services as charging fees that are under-recovering so significantly that the 10% increase would be insufficient to fully cover their costs. The MHRA therefore proposed to increase these fees over the 10% increase. Each specific fee uplift varies as it reflects the cost of the activity, tasks and workload involved in delivering the service, however all of them are set only to achieve cost recovery.

Summary of consultation responses

1. **Most respondents did not support the proposal for an additional increase for 61 significantly under recovering fees.**

2. There were 93 responses, of which **41 (44%) supported** and **52 (56%) did not**.

Those supporting the proposal accepted that it was necessary for the Agency to cover rising costs to deliver service standards. There was also an expectation that increased fees should be accompanied with customer service improvements for those paying them; notably, greater consistency, shorter timelines, and greater transparency and accountability for service performance.

Many respondents (both those who supported the proposal and those who did not) felt that while the 10% increase in the first proposal was intuitive and reasonable (as it was across all fees and linked to staff pay costs) these fee increases were harder to accept as the increases were higher, varied across activities, and respondents felt there was insufficient explanation.

Several respondents raised some specific concerns regarding particular fees, for example, fees relating to conformity assessment bodies. Similarly to proposal 1, a number of respondents commented on the impact of increased costs in the current economic climate, particularly on small businesses.

Government response

After consideration of responses, for the reasons outlined below, it remains the Agency's intention to proceed with introducing legislation to amend these Agency statutory fees to ensure cost recovery, as set out in Table 2. Three fees that were identified as duplicates in the consultation have been removed.

Whilst concern about these higher fee increases is understandable, these fees have been calculated on same basis as all other Agency statutory fees, to ensure we are cost recovering for the activity involved in delivering the service in accordance with Managing Public Money guidelines. This was informed by a review that accounted for all activities and calculated costs based on staff time required to deliver the service. Each specific fee uplift varies as it reflects the cost of the activity, tasks and workload involved in delivering the service.

The MHRA's statutory fees have not been increased since financial year 2016/17 for medicines, financial year 2017/18 for medical devices, and financial year 2010/11 for blood components for transfusion. Decisions not to adjust these statutory fees in recent years were made to provide certainty and stability for industry throughout the EU Exit period, and while the Agency and wider healthcare system responded to the unprecedented challenge of the COVID-19 pandemic.

To ensure financial sustainability, it is essential that the MHRA cost-recovers across all services. The statutory fees set out in this proposal currently significantly under-recover costs and therefore the new fees have been calculated to ensure the fees fairly match the cost of regulation and a consistent cost-recovery approach is applied across all our statutory fees.

The Agency recognises the importance of providing consistent service standards across all our services. By ensuring the Agency is sufficiently resourced and operating a sustainable cost recovery fee model, this will help us deliver the required service standards more consistently.

The Agency is also delivering an ambitious Transformation Programme which is driving change right across the organisation. We have now put in place a new, integrated organisational structure with a clear mission for oversight of healthcare products from first discovery and development through to deployment.

Work is now under way on optimising the services we offer and developing new services. This is being supported by a substantial technology investment programme which includes upgrading our support systems, replacing legacy systems and investing in new technology - which will all enable improvements in regulatory processes and provide a more efficient and streamlined service. In addition, our investments will:

1. Deliver significant cost reductions and increase efficiencies within the Agency's technology estate.

2. Enable our staff to work effectively by providing underpinning platforms and enhancing collaborative opportunities across the new Agency structure.

3. Improve access to the Agency's services for patients, the public, industry and our many other stakeholders, ensuring information is provided in a user-friendly way.

In relation to concerns around the potential impact of increased costs on small businesses, the Agency's fees legislation has provision for certain payment easements for small companies and payment waivers for SMEs. More information on financial support offered to SMEs and how to apply for SME status can be found on our website. In addition, for the fees relating to 'safety and quality vetting of unlicensed imported medicines', we have corrected historical imbalances where smaller importers paid more per individual import than larger importers (that had a lower average unitary cost). This means smaller importers of these medicines will see a reduction in their fees.

5.3. Proposal 3: Introduce 22 new fees for services offered by the MHRA

The third proposal was to introduce 22 new fees to ensure that the Agency can recover the costs for these services in line with HM Treasury's principles on Managing Public Money. As with all other statutory fees, these new fees were set according to estimates of the cost of the activity, workload and tasks involved in delivering the service.

Summary of consultation responses

1. **Most respondents supported the proposal to introduce 22 new fees for services offered by the MHRA.**

2. There were 96 responses, of which **53 (55%) supported** and **43 (45%) did not**.

Those supporting the proposal provided similar comments to Proposal 2. There was a general understanding that the Agency must cover rising costs to deliver service standards. Alongside the acceptance of the need for new fees there was also an expectation that increased fees should be accompanied with customer service improvements for those paying them; notably, greater consistency, shorter timelines, and greater transparency and accountability for service performance.

The main themes from those who did not support the proposal echoed those raised in relation to the first two proposals, with the added dimension that these were new fees rather than an uplift to existing ones. The concern was about the impact of increased costs (particularly on small businesses) in the current economic climate.

Another common response was that current service standards did not justify the fee increase, and that they should be improved before fee increases. In addition, several respondents had concerns regarding some specific new fees proposed, for example fees relating to the Innovative Licensing and Access Pathway (ILAP); Clinical Trials – Complex Amendments and Assessment of Annual Safety Reports; and fees relating to conformity assessment bodies.

Government response

Most respondents were supportive of this proposal and there was recognition of the need to introduce new fees for services that have been brought in since the last round of fee changes. Therefore, we will be introducing legislation to make provision for the 18 new fees set out in Table 3.

The new fees outlined in this proposal are necessary to ensure that we are cost recovering for regulatory work across all our services and are sufficiently resourced to provide the services that patients, the public and industry expect.

We have given further consideration to each of the new fees outlined in this proposal and we have decided not to take forward 4 of the new fees proposed in the consultation at this current time. The new fees that we will not be implementing currently are for: ‘Scientific Advice – aligned to the ILAP Innovation Passport’ (this fee will remain £3,624); Scientific Advice – aligned to the ILAP Target Development Profile’ (this fee will remain £4,451); ‘In Vitro Diagnostic Performance Report’; and ‘Clinical Trials – Complex Amendments’.

We recognise that there were concerns about some specific fees, however these fees are for new services that the Agency is delivering and to meet guidelines on public spending, set by HM Treasury, we are required to cost recover for these activities. These fees have been calculated on the same basis as all other Agency statutory fees, to ensure we are cost recovering for the activity involved in delivering the service. This was informed by a review

that accounted for all activities and calculated costs based on staff time required to deliver the service.

The Agency has committed to keeping these new fees under review over the next 12-month period so they can be adjusted again in April 2024, if required, to ensure they are as close to cost recovery as possible.

5.4. Would you consider these proposals to impact certain types of business disproportionately?

This question asked respondents whether they thought the proposals might adversely impact certain types of business disproportionately.

Summary of consultation responses

1. **Most respondents believed that certain types of businesses would be impacted disproportionately.**

2. There were 96 responses, of which **85 (89%) agreed** and **11 (11%) did not**.

Of the respondents who believed that there would be a disproportional impact on certain types of business, the common theme was that impact would most affect smaller or less well-resourced organisations. This was because the costs of fees would be the same irrespective of organisation size. The most cited examples were SMEs, academic organisations or charities.

A smaller number of respondents believed there would be a disproportional impact on specific parts of the sector who also must deal with greater number of licences or lower profit margins e.g., registration costs for medical device manufacturers with a relatively greater product range, or for companies dealing with generics where profit margins tend to be lower.

Government response

It is understandable that respondents felt that the increased fees may affect SMEs to a greater extent than larger organisations. The Agency's fees legislation already has provision for certain payment easements for small companies and payment waivers for SMEs, including:

Payment Easements Available for Small Companies

Major applications

25% of the application fee for a new active substance at the time of the application with the remaining 75% payable within 30 days of the Marketing Authorisation (MA) being determined.

Complex applications

50% of the application fee for a new active substance at the time of the application with the remaining 50% payable within 30 days of the MA being determined

Applications for Manufacturers' or Wholesale Dealer's licences

50% at time of application with 50% payable 12 months after that time.

The "50% rule" at time of application then 50% payable 12 months after also applies to the payment of applications for traditional herbal medicines registrations and applications for complex variations to traditional herbal registrations.

In respect to inspection fees in connection with applications for a marketing authorisation, traditional herbal registration, manufacturer's licence, manufacturer's authorisation or wholesale dealer's licence, the fee payable is 50% within 14 days following receipt of written notice requiring those fees, with 50% payable 12 months after that date.

Payment Waivers for Small and Medium Companies (SME)

1. Fees payable in connection with a meeting mentioned in any of regulations 4 to 10, as set out in the Human Medicines (Amendment etc) (EU Exit) Regulations 2020.

2. 100% of initial application fee where the licensing authority grants an orphan marketing authorisation

3. 100% of the application for variation of orphan marketing authorisation made within the first 12 months of the date of grant.

Full information on the financial support offered to SMEs and how to apply for SME status can be found on our website.

When setting fees, the Agency is guided by the principles set by HM Treasury in Managing Public Money. The standard approach is that the same charge should apply to all users of a defined category of service and different groups of customers should not be charged different amounts for a service costing the same.

It is necessary for the Agency to cost recover across all our services to ensure we are resourced to provide the level of service that patients, the public and industry want and expect. Without amending our statutory fees, we will not recover our costs and will not be

able to provide the services industry require to enable them to market their products in the UK.

5.5. Do you think any of the proposals could have an impact on the development and access to medicines or medical devices for rare conditions or minority groups will smaller patient populations?

This question asked respondents whether they thought the proposals might adversely impact the development and access products for rare medical conditions or minority groups will smaller patient populations.

Summary of consultation responses

- **Most respondents believed that there would be an impact on the development and access to medicines and medical devices for rare conditions or minority groups with smaller patient populations.**

- There were 95 responses, of which **70 (74%) agreed** and **25 (26%) did not**.

The main theme raised by respondents who believed there would be a risk was that products for rare conditions or minority groups are likely to be relatively less profitable and so higher fees run the risk of them being withdrawn - particularly in the current economic climate.

Some respondents said that additional costs might disincentivise research and development particularly for SMEs, academia and charities and / or encourage organisations to seek alternative markets to the UK, especially if the costs were not competitive compared to what was charged in those markets or not linked to the size of the market.

Government response

We recognise the concerns raised that increasing fees may have an adverse impact on development and access to medical products for rare conditions or minority groups with smaller patient populations. The UK is a recognised leader in research, treatment, and care for rare diseases and has made important strides in the treatments made available for rare disease patients. The MHRA is committed to improving development and access to medicinal products for rare conditions and has a number of initiatives designed to support patient access to medical products, and in particular for rare conditions, we offer a number of important services in this regard:

The MHRA introduced the Early Access to Medicines Scheme (EAMS) in 2014 to give people across the UK early access to new medicines that do not yet have a marketing authorisation, when there is a clear unmet clinical need. Since its launch, rare disease patients living with Duchenne muscular dystrophy and haemophilia have benefited from the scheme with earlier access to life-changing treatments.

In 2021, the MHRA launched the Innovative Licensing and Access Pathway (ILAP), which aims to accelerate the time to market, facilitating patient access to medicines. By supporting expedited, efficient and innovative approaches to product development and patient access, ILAP allows the MHRA and its partner agencies to support the path to market of innovative and novel treatments, while ensuring there are no compromises in assessing the safety and efficacy of the treatments.

ILAP's 'innovation passport' designation is the gateway to the pathway and includes a rare disease and/or other special population component among the criteria. The decision on whether to issue an innovation passport is made between the partners and includes input from the ILAP Patient and Public Reference Group, which includes rare disease representation.

The MHRA also offers significant incentives in the form of market exclusivity and full or partial refunds for marketing authorisation fees to encourage development of medicines in rare diseases. Waivers from scientific advice fees are also available for UK based SMEs. The proposed fee changes will not impact on these incentives and waivers, which continue to be available. More information can be found on our website.

5.6. Do you think any of the proposals pose a risk to existing products being withdrawn from the market?

This question asked respondents whether they thought the proposals might pose a risk of existing products being withdrawn from the UK market.

Summary of consultation responses

1. **Most respondents believed that would be a risk of existing products being withdrawn from the market.**

2. There were 95 responses, of which **55 (58%) said yes** and **40 (42%) did not**.

The main theme raised by respondents who believed that there would be a risk was that increased costs might result in companies streamlining product portfolios and withdrawing lower profit products if they stop being cost-effective - particularly in the current economic climate.

Some respondents raised the risk of companies seeking alternative markets to the UK. As with question 4.4. and 4.5, it was noted that product withdrawals might be more likely from smaller companies, and / or for less profitable products that might be those for rare conditions or minority groups will smaller patient populations.

Of those who did not believe there would be any risks with existing product being withdrawn, very few respondents provided additional comments.

Government response

The MHRA is committed to delivering on ambitions set out in the UK Life Sciences Vision, to ensure the UK is an attractive environment for investment in the Life Sciences, encouraging companies to innovate, grow, and invest.

Adjusting our statutory fees is intended to have a positive effect on the UK Life Sciences industry. By ensuring the MHRA is accurately recovering the costs involved in delivering services for industry, the MHRA will be in a better position to deliver the level of service that industry wants and expects.

We do not expect these fee proposals to impact the UK's favourability globally. It is standard practice for regulatory agencies, across the world, to periodically update fees to reflect the costs of their regulatory activities. As an example, the European Medicines Agency (EMA) have consistently increased their fees year on year, and in April 2022 the EMA announced an inflationary increase to fees, compounded across 2020 and 2021.

5.7. Do you think any of the proposals could have an impact on research, clinical trials or clinical investigations in the UK?

This question asked respondents whether they thought the proposals might have an adverse impact on research, clinicals trials or clinical investigations in the UK.

Summary of consultation responses

1. **Most respondents believed that there would be an impact on research, clinical trials or clinical investigations in the UK.**

2. There were 94 responses, of which **63 (67%) agreed** and **31 (33%) did not**.

Of the respondents who believed that there would be an impact, the main theme was that costs might inhibit research and development, particularly if fees deter smaller or less well-resourced organisations.

Some respondents said that additional costs might encourage organisations to seek alternative markets to the UK, especially if the costs were not competitive compared to what was charged in those markets or not linked to the size of the market.

Some respondents noted that it was important to ensure that the MHRA was sufficiently resourced to deliver its work so service improvements were necessary to justify increasing fees and mitigate the potential impact.

Of those who did not believe there would be any impacts on research, clinical trials or clinical investigations in the UK, very few provided additional comments.

Government response

The MHRA is committed to ensuring the UK remains a centre of excellence for research, clinical trials and clinical investigations. We have consulted on proposals to reform the UK clinical trials regulatory framework to support the development of safe and innovative medicines, and ensure that the UK retains and grows its reputation as a world leading base for life sciences. The consultation set out proposals to update and strengthen the clinical trials legislation to:

1. Ensure patients and their safety are at the focus of all clinical trials and bring the benefits of clinical trials to everyone

2. Create a proportionate and flexible regulatory environment

3. Cement the UK as a destination for international trials

4. Provide a framework that is streamlined, agile and responsive to innovation.

Further information on our proposals to reform our clinical trials legislation can be found on our website.

The Agency has already introduced several new initiatives to improve our approach to clinical trials, supporting the Government's commitment to make the UK the best place to develop and run clinical trials and develop new healthcare products.

In 2022, we introduced the combined review service which offers a single application route for Clinical Trial Authorisation and Research Ethics Committee opinion and a coordinated review process leading to a single UK decision for clinical trials. This is reducing duplication, saving applicants time and effort, and speeding up approval times.

A pilot of Combined Investigational Medicinal Products (IMP)/Device research was also introduced this year to deliver the Agency's objective for a single decision on research using

both a medicines and devices and will provide a more streamlined route for combined IMP/devices clinical trials.

Some respondents were concerned that increased costs might inhibit research and development, particularly if fees deter small organisations smaller organisations. The Agency already has provision for payment easements for small companies and payment waivers for Small and Medium-sized Enterprises (SMEs). More information and how to apply can be found on our website.

In relation to concerns around organisations seeking alternative markets to the UK, we do not consider that these fee proposals will impact the MHRA's favourability in the market globally. It is standard practice for regulatory agencies, across the world, to periodically update fees to reflect the costs of their regulatory activities. As an example, the European Medicines Agency (EMA) have consistently increased their fees year on year, and in April 2022 the EMA announced an inflationary increase to fees, compounded across 2020 and 2021.

Some respondents commented on the importance of more consistent service standards and we recognise that this is a valid concern. By ensuring the Agency is sufficiently resourced and operating a sustainable cost recovery fee model, this will help us deliver the required service standards more consistently.

5.8. Impacts on protected characteristics

Respondents were asked two questions about potential impacts on protected characteristics. Data is collected on this in consultations to ensure that changes to Government policy do not have unintended impacts on protected characteristics.

The first question was: "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 impact different people differently with reference to their protected characteristics. Do you agree?"

Summary of consultation responses

1. **Most respondents agreed there was no risk of impacting different people differently with reference to their protected characteristics.**

2. There were 94 responses, of which **79 (84%) agreed** and **15 (16%) did not.**

Very few respondents provided additional comments. Of those that did, similar to question 4.5, the main theme was that raising fees could disproportionally impact the development or availability of products for rare conditions or minority groups with smaller patient populations,

and that this might impact different people differently based on their protected characteristics.

The second question was: *“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?”*

Summary of consultation responses

1. **Most respondents agreed there was no risk of impacting different people differently with reference to their protected characteristics or where they live in Northern Ireland.**

2. There were 92 responses, of which **74 (80%) agreed** and **18 (20%) did not.**

Very few respondents provided extra comments so there were no notable themes.

Government response

A large majority of respondents agreed that these proposals do not risk impacting different people differently with reference to their protected characteristics or where they live in Northern Ireland. We recognise that a small proportion of respondents voiced concerns around the impact of increased fees on development or access to products for rare conditions or minority groups with smaller patient populations

The MHRA is committed to improving development and access to medicinal products for rare conditions and for minority groups with smaller patient populations; we have a number of important initiatives designed to support patient access to medical products.

For example, the MHRA introduced the Early Access to Medicines Scheme (EAMS) in 2014 to give people across the UK early access to new medicines that do not yet have a marketing authorisation, when there is a clear unmet clinical need. Since its launch, rare disease patients living with Duchenne muscular dystrophy and haemophilia have benefited from the scheme with earlier access to life-changing treatments.

In 2021, the MHRA launched the Innovative Licensing and Access Pathway (ILAP), which aims to accelerate the time to market, facilitating patient access to medicines. By supporting expedited, efficient and innovative approaches to product development and patient access, ILAP allows the MHRA and its partner agencies to support the path to market of innovative and novel treatments, while ensuring there are no compromises in assessing the safety and efficacy of the treatments.

The MHRA also offers significant incentives in the form of market exclusivity and full or partial refunds for marketing authorisation fees to encourage development of medicines in rare diseases. Waivers from scientific advice fees are also available for UK based SMEs. The proposed fee changes will not impact on these incentives and waivers, which continue to be available. More information can be found on our website.

6. Consideration of matters set out in Section 2 and Section 15 of the Medicines and Medical Devices Act

The Medicines and Medical Devices Act 2021 (the Act) received Royal Assent on 11 February 2021. We propose to make the legislative changes for fees relating to medicines and medical devices under consultation in this document using powers in Part 2 of the Act, which provides powers to make regulations about human medicines and Part 4 in relation to medical devices.

This consultation is conducted pursuant to the consultation requirement in section 45(1) of the Act.

Sections 2 (in relation to medicines) and 15 (in relation to medical devices) of the Act state that safeguarding public health must be the overarching objective of the appropriate authority when making regulations. These sections require that when assessing whether regulations would contribute to that objective, the appropriate authority must have regard to three factors:

(a) The safety of human medicines and medical devices, and that the benefits of doing so outweigh any risks

(b) The availability of human medicines and medical devices

(c) The likelihood of the relevant part of the United Kingdom being seen as a favourable place in which to –

(i) Carry out research relating to human medicines and medical devices

(ii) Conduct clinical trials of medicines,

(iii) Develop medical devices, or

(iii) Manufacture or supply human medicines and medical devices

For medicines, the appropriate authority is the Secretary of State in relation to Great Britain and the Department of Health in Northern Ireland in relation to Northern Ireland. For medical devices, the appropriate authority is the Secretary of State.

Below the MHRA has (on behalf of the Secretary of State) and the Department of Health in Northern Ireland, assessed the proposals against each of the factors set out in the Act.

Safety

While all decisions relating to the safety of human medicines and medical devices are made objectively and independently of the price paid for the service, in ensuring that the MHRA statutory fees reflect the cost of the activity and work involved in delivering them, the aim is to ensure the MHRA is sufficiently funded and resourced to carry out the necessary and required work relating to safety in a timely manner.

Availability

There is a risk that increasing fees may deter companies from submitting applications to the MHRA, which would have an impact on the availability of medicines and medical devices. However, this risk is believed to be low given that annual fee increases across regulators is a standard approach and we would expect this to be built into company budgeting as a standard practice. As set out earlier in this paper, it is important that the MHRA is properly resourced to deliver the service that industry wants and expects, and therefore, on balance, the decision has been made to implement these proposals.

Favourability

The purpose of adjusting MHRA statutory fees is intended to have a positive effect on the UK Life Sciences industry.

A significant number of respondents to this consultation recognised the importance of ensuring the MHRA is sufficiently resourced to provide the required level of service and cost recovering for regulatory activity. By ensuring the MHRA is accurately recovering the costs involved in delivering services for industry, the MHRA will be in a better position to deliver the level of service that industry wants and expects.

Additionally, these fee proposals are not expected to impact the MHRA's favourability in the market globally. It is standard practice for regulator fees to be reviewed annually. As an example, the EMA have consistently increased their fees year on year, and in April 2022 the EMA announced an inflationary increase to fees, compounded across 2020 and 2021. The proposed adjustments to MHRA statutory fees are akin to the year-on-year increases by the EMA and other regulators.

Conclusion

Based on our assessment of the statutory fee proposals against each of the factors set out in the Act to which we must have regard, we consider the requirements of the Act to be fulfilled as the proposals will ensure the MHRA is sufficiently funded and resourced to deliver

a responsive and efficient regulatory service that safeguards and improves public health by facilitating access to high-quality, safe, effective and innovative medical products.

7. Conclusions and next steps

We welcome the engagement we have received with the consultation and appreciate the constructive and considered responses received. Having carefully considered all responses, we will now take forward legislation to update the MHRA's statutory fees as outlined in this response document. A full list of the new fees we will be implementing from April 2023 can be found in Annex 1.

The Agency plans to develop a new Fees and Charges Plan moving forwards and is committed to engaging with stakeholders during its development. We will be considering suggestions that we have received in response to this consultation to help us shape the future fee charging mechanism.

We thank everyone who took the time to respond to this consultation.

Annex A - MHRA statutory fee changes

Table 1 – 10% Indexation increase in line with increased pay costs

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
1. Active pharmaceutical ingredients manufacturers and importers registration: fees	Fees for registration of active substance importer or distributor	New applications	Additional fee if the risk assessment of the initial application triggers an inspection	582	**640**
1. Active pharmaceutical ingredients manufacturers and importers registration: fees	Fees for registration of active substance importer or distributor	Variations	Notification of changes (variation)	257	**283**
1. Active pharmaceutical ingredients manufacturers and importers registration: fees	Fees for registration of active substance importer or distributor	Annual compliance report	Assessment of the annual compliance report	257	**283**
1. Active pharmaceutical ingredients manufacturers and importers registration: fees	Fees for registration of active substance importer or distributor	Annual compliance report	Annual compliance report where a variation is required	514	**565**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
2. Active substance importers or distributors: fees			Application for registration	1,803	**1,983**
2. Active substance importers or distributors: fees			Additional fee for the first day of inspection if triggered following risk-assessment of the application	582	**640**
2. Active substance importers or distributors: fees			Persons appointed appeals procedure fee	10,000	**11,000**
3. Active substance manufacturers: fees			Application for registration	3,143	**3,457**
3. Active substance manufacturers: fees			Additional fee for the first day of an inspection if triggered following risk-assessment of the application	792	**871**
4. Blood banks: application fees for a Review Panel hearing			Fee	10,000	**11,000**
5. Blood banks and other blood establishments: fees	Blood Establishments	New Applications	Standard application	3,074	**3,381**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
5. Blood banks and other blood establishments: fees	Blood Establishments	Variations	Standard variation	518	**570**
5. Blood banks and other blood establishments: fees	Blood Establishments	Periodic Fee	Annual fee	463	**509**
5. Blood banks and other blood establishments: fees	Hospital Blood Banks and facilities	Compliance	Annual fee	683	**751**
7. Broker registration fees	Broker registration fees	New Applications	Additional fee if the risk assessment of the initial application triggers an inspection	582	**640**
7. Broker registration fees	Broker registration fees	Annual Compliance Report	Annual Compliance where a variation is required	514	**565**
8. Clinical trials: application fees		Applications with an IMP dossier	Higher fee (Phase 1, Full and Simplified IMPD)	3,060	**3,366**
8. Clinical trials: application fees		Applications without an IMP dossier	Lower fee (Phase IV, Cross referral, Additional protocol)	225	**248**
8. Clinical trials: application fees		CT variations / amendments		225	**248**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
10. Drug-device combination products: fees			Initial Consultation for a Device which incorporates one or more known medicinal substances from an approved manufacturer of that substance	4,136	**4,550**
10. Drug-device combination products: fees			Further consultation of a Device which incorporates one or more known medicinal substances from an approved manufacturer of that substance	818	**900**
10. Drug-device combination products: fees			Initial Consultation for a Device which incorporates one or more known medicinal substances from a new source	9,640	**10,604**
10. Drug-device combination products: fees			Further consultation of a Device which incorporates one or more known medicinal substances from a new source	2,228	**2,451**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
10. Drug-device combination products: fees			Initial consultation for a Device which incorporates a new active substance	42,296	**46,526**
10. Drug-device combination products: fees			Further consultation of a Device which incorporates a new active substance	10,501	**11,551**
14. Licence applications: marketing authorisations (including extension applications) fees	Major		Major Orphan (reduced in exceptional circumstances)	29,732	**32,705**
14. Licence applications: marketing authorisations (including extension applications) fees	Major		Incoming mutual recognition procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	62,421	**68,663**
14. Licence applications: marketing authorisations (including extension applications) fees	Major		European reference product application for sale or supply in Northern Ireland	62,421	**68,663**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
14. Licence applications: marketing authorisations (including extension applications) fees	Major		Decentralised procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	62,421	**68,663**
14. Licence applications: marketing authorisations (including extension applications) fees	Major		Major: (Previously granted by EU) - unfettered access route to GB	18,437	**20,281**
14. Licence applications: marketing authorisations (including extension applications) fees	Major		Major: (Previously granted by EEA) – application for GB or UK, excluding GB unfettered access route (MRDC reliance procedure)	62,421	**68,663**
14. Licence applications: marketing authorisations (including extension applications) fees	Major		Major: (Previously granted by EU) - automatic recognition application (EC Decision reliance procedure)	18,437	**20,281**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
14. Licence applications: marketing authorisations (including extension applications) fees	Major		National fee (any other case including hybrid applications)	92,753	**102,028**
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged complex		Incoming mutual recognition procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	17,330	**19,063**
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged complex		European reference product application for sale or supply in Northern Ireland	17,330	**19,063**
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged complex		Decentralised procedure for the sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	17,330	**19,063**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged complex		Complex: (Previously granted by EU) - unfettered access route to GB	10,443	**11,487**
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged complex		Complex: (Previously granted by EEA) – application for GB or UK, excluding GB unfettered access route (MRDC reliance procedure)	17,330	**19,063**
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged complex		Complex: (Previously granted by EU) - automatic recognition application (EC Decision reliance procedure)	10,443	**11,487**
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged complex		National fee (any other case including hybrid applications)	25,643	**28,207**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged standard		Incoming mutual recognition procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for a UKMA(GB)	6,350	**6,985**
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged standard		European reference product application for sale or supply in Northern Ireland	6,350	**6,985**
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged standard		Decentralised procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	6,350	**6,985**
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged standard		Standard: (Previously granted by EU) - unfettered access route to GB	5,783	**6,361**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged standard		Standard: (Previously granted by EEA) – application for GB or UK, excluding GB unfettered access route (MRDC reliance procedure)	6,350	**6,985**
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged standard		Standard: (Previously granted by EU) - automatic recognition application (EC Decision reliance procedure)	5,783	**6,361**
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged standard		National fee (all other cases)	9,402	**10,342**
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged simple		Incoming mutual recognition procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	2,564	**2,820**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged simple		Decentralised procedure for sale or supply in Northern Ireland and any subsequent Unfettered access route for UKMA(GB)	2,564	**2,820**
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged simple		Simple: (Previously granted by EU) - unfettered access route to GB	2,564	**2,820**
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged simple		Simple: (Previously granted by EEA) – application for GB or UK, excluding GB unfettered access route (MRDC reliance procedure)	2,564	**2,820**
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged simple		Simple: (Previously granted by EU) - automatic recognition application (EC Decision reliance procedure)	2,564	**2,820**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
14. Licence applications: marketing authorisations (including extension applications) fees	Abridged simple		National fee (all other cases)	2,564	**2,820**
14. Licence applications: marketing authorisations (including extension applications) fees	Extension application group		Incoming mutual recognition (UK CMS)	17,330	**19,063**
14. Licence applications: marketing authorisations (including extension applications) fees	Extension application group bulk		Incoming mutual recognition (UK CMS)	6,350	**6,985**
15. Licence applications: manufacturers licence (including THMPD and homeopathic medicinal products) fees			Standard	3,143	**3,457**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
15. Licence applications: manufacturers licence (including THMPD and homeopathic medicinal products) fees			Non-orthodox practitioner (NOP)	183	**201**
15. Licence applications: manufacturers licence (including THMPD and homeopathic medicinal products) fees			Change of ownership	344	**378**
16. Licence applications: parallel imports fees			Complex application	18,180	**19,998**
16. Licence applications: parallel imports fees			Simple application	1,792	**1,971**
16. Licence applications: parallel imports fees			Change of ownership (including THMPD registrations)	442	**486**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
17. Licence applications: Phase 1 Accreditation Scheme fees		Phase I Accreditation Scheme	Accreditation of Phase 1 units	117	**129**
17. Licence applications: Phase 1 Accreditation Scheme fees		Phase I Accreditation Scheme	Certificate of accreditation	62	**68**
18. Medicines export certificates: fees		Urgent request: two working days per set	Original and two copies	152	**167**
18. Medicines export certificates: fees		Standard request: ten working days per set	Original and two copies	68	**75**
18. Medicines export certificates: fees		Standard request: ten working days per set	Each additional copy	34	**37**
19. Periodic fees for holding a marketing authorisation			New active substance (1)	9,710	**10,681**
19. Periodic fees for holding a marketing authorisation			Derivatives with a different route of administration (1) or complex abridged (2)	9,710	**10,681**
19. Periodic fees for holding a marketing authorisation			Other derivatives (1)	6,554	**7,209**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
19. Periodic fees for holding a marketing authorisation		Prescription only medicine	Standard fee	2,428	**2,671**
19. Periodic fees for holding a marketing authorisation		Prescription only medicine	Reduced rate fee	1,211	**1,332**
19. Periodic fees for holding a marketing authorisation		Prescription only medicine	‘Maintenance’ fee	307	**338**
19. Periodic fees for holding a marketing authorisation		Prescription only medicine	All others (P, GSL, PLPI and None)	307	**338**
19. Periodic fees for holding a marketing authorisation			Herbal	76	**84**
19. Periodic fees for holding a marketing authorisation			Homeopathic and Anthroposophic PLRs (per PLR)	76	**84**
19. Periodic fees for holding a marketing authorisation			National Rules Homeopathic Authorisation	76	**84**
19. Periodic fees for holding a marketing authorisation			Manufacturer’s licence	468	**515**
19. Periodic fees for holding a marketing authorisation			Wholesale dealer’s licence	288	**317**
19. Periodic fees for holding a marketing authorisation			Wholesale dealer’s licence (reduced rate or GSL) (4)	172	**189**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
19. Periodic fees for holding a marketing authorisation			THMPD registration	76	**84**
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees		Licence Renewal Applications	Manufacturers' licences Non-orthodox practitioner (NOP)	178	**196**
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees		First renewal of a market authorisation granted with a new active substance	UKMA(GB) granted under the unfettered access route	747	**822**
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees		First renewal of a market authorisation granted with a new active substance	UKMA(GB) previously granted by EU (automatic recognition)	747	**822**
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees		First renewal of a market authorisation granted with a new active substance	All other cases	9,682	**10,650**
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees		Reclassification	P to GSL - Additional fee for MA or PI application with reclassification element from P to GSL (3), (4)	8,162	**8,978**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees		Reclassification	Reclassification variation application P to GSL	8,162	**8,978**
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees		Assessment of labels and leaflets	Single or first application (5)	518	**570**
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees		Assessment of labels and leaflets	National (BROMI) - Article 61 (3) Notification (6)	186	**205**
20. Licence renewals, reclassifications and assessment of labels and leaflets: fees		Assessment of labels and leaflets	Parallel imports	328	**361**
21. Orphan Marketing Products: fees			Orphan Major (Full fee)	92,753	**102,028**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
21. Orphan Marketing Products: fees			Orphan Major (exceptional circumstances in which point 6 pf Part II of Annex 1 in the 2001 Directive applies)	29,732	**32,705**
21. Orphan Marketing Products: fees			Orphan Complex (Full Fee)	25,643	**28,207**
21. Orphan Marketing Products: fees			Orphan Standard (Full Fee)	9,402	**10,342**
22. Pharmacovigilance (PV) Safety Review: fees			PV Major Safety Review (1-2 active ingredients)	51,286	**56,415**
22. Pharmacovigilance (PV) Safety Review: fees			PV Major Safety Review (3 active ingredients)	59,595	**65,555**
22. Pharmacovigilance (PV) Safety Review: fees			PV Major Safety Review (4 active ingredients)	67,904	**74,694**
22. Pharmacovigilance (PV) Safety Review: fees			PV Major Safety Review (5 or more active ingredients)	76,213	**83,834**
22. Pharmacovigilance (PV) Safety Review: fees			PV Periodic Safety Update Report (PSUR) single assessment: Full	890	**979**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
			Fee		
22. Pharmacovigilance (PV) Safety Review: fees			PV Periodic Safety Update Report (PSUR) single assessment: Half Fee	445	**490**
22. Pharmacovigilance (PV) Safety Review: fees			PV Post Authorisation Safety Study (PASS) protocol	8,309	**9,140**
22. Pharmacovigilance (PV) Safety Review: fees			Assessment of PASS Results	8,309	**9,140**
23. Plasma Master File (PMF) & Vaccine Antigen Master File certification or certified annual update work: fees			Certification of new PMF (for scientific & technical evaluation)	8,309	**9,140**
23. Plasma Master File (PMF) & Vaccine Antigen Master File certification or certified annual update work: fees			Vaccine Antigen Master File (VAMF) certification	8,309	**9,140**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
24. Pre-Assessment (Rolling Review): fees			Application by pre-assessment (NAS) - Module 3 (chemical, pharmaceutical and biological information)	23,188	**25,507**
24. Pre-Assessment (Rolling Review): fees			Application by pre-assessment (NAS) - Module 4 (non-clinical reports)	23,188	**25,507**
24. Pre-Assessment (Rolling Review): fees			Application by pre-assessment (NAS) - Module 5 (clinical study reports)	23,188	**25,507**
24. Pre-Assessment (Rolling Review): fees			Application by pre-assessment (Biosimilar) - Module 3 (chemical, pharmaceutical and biological information)	4,333	**4,766**
24. Pre-Assessment (Rolling Review): fees			Application by pre-assessment (Biosimilar) - Module 4 (non-clinical reports)	4,333	**4,766**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
24. Pre-Assessment (Rolling Review): fees			Application by pre-assessment (Biosimilar) - Module 5 (clinical study reports)	4,333	**4,766**
26. Scientific advice meetings: fees			Quality development only	2,201	**2,421**
26. Scientific advice meetings: fees			Safety development only	2,201	**2,421**
26. Scientific advice meetings: fees			Quality and safety development	3,061	**3,367**
26. Scientific advice meetings: fees			Clinical development only	2,763	**3,039**
26. Scientific advice meetings: fees			Quality and clinical development	3,624	**3,986**
26. Scientific advice meetings: fees			Safety and clinical development	3,624	**3,986**
26. Scientific advice meetings: fees			Quality, safety and clinical development	4,487	**4,936**
26. Scientific advice meetings: fees	Pre-consultation application meetings on devices incorporating an ancillary medicinal		Quality development only	749	**824**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
	substance				
26. Scientific advice meetings: fees	Pre-consultation application meetings on devices incorporating an ancillary medicinal substance		Safety development only	749	**824**
26. Scientific advice meetings: fees	Pre-consultation application meetings on devices incorporating an ancillary medicinal substance		Quality and safety development	949	**1,044**
26. Scientific advice meetings: fees	Pre-consultation application meetings on devices incorporating an ancillary medicinal substance		Clinical development only	949	**1,044**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
26. Scientific advice meetings: fees	Pre-consultation application meetings on devices incorporating an ancillary medicinal substance		Quality and clinical development	1,299	**1,429**
26. Scientific advice meetings: fees	Pre-consultation application meetings on devices incorporating an ancillary medicinal substance		Safety and clinical development	1,299	**1,429**
26. Scientific advice meetings: fees	Pre-consultation application meetings on devices incorporating an ancillary medicinal substance		Quality, safety and clinical development	1,648	**1,813**
26. Scientific advice meetings: fees	Pre-consultation application meetings on devices incorporating an ancillary medicinal substance		Broader scope meetings	4,451	**4,896**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
26. Scientific advice meetings: fees	Pharmacovigilance advice meetings		Standard meeting	3,061	**3,367**
26. Scientific advice meetings: fees	Pharmacovigilance advice meetings		Major meeting	3,624	**3,986**
26. Scientific advice meetings: fees	Pharmacovigilance advice meetings		Post-authorisation regulatory advice meetings	2,763	**3,039**
26. Scientific advice meetings: fees	Pharmacovigilance advice meetings		Advertising advice	2,201	**2,421**
26. Scientific advice meetings: fees	Pharmacovigilance advice meetings		Advice on labels and leaflets	2,201	**2,421**
26. Scientific advice meetings: fees	Reclassification advice meetings		Pharmacy to General Sales List switch	2,763	**3,039**
26. Scientific advice meetings: fees	Reclassification advice meetings		Prescription Only Medicine to Pharmacy switch	3,624	**3,986**
30. Testing of samples: fees		Plasma pools which require three or fewer tests	Fee payable where the licensing authority carries out a full assessment	180	**198**
30. Testing of samples: fees		Plasma pools which require three or fewer tests	Fee payable where the licensing authority carries out a paper-based assessment	90	**99**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
30. Testing of samples: fees		Plasma pools which require four or five tests	Fee payable where the licensing authority carries out a full assessment	215	**237**
30. Testing of samples: fees		Plasma pools which require four or five tests	Fee payable where the licensing authority carries out a paper-based assessment	90	**99**
30. Testing of samples: fees		Plasma pools which require six or more tests	Fee payable where the licensing authority carries out a full assessment	230	**253**
30. Testing of samples: fees		Plasma pools which require six or more tests	Fee payable where the licensing authority carries out a paper-based assessment	90	**99**
30. Testing of samples: fees		Band A – single component product, other than Botulinum toxin. requiring five or fewer in vitro tests	Fee payable where the licensing authority carries out a full assessment	1,660	**1,826**
30. Testing of samples: fees		Band B – Factor VIII, Factor VIX or intravenous Immunoglobin	Fee payable where the licensing authority carries out a full assessment	1,910	**2,101**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
30. Testing of samples: fees		Band C – Multi-component product, or Botulinum toxin, requiring five or fewer in vitro tests	Fee payable where the licensing authority carries out a full assessment	2,340	**2,574**
30. Testing of samples: fees		Band D – product requiring six to nine in vitro tests	Fee payable where the licensing authority carries out a full assessment	3,690	**4,059**
30. Testing of samples: fees		Band E – product requiring (a) ten or more in vitro tests, or (b) one or more in vivo tests	Fee payable where the licensing authority carries out a full assessment	6,410	**7,051**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
30. Testing of samples: fees		Band F – one or more tests that must be carried out under containment measures applicable to hazard Group 3 or 4 biological agents under Control of Substances Hazardous to Health Regulations 2002 (123) or requires use of human tissue cells as part of testing	Fee payable where the licensing authority carries out a full assessment	10,350	**11,385**
34. Variations: licence variations application fees		Type II complex	National	8,309	**9,140**
34. Variations: licence variations application fees		Extended type II complex	National	25,643	**28,207**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
34. Variations: licence variations application fees		Chapter II of Commission Regulation (EC) /1234/2008 (as amended for CMS). In addition, variations submitted under the relevant National reliance/recognition routes.	Single kind variation - Type II Complex Variation	2,493	**2,742**
34. Variations: licence variations application fees		Chapter II of Commission Regulation (EC) /1234/2008 (as amended for CMS). In addition, variations submitted under the relevant National reliance/recognition routes.	Single kind variation - Extended Type II Complex Variation	7,693	**8,462**
35. Variations: licence variations applications groups fees			Minor variation (Type IB) group fee (national)	622	**684**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
35. Variations: licence variations applications groups fees			Major variation (Type II) group fee (national)	1,652	**1,817**
35. Variations: licence variations applications groups fees			Major variation (Type II) complex group fee (national)	9,010	**9,911**
35. Variations: licence variations applications groups fees			Major variation (Type II) extended complex group fee (national)	26,276	**28,904**
35. Variations: licence variations applications groups fees		Chapter II of Commission Regulation (EC) /1234/2008 (as amended for CMS). In addition, variations submitted under the relevant National reliance/recognition routes.	Major Variation (Type II) Complex Group Application	2,703	**2,973**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
35. Variations: licence variations applications groups fees		Chapter II of Commission Regulation (EC) /1234/2008 (as amended for CMS). In addition, variations submitted under the relevant National reliance/recognition routes.	Major Variation (Type II) Extended Complex Group Application	7,883	**8,671**
36. Variations: other licence variations applications fees		Parallel import (PI)	Standard	357	**393**
36. Variations: other licence variations applications fees		Manufacturer's licences (including traditional herbal medicines)	Standard	514	**565**
36. Variations: other licence variations applications fees		Manufacturer's licences (including traditional herbal medicines)	Administrative	257	**283**
36. Variations: other licence variations applications fees		Wholesale dealers' licences (includes Traditional Herbal Medicinal Products)	Standard	486	**535**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
36. Variations: other licence variations applications fees		Wholesale dealers' licences (includes Traditional Herbal Medicinal Products)	Administrative	257	**283**
36. Variations: other licence variations applications fees		Clinical trial authorisations	Amendments to 1 part of dossier	225	**248**
36. Variations: other licence variations applications fees		Clinical trial authorisations	Amendments to 2 parts of dossier	225	**248**
36. Variations: other licence variations applications fees		Clinical trial authorisations	Amendments to 3 parts of dossier	225	**248**
36. Variations: other licence variations applications fees		Clinical trial authorisations	Protocol	225	**248**
38. Wholesale distribution authorisations: fees		New Applications	Change of ownership	399	**439**
38. Wholesale distribution authorisations: fees		New Applications	Standard variation	486	**535**
38. Wholesale distribution authorisations: fees		New Applications	Administrative variation	257	**283**
38. Wholesale distribution authorisations: fees		Inspections	Issue of Good Distribution Practice	68	**75**

Level 1 Descriptor	Level 2 Descriptor	Level 3 Descriptor	Fee Name	Current Fee (£)	New Fee (£)
			Certificates		

Table 2 – Fees that increase above indexation to achieve cost-based recovery

Fee Name	Current Fee (£)	New Fee (£)
Inspection - Full day rate (Good Manufacturing Practice, Good Clinical Practice and Pharmacovigilance)	2,655	**3,651**
Inspection - Full day rate (Good Distribution Practice)	1,936	**2,662**
Inspection - Full day rate (Blood banks and other blood establishments)	2,583	**3,552**
Inspection - Half day rate (Good Manufacturing Practice, Good Clinical Practice and Pharmacovigilance)	1,328	**1,825**
Inspection - Half day rate (Good Distribution Practice)	968	**1,331**
Inspection - Half day rate (Blood banks and other blood establishments)	1,292	**1,776**
Inspection - Office based evaluation and risk assessments (Good Manufacturing Practice, Good Clinical Practice and Pharmacovigilance)	1,863	**2,562**
Inspection - Office based risk assessments (Wholesale distribution authorisations)	1,354	**1,862**
Inspection – Traditional Herbal Medicinal Product/Homeopathic only (Wholesale distribution authorisations)	1,367	**1,880**
Inspection - reduced rate Traditional Herbal Medicinal Product/Homeopathic only (Wholesale distribution authorisations)	744	**1,023**
Variation - Extended application group (National fee)	25,643	**33,003**
Variation - Single kind variation - Type IB (Falling under scope of Chapter II Commission Regulation 1234/2008)	277	**344**

Fee Name		Current Fee (£)	New Fee (£)
Variation - Single kind variation - Type II (Falling under scope of Chapter II Commission Regulation 1234/2008)		277	**344**
Variation - Type IB National		277	**344**
Variation - Reclassification Type IB		277	**344**
Variation - Minor Variation (Type IB) Group Application (Falling under scope of Chapter II Commission Regulation 1234/2008)		277	**344**
Certified Annual Update of a Plasma Master File (PMF)		277	**344**
Variation - Major (Type II) Group Application (Falling under scope of Chapter II Commission Regulation 1234/2008)		496	**1,255**
Variation - Type II Standard National		734	**1,308**
Variation - Reclassification variation application (MA) (analogous product)		734	**1,308**
Certified Annual Update of a Plasma Master File (PMF) - significant changes to safety information		734	**1,308**
Parallel imports fees - standard application		6,663	**8,722**
Reclassification – Prescription Only Medicine to Pharmacy (Additional for MA or PI application)		11,992	**33,003**
Reclassification – Prescription Only Medicine to Pharmacy (variation application)		11,992	**33,003**
Safety and quality vetting of	Number of annual notifications: 1 - 20	130	**70**

Fee Name		Current Fee (£)	New Fee (£)
unlicensed imported medicines fees:	Number of annual notifications: 21 - 100	519	**350**
	Number of annual notifications: 101 - 1,000	2,077	**2,400**
	Number of annual notifications: 1,001 - 5,000	10,383	**12,000**
	Number of annual notifications: 5,001 - 20,000	25,957	**30,000**
	Number of annual notifications: 20,001 - 50,000	51,914	**60,000**
	Number of annual notifications: 50,001 - 100,000	103,828	**120,000**
	Number of annual notifications: 100,001 +	155,742	**200,000**
Band A – single component product, other than Botulinum toxin. requiring five or fewer in vitro tests		305	**367**
Band B – Factor VIII, Factor VIX or intravenous Immunoglobin		305	**367**
Band C – Multi-component product, or Botulinum toxin, requiring five or fewer in vitro tests		305	**992**
Band D – product requiring six to nine in vitro tests		677	**992**
Band E – product requiring (a) ten or more in vitro tests, or (b) one or more in vivo tests		677	**1,849**

Fee Name		Current Fee (£)	New Fee (£)
Band F – one or more tests that must be carried out under containment measures applicable to hazard Group 3 or 4 biological agents under Control of Substances Hazardous to Health Regulations 2002 (123) or requires use of human tissues or cells as part of testing		677	**1,849**
Initial application for designation (covers both Approved Body and Notified Body)		8,252	**35,672**
Re-application to address ground for rejection of a previous application		2,063	**8,918**
Initial designation audit		15,904	**58,341**
Surveillance		10,160	**45,675**
Witnessed Audit		4,404	**10,072**
Re-designation application fee		8,252	**35,672**
Re-designation audit		15,904	**58,341**
Follow up Audit - Major Closure		3,876	**22,789**
Follow up Audit - Special Clinical		2,586	**18,583**
Follow up Audit - Process Specific		3,876	**22,789**
TSE Applications UK Conformity Assessment Bodies		532	**1,297**
In addition to each of the above, these two fees are for time spent on audit and travel:	Half day rate for auditing	361	**631**
	Hourly rate for travel	90	**171**
Class I, IIa, or IIb other than implantable or long-term invasive devices:		3,820	**7,472**

Fee Name	Current Fee (£)	New Fee (£)
Notification		
Class I, IIa, or IIb other than implantable or long-term invasive devices: Notification - re-notification in the event of an objection	2,920	**5,711**
Class IIb implantable or long-term invasive, Class III, and active implantable devices: Notification	5,040	**15,627**
Class IIb implantable or long-term invasive, Class III, and active implantable devices: Notification - re-notification in the event of an objection	3,570	**11,069**
Devices Registration	100	**240**
Devices Registration amendment	100	**240**
Devices Blood bank annual fee	492	**967**

Table 3 – New Fees

Fee Name		New Fee (£)
Conformity Assessment Body Designation Applications – Extension to scope, new UKCA codes or Annex (covers both Approved Body and Notified Body)		**18,212**
Conformity Assessment Body Designation Applications – Extension to scope, where codes are limited (covers both Approved Body and Notified Body)		**12,571**
Conformity Assessment Body Audits – Subsidiary audit subject to additional fees calculated by hourly rate and travel rates (covers both Approved Body and Notified Body)		**22,789**
Clinical investigations consultation fee (optional) – Device Regulatory Advice meeting		**906**
Clinical Investigations consultation fee optional service – Clinical Investigations statistical review		**782**
Early Access to Medicines Scheme (EAMS) – Promising Innovative Medicine (PIM) designation		**3,986**
EAMS - fee for the assessment of the scientific opinion for new chemical or biological medicinal products		**25,643**
EAMS renewal fee for new chemical or biological medicinal products (if applicable)		**12,821**
EAMS - fee for the assessment of the scientific opinion for new indications		**8,309**
EAMS renewal fee for new indications (if applicable)		**4,154**
Safety and quality vetting of unlicensed imported medicines fees:	Number of annual product codes: 1-5	**100**
	Number of annual product codes: 6-10	**200**
	Number of annual product codes: 11-20	**400**
	Number of annual product codes: 21-50	**1,000**

Fee Name		New Fee (£)
	Number of annual product codes: 51-100	**2,000**
	Number of annual product codes: 101-200	**4,000**
	Number of annual product codes: per additional 100 product codes above 200	**2,000**
Clinical Trials - Assessment of annual safety reports		**248**

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