Title: Amendments to the fees charged by the MHRA in relation to the regulation of medical devices and blood components for transfusion **IA No:** **Lead department or agency:** Medicines and Healthcare products Regulatory Agency	**Impact Assessment (IA)** **Date:** 23 January 2023 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary Legislation **Contact for enquiries:** maham.masood@mhra.gov.uk

Summary: Intervention and Options

RPC Opinion: N/A de minimus

Cost of Preferred Option (in 2019 prices, 2020 present value base year)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
£0m	-£12.5m	£1.5m	Not a qualifying provision

What is the problem under consideration? Why is government action or intervention necessary?

The MHRA has recently undertaken a review of its statutory fees. The review found that numerous areas of the MHRA's work are under-recovering costs. Adjustments therefore need to be made to the MHRA's medical devices and blood components for transfusion fees to ensure all costs involved in delivering the regulatory activities associated with each fee are recovered. This is essential for ensuring the MHRA works within the principles of HM Treasury's Managing Public Money guidance, and also to ensure the MHRA is self-sufficient and financially sustainable in the long-term.

What are the policy objectives of the action or intervention and the intended effects?

The objective of this policy is to ensure full cost recovery of regulatory work done by the MHRA in accordance with Managing Public Money principles. This is essential for ensuring the MHRA is self-sufficient and financially sustainable in the long-term.

This approach is intended to make sure that the government neither profits at the expense of consumers or industry, nor makes a loss for taxpayers to subsidise.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option one: Do nothing. In the do nothing option we maintain fees at the current level. This would mean the MHRA continues to under recover the costs of its regulatory activities.

Option two: Increase medical devices and blood components for transfusion fees to ensure cost recovery. Increase fees to ensure all costs involved in delivering the regulatory activities associated with each fee are recovered.

Option two is the preferred option as this best meets the policy objective.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 2024

Is this measure likely to impact on international trade and investment?		No		
Are any of these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** N/A	**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Deputy Director of Finance R Braithwaite Date: 23 January 2023

Summary: Analysis & Evidence

Policy Option 1

Description: Do nothing: maintain current medical devices and blood components for transfusion fee levels

FULL ECONOMIC ASSESSMENT

Price Base Year 2023	PV Base Year 2023	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 0	**High:** 0	**Best Estimate:** 0

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	0		0	**0**
High	0		0	**0**
Best Estimate	0		0	**0**

Description and scale of key monetised costs by 'main affected groups'

As this is the baseline, the costs and benefits are zero.

Other key non-monetised costs by 'main affected groups'

Under this option, the MHRA is not able to fully recover the costs of its regulatory activities, which would jeopardise its ability to be self-sufficient and financially sustainable in the long-term.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	0		0	**0**
High	0		0	**0**
Best Estimate	0		0	**0**

Description and scale of key monetised benefits by 'main affected groups'

As this is the baseline, the costs and benefits are zero.

Other key non-monetised benefits by 'main affected groups'

Under this option organisations which use the MHRA's services would continue to pay lower fees, which do not reflect the full cost of the services provided to them.

Key assumptions/sensitivities/risks	Discount rate (%)	3.5

The key risk of this option is that the MHRA would not be self-sufficient and financially sustainable in the long-term. This would risk the quality of the delivery of the regulatory service it provides. Underfunded services would need to be subsidised, which does not align with Managing Public Money principles.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 0	**Benefits:** 0	**Net:** 0	

Summary: Analysis & Evidence Policy Option 2 (Recommended)

Description: Increase medical devices and blood components for transfusion fees to ensure cost recovery

FULL ECONOMIC ASSESSMENT

Price Base Year 2023	PV Base Year 2023	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 0	**High:** 0	**Best Estimate:** 0

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	0		£1.7m	£14.5m
High	0		£2.1m	£17.7m
Best Estimate	0		**£1.9m**	**£16.0m**

Description and scale of key monetised costs by 'main affected groups'

The cost of this policy is the additional fees paid by organisations which use the MHRA's services. Assuming the volumes of business remain constant to previous years, we expect this to cost £1.9m per year.

This is an economic transfer, as it is not a new use of resources, rather a transfer of payment from industry to MHRA.

Other key non-monetised costs by 'main affected groups'

There are no non-monetised costs of this option.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	0		£1.7m	£14.5m
High	0		£2.1m	£17.7m
Best Estimate	0		**£1.9m**	**£16.0m**

Description and scale of key monetised benefits by 'main affected groups'

The benefit of this policy is the additional income gained by MHRA. Assuming the volumes remain constant, we expect the income for MHRA to increase by £1.9m per year.

This is an economic transfer, as it is not a new use of resources, rather a transfer of payment from industry to MHRA.

Other key non-monetised benefits by 'main affected groups'

This option means that the MHRA's funding will be in accordance with Managing Public Money guidance, and it will allow the MHRA to maintain the quality of the delivery of the regulatory service it provides.

This will secure the long-term financial sustainability of the MHRA and enable the delivery of 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.

Key assumptions/sensitivities/risks	Discount rate (%)	3.5%

We have made an assumption in the analysis that the volume of business the MHRA receives will remain constant. It is likely the actual volume forecasts will fluctuate. To account for this sensitivity, we have provided a high and low estimate of the costs, based on the volumes fluctuating 9% lower and 10.9% higher than our best estimate. These high and low range scenarios are based on analysis of historical fluctuations.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 1.9	**Benefits:** 0	**Net: 1.9**	n/a

Evidence Base

Background

1. The MHRA regulates medicines, medical devices and blood components for transfusion in the United Kingdom, carrying out regulatory functions on behalf of the Secretary of State. Generally, whenever the MHRA provides a direct service for medicines, medical devices 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 secondary legislation, legislative change is required to amend them.
2. The principles for how the MHRA charges fees are set by HM Treasury in Managing Public Money. The basic principle is to set statutory fees and charges to recover full costs. This means that the regulated bear the cost of regulation and the MHRA does not profit from fees or make a loss which must then be subsidised by Government departments or the UK taxpayer.
3. In setting the cost of fees, the MHRA has taken numerous factors into account to ensure costs are recovered, including identifying activities involved in delivering a service, the time these activities take, and the staff grade and seniority required to complete the task. In addition, the MHRA is required to factor in corporate overhead costs and system investments.
4. 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, the fees have not been updated since financial year 2017/18 for medical devices, and financial year 2010/11 for blood components for transfusion. This means that there have been fee decreases in real terms (i.e. accounting for the effects of inflation).
5. Decisions to not adjust fees in recent years were made to provide certainty and stability for the health and social care sector and industry throughout the EU Exit period, and while the MHRA and wider healthcare system responded to the COVID-19 pandemic. However, it is not sustainable for the MHRA to continue charging fees at their current level as they do not adequately recover costs.
6. This impact assessment, and the accompanying statutory instrument, cover the fee increases in relation to medical devices and blood components for transfusion regulatory services.
7. The MHRA is also implementing fee increases for the medicines regulatory services that it provides. The medicines regulatory services fee increases are out of scope of this impact assessment, as they are not part of the statutory instrument this impact assessment is supporting. They have been assessed in a separate impact assessment.

Problem under consideration and rationale for intervention

8. The MHRA has recently undertaken a review of its statutory fees. The review identified numerous areas of the MHRA's work that are under-recovering costs. Adjustments therefore need to be made to the MHRA's medical devices and blood components for transfusion fees to ensure all costs involved in delivering the activity associated with each fee are recovered.

9. This approach is intended to make sure that the government neither profits at the expense of consumers or industry, nor makes a loss for taxpayers to subsidise.

10. This is essential for ensuring the MHRA works within the principles of HM Treasury's Managing Public Money[1], and also to ensure the MHRA is self-sufficient and financially sustainable in the long-term.

Policy objective

11. The objective of this policy is to ensure full cost recovery of work done by the MHRA in line with Managing Public Money principles. The fee updates are necessary to ensure the MHRA's long-term financial sustainability and enable the MHRA 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.

Description of options considered

Option one: Do nothing.

12. In the 'do nothing' option we maintain fees at the current level. This would mean the MHRA continues to under recover the costs of its regulatory activities.

Option two: Increase medical devices and blood components for transfusion fees to ensure cost recovery (preferred option).

13. Increase medical devices and blood components for transfusion fees, to ensure all costs involved in delivering the regulatory activities associated with each fee are recovered.

Summary and preferred option with description of implementation plan

14. The fee increases will be implemented from April 2023. There are three fee increase categories that the MHRA is taking forward. The detailed list of fee increases can be seen in Annex A.

Category 1

15. A 10% indexation uplift is applied across the fees. The indexation is linked to staff costs which, in line with the Civil Service pay award, have risen by 10% since the last medicines fees review in 2016. Staff costs account for over half of the MHRA's total expenditure and therefore have a significant impact on the fees charged.

16. The remaining expenditure include items such as IT, laboratories and accommodation. These costs have risen in line with inflation, and the Consumer Prices Index (CPI) is 21% since 2016, however MHRA's cost reduction programmes mean the MHRA is able to cover most increases within the 10% uplift.

Category 2

17. Through a review of its fees, the MHRA identified fees which are under-recovering so significantly that the 10% indexation uplift would mean they still do not achieve cost recovery. The MHRA is therefore uplifting these fees on top of the indexation increase to achieve full cost recovery. Each specific fee uplift varies as it reflects the cost of the

[1] Managing public money - GOV.UK (www.gov.uk)

activity, tasks and workload involved in delivering the service and is set solely to achieve cost recovery.

Category 3

18. We will introduce new fees, to ensure that the MHRA appropriately recovers the cost of the regulatory activity across all its services, in accordance with HM Treasury's principles on Managing Public Money.

19. The fees have been set according to estimates of the cost of the activity, workload and tasks involved in delivering the service. The fees for these services will be kept under review over the next 12-month period and will be adjusted in April 2024, if required, to ensure they are as close to cost recovery as possible.

Monetised and non-monetised costs and benefits of each option

20. The options in this impact assessment are only seeking to set appropriate fees for services the MHRA already provides. The impact assessment is not assessing the provision of any new services.

21. As this impact assessment only deals with where the funding for the services will come from, all of the costs and benefits are economic transfers, therefore the net present value will be zero.

Option one: do nothing.

22. Option one is our baseline, therefore the costs and benefits are zero.

Costs

23. Under this option, the MHRA is not able to fully recover the costs of its fees, which would jeopardise its ability to be self-sufficient and financially sustainable in the long-term. This would risk the quality of the delivery of the regulatory service it provides. Underfunded services would need to be subsidised, which does not align with Managing Public Money principles.

Benefits

24. Under this option, organisations which use the MHRA's services would continue to pay lower fees, which do not reflect the full cost of the services provided to them.

Option two: Increase medical devices and blood components for transfusion fees

Costs

25. The cost of this policy falls on the organisations who use the MHRA's services. These are direct costs to business and are included in the business net present value, net cost to business per year and equivalent annual direct impact on business calculations.

26. We have estimated the total cost of the fee rise to businesses is between £1.7m per year to £2.1m per year, with a best estimate of £1.9m per year. This calculation is based on the fee increases outlined in Annex A, and we have taken previous years volumes and assumed they will be consistent.

27. It is likely the actual volume forecasts will fluctuate. To account for this sensitivity, we have also provided a high and low estimate of the costs, based on the volumes

fluctuating 9% lower and 10.9% higher than our best estimate. Please see the 'Risks and assumptions' section for information on this sensitivity analysis.

28. As businesses already have processes for checking and paying fees, we do not expect there to be any additional transitional or familiarisation costs from this option.

Benefits

29. The direct benefits of this policy fall on the MHRA, who will receive additional income as a result of the increase in fees. The benefits to the MHRA will be equal to the costs to industry, therefore the benefit of this policy is between £1.7m per year to £2.1m per year, with a best estimate of £1.9m per year.

30. This option means that the MHRA's funding will be in accordance with Managing Public Money guidance, and it will allow the MHRA to maintain the quality of the delivery of the regulatory service it provides.

31. This will secure the long-term financial sustainability of the MHRA and enable the delivery of 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.

Risks and assumptions

32. The key assumption in this analysis is the volume forecasts for the MHRA's activities. To account for this, we have conducted sensitivity analysis around this assumption.

33. To examine how much the income may fluctuate, we have analysed the fluctuation in MHRA's income over an eleven-year period, from 2011/12 to 2021/22. The analysis showed that:

    a. The lowest the income deviated below our best estimate was 9 percent.
    b. The highest the income deviated above our best estimate was 10.9 percent.
    c. The mean deviation was -1.3 percent.
    d. The standard deviation was 5.6 percent.

34. This analysis gives us reasonable confidence in our best estimate. However, to account for the fluctuation in volumes, we have provided a range of the costs and benefits based on volumes reducing 9% lower than or increasing 10.9% higher than our best estimate.

Rationale and evidence to justify the level of analysis used in the IA (proportionality approach)

35. This is a standard fee increase being done in line with Managing Public Money guidance. We have provided estimations of the cost to business of the fee increases in line with the Better Regulation Framework[2], and conducted relevant sensitivity analysis.

36. This impact assessment is valid for the De Minimis self-certification as the costs to UK businesses will sit well under the threshold of £5m per year. Even under a sensitivity analysis – doubling the high estimate of costs still remains below the De Minimis threshold.

[2] Better regulation framework - GOV.UK (www.gov.uk)

Wider impacts

Consultation

37. The MHRA launched a public consultation on 31 August 2022 to seek the views of stakeholders on proposals to amend the statutory fees charged for regulatory services. The consultation closed on 23 November 2022. The MHRA received a total of 99 responses to the consultation.

38. There was a 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 MHRA performance. By ensuring the MHRA is sufficiently resourced and operating a sustainable cost recovery fee model, this will help the MHRA deliver the required service standards more consistently.

39. The MHRA has analysed all responses and considered the feedback received alongside the necessity of actions that must be taken to operate on a cost recovery basis. A summary of the consultation responses and the Government's response can be found online: https://www.gov.uk/government/consultations/consultation-on-proposals-for-changes-to-the-medicines-and-healthcare-products-regulatory-agencys-statutory-fees

Impact on micro, small and medium businesses

40. Data from the MHRA systems shows that of the 6227 organisations in the MHRA's customer base, between 24 to 43 of them are micro, small or medium enterprises. This means micro, small or medium enterprises make up between 0.4% to 0.7% of the MHRA's customer base. Unfortunately, the MHRA do not have the granularity of data to split this down in to just small and micro business, however, it does give a good indicator of the number of smaller businesses impacted by the changes.

41. MHRA is conscious of the impact of regulation of fees on small businesses. The MHRA is obliged to recover the costs of the regulatory work it does from industry, so excluding micro, small and medium businesses from this legislation is not a viable option.

Equality assessment

42. Evidence gathered from the consultation suggested 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:

    a. 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.

    b. 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.

c. 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.

d. 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 the MHRA's website.

e. With regards to medical devices, the Government's response to the 2022 consultation on the future regulation of medical devices set out that the MHRA intends to introduce a pre-market approvals pathway for innovative MedTech that meets certain criteria. This would be limited to specific circumstances, such as use on certain groups of patients (e.g., small patient populations / rare conditions) and / or within specific healthcare institutions where there is an identified need, and would target SMEs. The MHRA will partner with the National Institute for Health and Care Excellence (NICE) and other key healthcare partners to establish critical end-to-end oversight.

Environment assessment

43. The changes are not thought to impact the environment.

Monitoring and Evaluation

44. The MHRA has a finance group who have well established reporting systems in place to closely monitor the impact of this policy. They will continue to use those financial accounting systems to assess whether the cost of MHRA fees accurately reflects the cost to MHRA of delivering those activities.

45. The MHRA's Chief Finance Officer will provide governance over the fees policy, to ensure the MHRA continues to adhere to Managing Public Money principles, and that it has the funding to provide a fit for purpose regulatory service.

Annex A: MHRA's medical devices and blood components for transfusion fee changes

Blood component fees

Table 1: 10% Indexation Increase					
Level 1 Descriptor	**Level 2 Descriptor**	**Level 3 Descriptor**	**Fee Name**	**Current Fee (£)**	**Revised Fee (£)**
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
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

Table 2: Cost Recovery		
Fee Name	**Current Fee (£)**	**Revised Fee (£)**
Inspection - Full day rate (Blood banks and other blood establishments)	2,583	3,552
Inspection - Half day rate (Blood banks and other blood establishments)	1,292	1,776
Devices Blood bank annual fee	492	967

Medical Devices fees

Table 1: 10% Indexation Increase					
Level 1 Descriptor	**Level 2 Descriptor**	**Level 3 Descriptor**	**Fee Name**	**Current Fee (£)**	**Revised 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
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
26. Scientific advice meetings: fees	Pre-consultation application meetings on devices incorporating an ancillary medicinal substance*		Quality development only	749	824
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

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

Table 2: Cost Recovery

Fee Name	Current Fee (£)	Revised Fee (£)
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, the below 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: Notification	3,820	7,472
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

Table 3: Proposed New Fees	
Fee Name	**Proposed 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