Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

CONSULTATION DOCUMENT

To all licence holders, blood banks, blood establishments, online sellers and representative associations

Our Ref: MLX 389

Issued: 22/10/2015

Respond by: 19/11/2015

Enquiries to: consultations@mhra.gsi.gov.uk

MHRA (MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY) REGULATORY FEES – PROPOSALS FOR 1 APRIL 2016

INTRODUCTION

1. The aim of this consultation is to seek the views of stakeholders on two proposals for changes to the Medicines (Products for Human Use)(Fees) Regulations 2013.

2. The first proposal reduces many of the fees charged by MHRA for the regulation of human medicinal products.

3. The second proposal introduces a new fee for online sellers of human medicine to the public to ensure full cost-recovery of new work done by MHRA under the EU Falsified Medicines Directive[1].

4. The implementation date for these changes is 1 April 2016.

MEDICINES LICENSING FEES

5. MHRA plans to reduce some of its existing statutory fees by between 10 and 15% to better bring them into line with cost recovery, as required by the terms of MHRA's Trading Fund status, recommendation 2 of the Agency's recent

[1] 2011/62/EU, transposed into the Human Medicines Regulations 2012, with the provisions for online sellers set out in regulations 256A to 256N

Triennial Review and guidance on management of public money[2]. Further details on the changes in fees are at Annexes A and B.

6. MHRA continuously monitors income and costs in order to ensure that fees reflect fairly the cost of providing the respective services to industry.. Fees can be changed following fluctuations in volume and other factors such as efficiency savings made by MHRA, such as in this case some recent reductions in head count (125 posts or 14% over 3 years from 2014) and accommodation costs (33% over the same period). .

7. Also, The Agency is currently replacing its IT systems, providing an opportunity to modernise how it interacts with industry. This will mean that industry can deal with the agency easier, faster and at lower cost, all of which is vital to the stimulation of innovation. The way in which IT is procured will also change through less reliance on a single supplier and greater use of Cloud technologies and other delivery models. These changes will drive efficiency in how the agency works, reducing its overall costs.

8. MHRA only makes fees adjustments as and when necessary and may make further fee changes in 2017/18 if required. The overall objective is to avoid fee volatility, such as the unpopular fluctuations in fees levels during the period 2003-2008.

9. Informal consultation with the industry, for example in the Medicines Industry Liaison Group meetings, indicates that primary concerns among industry stakeholders are the quality and stability of MHRA's services. Industry has also indicated a desire for stability and predictability in MHRA's fees structure, as opposed to the uncertainty of the 2003-2008 period.

NEW FEE FOR ONLINE SELLERS OF HUMAN MEDICINE TO THE PUBLIC

10. From 1 July 2015, in accordance with the EU Falsified Medicines Directive, MHRA has operated a statutory registration scheme and logo system for UK-based online sellers of human medicine to the public. The MHRA scheme is a direct transposition of the EU Directive, without gold plating, and makes it easier for potential consumers to check whether websites selling medicines are operated by legal suppliers. MHRA proposes to introduce a fee to recover the costs of operating this scheme.

11. Total costs for the first year are estimated to be approximately £0.4m with an anticipated volume (traders who will apply) of approximately 4000. We are

[2] https://www.gov.uk/government/publications/managing-public-money

aiming to keep costs (and therefore fees) as low as possible, including through the avoidance of gold plating, and careful consideration has been given to the level of fees we intend to charge in order to recover the costs.

12. To recover the cost of the scheme, MHRA proposes to introduce an application fee of £100, and an ongoing annual service fee of £97. These figures have been set in order to recover only the estimated costs and could be revised based on any further evidence of likely volumes from this consultation.

13. We propose charging sellers who did not pay an initial application fee[3] a one-off supplement to the annual service fee, equal to the application fee. This will ensure the costs are attributed fairly across retailers using the service.

14. At this stage the likely impact on industry is unknown, although smaller sellers are likely to be more affected than larger ones by the proposed fees. However we consider that there is no viable alternative in order to cover the cost of this function.

15. We have developed a clear communications campaign to ensure that all businesses understand what is required and what compliance looks like, thereby minimising familiarisation costs.

CONCLUSION

16. The fee proposals set out in this document are designed to meet the following goals:

    - For industry, proportionate and lower medicines licensing fees that continue to enable MHRA to respond efficiently and effectively.

    - For MHRA, full cost recovery of new work done under the Falsified Medicines Directive, in line with the principles on managing public money and MHRA's status as a Government Trading Fund.

HOW TO RESPOND

17. Any comments on these proposals should be sent to: consultations@mhra.gsi.gov.uk by **19/11/2015** using the reply sheet provided at Annex C and using the subject reference of "Fees Consultation **MLX 389**".

[3] Those who submitted a valid notification to the MHRA between 16 June 2015 and 31 March 2016.

18. There are four specific questions listed on the reply sheet on which we would be grateful for any views or information. Emailed responses are preferred, but if you wish to send responses by post, the address is: Matthew Garland, 5th Floor, Teal Area, 151 Buckingham Palace Road, Victoria, London, SW1W 9SZ.

Confidentiality of Information

19. We manage the information you provide in response to this consultation in accordance with MHRA's Information Charter.

20. Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

21. If you would like the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could identify any information you wish to be withheld (which may be either all or part of your response) and explain to us why you regard it as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an absolute assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on MHRA.

22. MHRA will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.
23. More information about the Freedom of Information Act can be found on the website of the Ministry of Justice – www.justice.gov.uk/guidance

IMPACT ASSESSMENTS

24. Impact assessments for these proposals can be found by accessing the following link: **[insert weblink].**

25. In giving your views on the proposals described in this document, it would be particularly helpful if you could identify and quantify the effects these

proposals are likely to have on your business. We would particularly like to hear from smaller companies.

THE PRINCIPLES OF CONSULTATION

26. The Civil Service Reform Plan commits the Government to improving policy making and implementation with a greater focus on robust evidence, transparency and engaging with key groups earlier in the process.

27. For details of the revised principles of engagement, please see http://www.cabinetoffice.gov.uk/sites/default/files/resources/Consultation-Principles.pdf

28. The policy proposals addressed in this consultation document have been the subject of discussion with industry stakeholders. For this reason, we consider that a four-week consultation period is appropriate.

COMMENTS OR COMPLAINTS

29. If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

By post: Consultations Coordinator

Department of Health

3E48, Quarry House

Leeds

LS2 7UE

By e-mail: consultations.co-ordinator@dh.gsi.gov.uk
(Please do not send consultation responses to these addresses.)

ANNEX A

DETAIL OF PROPOSALS

1. Decrease in fees

The proposal is to decrease all Marketing Authorisation and Variation applications by 10% with the exception of:

- Decentralised RMS which will reduce by 15%;
- Periodic Fees which will reduce by 5%. The New Active Substance fee will reduce to the Complex fee;
- Fees relating to Inspections, Wholesale, Manufacturers and the existing Falsified Medicines Directive will remain the same.

2. Introduction of fees for online sellers of medicine

The proposal is to introduce fees to cover the cost of registering online sellers of human medicine to the public and issuing them with the EU common logo, as well as the ongoing costs of maintaining the publicly available register, in accordance with the Falsified Medicines Directive (2011/62/EU).

Application fee: £100

Annual service fee: £97

We also propose charging online sellers who did not pay an initial application fee (i.e. those who submitted a valid notification to the MHRA between 16 June 2015 and 31 March 2016) a one-off supplement to the annual service fee, equal to the cost of the application fee. This would ensure that costs are attributed fairly across retailers using the service.

The MHRA is aiming to charge fees at the minimum level required to ensure cost recovery. We have developed a clear communications campaign to ensure that all businesses are clear what is required and what compliance looks like, thereby minimising familiarisation costs.

The proposed fee levels will be reviewed and revised pending evidence from this consultation.

Annex B

PROPOSED MHRA FEES FROM 1 APRIL 2016

PROPOSED FEES FROM 1 APRIL 2016

CAPITAL FEES

LICENCE APPLICATIONS **MARKETING AUTHORISATIONS (including Extension Applications)**	**Current fee £**	**Proposed Fee £**
MAJOR		
National Fee (including Hybrid applications)	103,059	**92,753**
Decentralised procedure where UK is CMS	99,507	**89,556**
MAJOR (Reduced in exceptional circumstances[1] OR Orders under Section 104/105)	33,035	**29,732**
OUTGOING MUTUAL RECOGNITION (UK RMS)		
- 1ST WAVE	46,192	**41,573**
- 2ND WAVE	30,342	**27,308**
INCOMING MUTUAL RECOGNITION (UK CMS) and European reference products	69,357	**62,421**
ABRIDGED COMPLEX		
National Fee (including Hybrid applications)	28,492	**25,643**
Decentralised procedure where UK is CMS	27,511	**24,760**
OUTGOING MUTUAL RECOGNITION (UK RMS)		
- 1st WAVE	11,948	**10,753**
- 2nd WAVE	7,925	**7,133**
INCOMING MUTUAL RECOGNITION (UK CMS) and European reference products	19,256	**17,330**
ABRIDGED STANDARD		
National Fee	10,447	**9,402**
Decentralised procedure where UK is CMS	10,087	**9,078**
OUTGOING MUTUAL RECOGNITION (UK RMS)		
- 1st WAVE - 2nd WAVE	4,758 3,963	**4,282** **3,567**
INCOMING MUTUAL RECOGNITION (UK CMS) and European reference products	7,056	**6,350**
ABRIDGED SIMPLE		
National Fee	2,849	**2,564**
Decentralised procedure where UK is CMS	2,849	**2,564**
OUTGOING MUTUAL RECOGNITION (UK RMS)	2,849	**2,564**
OUTGOING MUTUAL RECOGNITION *(INFORMED CONSENT)*	2,849	**2,564**
- 1st WAVE	2,849	**2,564**
- 2nd WAVE	2,849	**2,564**
Duplicates for all of the above Outgoing Mutual Recognition applications when undertaken at the same time as the lead application	2,849	**2,564**

DECENTRALISED PROCEDURE WHERE UK IS RMS	Current fee £	Proposed fee £
MAJOR	143,134	**121,664**
ABRIDGED COMPLEX	41,922	**35,634**
ABRIDGED STANDARD	18,422	**15,659**
ABRIDGED SIMPLE	9,535	**8,105**
EXTENSION APPLICATION		
Extension Application Group (**National fee**)	28,492	**25,643**
Extension Application Group Bulk (**National fee**)	10,447	**9,402**
Extension Application Group		
Decentralised procedure where the UK is RMS	41,922	**35,634**
Decentralised procedure where UK is CMS	27,511	**24,760**
OUTGOING MUTUAL RECOGNITION (UK RMS)		
- 1st WAVE	11,948	**10,753**
- 2nd WAVE	7,925	**7,133**
INCOMING MUTUAL RECOGNITION (UK CMS)	19,256	**17,330**
Extension Application Group Bulk		
Decentralised procedure where the UK is RMS	18,422	**15,659**
Decentralised procedure where UK is CMS	10,087	**9,078**
OUTGOING MUTUAL RECOGNITION (UK RMS)		
- 1st WAVE	4,758	**4,282**
- 2nd WAVE	3,963	**3,567**
INCOMING MUTUAL RECOGNITION (UK CMS)	7,056	**6,350**

PARALLEL IMPORT		
COMPLEX APPLICATION[2]	20,200	**18,180**
STANDARD APPLICATION [2]	7,403	**6,663**
SIMPLE APPLICATION	1,991	**1,792**
CHANGE OF OWNERSHIP (incl. THMPD registrations)		
	491	**442**
MANUFACTURERS LICENCE (including THMPD and Homoeopathic Medicinal Products		
STANDARD	3,143	**3,143**
Non Orthodox Practitioner (NOP)	183	**183**
CHANGE OF OWNERSHIP	344	**344**
WHOLESALE DEALERS LICENCE		
STANDARD *	1,803	**1,803**
CHANGE OF OWNERSHIP	399	**399**
EXPORT CERTIFICATES		
Per set (1 original + 2 copies)	68	**68**
Per set (URGENT)	152	**152**
Extra Copies (3rd copy +)	34	**34**
GMP CERTIFICATES		
1 additional copy	68	**68**
CLINICAL TRIALS		
Accreditation of Phase 1 Units	130	**117**
Certificate of accreditation	69	**62**

Notes:

1. To which Section G of Part IV of the Annex to Council Directive 75/318/EEC refers.
2. An application for a Parallel Import licence for a product where there is no common origin between the imported and UK reference product – similar definitions for incoming Mutual Complex and Standard applications apply
3. Special reduced rate to apply for wholesale dealers handling GSL products only and for registered retail pharmacies and small wholesale dealers where wholesaling of licensed products does not exceed 15% or £35,000 of total turnover in licensed products.

* This rate includes an additional element equivalent to an inspection fee of one day for standard applications and 3.5 hours for reduced rate applications. If the application for a WDL is withdrawn before the inspection takes place, the equivalent inspection fee will be refunded. If the inspection takes longer than 1 day for a Standard Application, or 3.5 hours for a reduced rate application, an invoice will be raised for the balance due.

APPEALS TO PERSONS APPOINTED (PA)

	Current fee	Proposed fee
Application for a PA hearing	£10,000	**£10,000**

Notes:

This fee will be payable on application for a Persons Appointed (PA) hearing and applies to all PA proceedings A fee will be payable in respect of requests for PA hearings relating to marketing authorizations, manufacturer's licenses and authorisations, clinical trials applications, herbal and homeopathic registration and blood establishments and blood banks.

If the outcome of the hearing is positive for the company and the original advice is overturned, the fee will be refunded. If an application is made and subsequently withdrawn before a panel has been appointed to consider the case, a partial refund will be made (60%). If the application is withdrawn after the panel has been appointed, no refund will be applicable.

DRUG / DEVICE COMBINATION PRODUCTS	Current fee £	Proposed fee £	Current fee £	Proposed fee £
			In respect of a request by Notified Body to the MHRA to supply an additional assessment report.	
DEVICE WHICH INCORPORATES:				
A known medicinal substance from a source previously used in medicinal products or in medical devices in respect of which MHRA has previously been consulted.	4,595	**4,136**	909	**818**
A known medicinal substance from a new source.	10,711	**9,640**	2,542	**2,228**
A new active substance.	46,996	**42,296**	11,668	**10,501**

Notes:

1. Where a device incorporates two or more medicinal substances the fee will relate to one of the substances only - the one which commands the highest fee.
2. The same fee will apply regardless of the strength or concentration of the medicinal substance. But only one fee will apply to multiple applications made at the same time for a range of similar devices (e.g. a range of catheters made of the same material) incorporating the same medicinal substance at the same level.
3. The fee for an additional assessment report will apply when changes to the device require assessment under the terms of the Directive and at any time after the initial assessment when further data is submitted to the MHRA for assessment.

SCIENTIFIC ADVICE MEETING	Current fee £	Proposed fee £
PRE-APPLICATION MEETINGS		
Quality development only	2,445	**2,201**
Safety development only	2,445	**2,201**
Quality and safety development	3,401	**3,061**
Clinical development only	3,070	**2,763**
Quality and clinical development	4,027	**3,624**
Safety and clinical development	4,027	**3,624**
Quality, safety and clinical development	4,985	**4,487**
Discussion on development of paediatric forms and uses meeting criteria for waiver set down in schedule 5 paragraph 10 of SI 2008 No 552		
DRUG / DEVICE MEETINGS		
Quality development only	832	**749**
Safety development only	832	**749**
Quality and safety development	1,054	**949**
Clinical development only	1,054	**949**
Quality and clinical development	1,443	**1,299**
Safety and clinical development	1,443	**1,299**
Quality, safety and clinical development	1,831	**1,648**
COMPANY DISCUSSION MEETINGS	4,945	**4,451**
PHARMACOVIGILANCE ADVICE MEETINGS		
STANDARD meeting	3,401	**3,061**
MAJOR meeting	4,027	**3,624**
POST-AUTHORISATION REGULATORY ADVICE MEETINGS	3,070	**2,763**
ADVERTISING ADVICE	2,445	**2,201**
ADVICE ON LABELS AND LEAFLETS	2,445	**2,201**
RECLASSIFICATION ADVICE MEETINGS		
P to GSL switch	3,070	**2,763**
POM to P switch	4,027	**3,624**

		Current fee £	Proposed fee £
LICENCE RENEWAL APPLICATIONS			
MANUFACTURERS' LICENCES	Non-Orthodox Practitioner (NOP)	178	**178**
OUTGOING MUTUAL RECOGNITION	FIRST RENEWAL OF A MAJOR APPLICATION[1]	10,758	**9,682**
	ALL OTHERS[2]	830	**747**

RECLASSIFICATION		Current fee £	Proposed fee £
POM to P – Additional for MA or PI application with reclassification element **from POM to P**[3,4]		13,324	**11,992**
- Reclassification variation application **POM to P**[3,4]		13,324	**11,992**
P to GSL – Additional fee for MA or PI application with reclassification element from **P to GSL**[3,4]		9,069	**8,162**
- Reclassification variation application **P to GSL**		9,069	**8,162**
Reclassification variation application (MA) (analogous product)[4]		816	**734**
Reclassification variation application (PI) (analogous product)		196	**176**
ASSESSMENT OF LABELS AND LEAFLETS			
Single or first application[5]		575	**518**
National (BROMI)[6]		207	**186**
PARALLEL IMPORTS		364	**328**

Notes:

1. If a number of such renewal applications are made at the same time and in relation to products with the same active ingredient, dosage form, indications, Periodic Safety Update Report (PSUR) and renewal date, the full fee is charged for the first application, but a fee of £747 will be payable in respect of each of the other applications.
2. If a number of such renewal applications are made at the same time and in relation to products with the same active ingredient, dosage form, indications, PSUR and renewal date, the full fee is charged for the first application, but a 50% "discount" applies to each other application.
3. Where the Agency is of the view that a reclassification application does not require consideration by a medicines advisory committee a 50% reduction of the fee applies.
4. If multiple MA applications with reclassification elements are made at the same time and in relation to products with the same active ingredient, the full additional fee is charged for one application but only £734 for each other application.
   If multiple reclassification variation applications are made at the same time and in relation to products with the same active ingredient, the full fee is charged for the one application but in relation to each other application the fee is only £734, or £367 in the case of other applications where there is an analogous product already with the same legal status.
5. For all label and leaflet applications, a bulk "discount" applies where a number of simultaneous applications are made for identical changes covering a range of strengths of the same dosage form. The first application is charged at the full rate shown and second and subsequent applications are charged at 50%.
6. See the MHRA website for explanation of national leaflets and labels.

LICENCE VARIATIONS APPLICATIONS		Current fee £	Proposed fee £
Type IA	National/CMS	No fee	**No fee**
Type IA	RMS	No fee	**No fee**
Type IB	National/CMS	308	**277**
Type IB	RMS or reference authority for worksharing	611	**550**
Type II	National/CMS	816	**734**
Type II	RMS or reference authority for worksharing	989	**890**
Type II Complex	National/CMS	9,232	**8,309**
Type II Complex	RMS or reference authority for worksharing	16,007	**14,406**
Extended Type II Complex	National/CMS	28,492	**25,643**
Extended Type II Complex	RMS or reference authority for worksharing	39,829	**35,846**

LICENCE VARIATIONS APPLICATIONS GROUPS	Current fee £	Proposed fee £
Minor Variation (Type IB) Group Fee where UK is:		
• Concerned Member State	691	**622**
• Reference Member State or Reference Authority for Work Sharing	1,361	**1,225**
Major Variation (Type II) Group Fee where UK is:		
• Concerned Member State	1,836	**1,652**
• Reference Member State or Reference Authority for Work Sharing	2,218	**1,996**
Major Variation (Type II) Complex Group Fee where UK is:		
• Concerned Member State	10,011	**9,010**
• Reference Member State or Reference Authority for Work Sharing	16,926	**15,233**
Major Variation (Type II) Extended Complex Group Fee where UK is:		
• Concerned Member State	29,196	**26,276**
• Reference Member State or Reference Authority for Work Sharing	40,804	**36,724**
Minor Variation (Type IB) Group Fee (National)	691	**622**
Major Variation (Type II) Group Fee (National)	1,836	**1,652**
Major Variation (Type II) Complex Group Fee (National)	10,011	**9,010**
Major Variation (Type II) Extended Complex Group Fee (National)	29,196	**26,276**

OTHER LICENCE VARIATIONS APPLICATIONS

PARALLEL IMPORT(PI)		**Current fee £**	**Proposed fee £**
STANDARD		397	**357**
ADMINISTRATIVE		No fee	**No fee**
Manufacturers' licences (includes traditional herbal medicines)			
STANDARD		514	**514**
ADMINISTRATIVE		257	**257**
NOP		257	**257**
Wholesale dealers' licences (includes THMPD)			
STANDARD		486	**486**
ADMINISTRATIVE		257	**257**
Clinical trial authorisations			
AMENDMENTS TO:	ONE PART OF DOSSIER	250	**225**
	TWO PARTS OF DOSSIER	250	**225**
	THREE PARTS OF DOSSIER	250	**225**
	Protocol	250	**225**
Traditional Herbal Registration Scheme			
Standard		267	**240**
Complex		706	**635**
New excipient		7,984	**7,186**
ADMINISTRATIVE		169	**152**

INSPECTION FEES

From 1 April 2013, fees for inspections will continue to be charged at a daily rate as follows:

Type of inspection	Current daily rate £	Proposed daily rate £
All GMP, GCP and Pharmacovigilance inspections including (This is not an exhaustive list): - intermediate biological sites - manufacturers of active pharmaceutical ingredients (API) - sterile, non-sterile and assembly sites - non-routine inspections - pharmacovigilance inspections, including those of service providers - clinical trials - contract laboratories - homoeopathic manufacturers - blood banks - blood establishments	2,655	**2,655**
Office based risk assessments *(see notes below)*	1,863	**1,863**
GDP (wholesale dealers including homoeopathic wholesalers):		
Full day rate	1,936	**1.936**
Reduced rate (*see notes below*)	968	**968**
Office based risk assessments *(see notes below)*	1,354	**1,354**

Notes:

- There is a minimum fee of one day (with the exception of the GDP inspections).
- The inspection daily rate is calculated against a standard 7 hour working day (excluding lunch breaks).Therefore the number of days spent on site for fees purposes will be calculated by dividing the number of hours on site by 7.Additional part days of less than 3.5 hours will be charged at half the daily rate and part days in excess of 3.5 hours will be charged at the full daily rate.
- The daily rate fee includes pre-inspection preparation, travelling time, reporting of inspections and resolving issues. It also incorporates activities such as evaluation of compliance assessment report and other support functions and directly related overheads.
- A reduced rate fee for a wholesale dealer inspection will be payable by wholesale dealers who handle GSL products only and for registered retail pharmacies and small wholesale dealers where wholesaling of licensed products does not exceed 15% or £35,000 of total turnover **ONLY** where an inspector spends less than 3.5 hours on site.
- For inspections where two (or more) fully qualified inspectors undertake the inspection, the time on site for fees purposes will be the aggregated time for both inspectors.

- For inspections attended by two or more inspectors, one or more of who is in training, only the cost of one inspector will be charged – the status of the inspectors should be made clear to the company at the start of the inspection.
- The office based risk assessment fee will be charged where a risk assessment is conducted which does not lead to an inspection

OTHER FEES FOR TRADITIONAL HERBAL MEDICINAL PRODUCTS (THMP) (not included elsewhere*):

	Current fee £	Proposed fee £
TRADITIONAL HERBAL REGISTRATION SCHEME		
STANDARD		
- 3 or fewer existing herbal active ingredient	2,692	**2,423**
- more than 3 existing herbal active ingredients	4,038	**3,634**
REDUCED		
Category I		
- 3 or fewer existing herbal active ingredients	599	**539**
- more than 3 existing herbal active ingredients	897	**807**
Category II		
- 3 or fewer existing herbal active ingredients	897	**807**
- more than 3 existing herbal active ingredients	1,347	**1,212**
COMPLEX		
- single new herbal active ingredient	5,384	**4,846**
- 2 or more new herbal active ingredients	8,077	**7,269**
SUPPLEMENTARY FEES:		
Ancillary vitamins / minerals:		
Existing Sources plus CEP	1,197	**1,077**
New sources (non-CEP)	2,393	**2,154**
New excipients	7,984	**7,186**
New sources TSE risk excipients (non-CEP)	709	**638**
Sterile products	2,393	**2,154**
Inspection of Manufacturers		
Full day	1,615	**1,615**
Half day	994	**994**
Inspection of Wholesale Dealers		
Full day	1,367	**1,367**
Half day	744	**744**
Inspection of non-orthodox practitioners		
	295	**295**

**For further fees relating to THMPD, see sections relating to Manufacturers' licences and Wholesale dealers' licences, variations, change of ownership and periodic fees.*

OTHER FEES FOR HOMOEOPATHIC MEDICINAL PRODUCTS *(not included elsewhere*):*

HOMOEOPATHIC NATIONAL RULES SCHEME AND SIMPLIFIED REGISTRATION SCHEME FEES

These are the proposed amendments to the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994

The U.K. introduced a new National Rules Scheme for homoeopathic medicinal products under Article 16.2 of Directive 2001/83, which started on 1 September 2006. Products are required to meet particular standards on safety, quality and patient information.

HOMOEOPATHIC NATIONAL RULES SCHEME				
	Current fee £	**Proposed fee £**	**Current fee £**	**Proposed fee £**
	5 or fewer stocks		More than 5 stocks	
STANDARD	1,209	**1,088**	1,458	**1,312**
REDUCED:				
Stock already assessed	898	**808**	1,127	**1,014**
Formulation already assessed	898	**808**	1,127	**1,014**
Both stock and formulation already assessed	574	**517**	813	**732**
SUPPLEMENTARY FEES	**Current fee £**		**Proposed fee £**	
New method of sterilisation (non-pharmacopoeial)	2,393		**2,154**	
New excipients	7,983		**7,185**	
New sources TSE risk actives/excipients (non-CEP)	705		**635**	

SIMPLIFIED HOMOEOPATHIC REGISTRATION SCHEME	**Current fee £**		**Proposed fee £**	
	5 or fewer stock	More than 5 stock	5 or fewer stock	More than 5 stock
STANDARD	878	1,149	**790**	**1,034**
REDUCED:				
Stock already assessed	531	782	**478**	**704**
Formulation already assessed	531	782	**478**	**704**
Both stock and formulation already assessed	177	437	**159**	**393**

SIMPLIFIED HOMOEOPATHIC REGISTRATION SCHEME MUTUAL RECOGNITION PROCEDURES			
Current fee £	**Proposed fee £**	**Current fee £**	**Proposed fee £**
Mutual recognition OUTGOING			
5 or fewer stocks		More than 5 stocks	
319	**287**	416	**374**
Mutual recognition INCOMING			
5 or fewer stocks		More than 5 stocks	
557	**501**	709	**638**

HOMOEOPATHIC VARIATIONS		**Current fee £**	**Proposed fee £**
Homoeopathic Simplified Scheme	New technical	270	**243**
	Other	137	**123**
Homoeopathic National Rules Scheme	New technical	270	**243**
	Indication	416	**374**
	Other	137	**123**

Note:

For variations to homoeopathic medicinal products registered under the Simplified Scheme or authorised under the National Rules Scheme, a bulk "discount" applies where a number of simultaneous applications are made for identical variations. In general, the first of those applications is charged at the full rate shown above and the second and subsequent applications, up to 30 variations, are charged at 50%. Subsequent simultaneous applications for identical variations are charged at 25% of the full rate shown.

* *Fees relating to Homoeopathic Manufacturers' licences and Wholesale Dealers' licences applications and annual periodic fees - see tables elsewhere.*

PROPOSED PERIODIC FEES FROM 1 APRIL 2013 - PER LICENCE PER FEE PERIOD

TYPE OF LICENCE	Current fee £	Proposed fee £
New Active Substance[1]	24,821	**9,710**
Derivatives with a different Route of Administration[1] Or Complex Abridged[2]	10,221	**9,710**
Other derivatives[1]	6,899	**6,554**
Parallel Import	323	**307**

NOTES:

1. Payable for first five complete fee periods following the year of grant. Includes Reduced Major Drugs with turnover greater than £200,000 - otherwise treat as POM.
2. Payable for first three complete fee periods following the year of grant.

Legal Status/Sale Category	FEE TYPE – see note 3	Current fee £	Proposed fee £
POM	Standard fee	2,556	**2,428**
	Reduced rate fee	1,275	**1,211**
	Lower fee	323	**307**
All Others (P, GSL and None)	Lower	323	**307**

Standard fee
This fee relates to Prescription Only Medicine (POM) products only and means the periodic fee payable where the value of the product sold or supplied does exceed £35,000 in the relevant fee period.

Reduced fee
This fee related to POM products only and means the periodic fee payable where the value of the product sold or supplied does not exceed £35,000 in the relevant fee period.

Lower Fee
This fee means the periodic fee payable relating to a POM is not expected to be manufactured, or imported into the United Kingdom during the relevant fee period and:
(a) that the medicinal product has not been manufactured or imported into the UK during the period of 12 months preceding the commencement of the relevant fee period; OR
(b) where the medicinal product had been manufactured or imported into the UK during the period referred to in (a) above that the value of that product sold or supplied did not exceed £1,000 during that period.

All other legal status medicinal products

Lower Fee
This fee is payable relating to pharmacy medicines, general sale list medicines or 'none' status medicines regardless of turnover.

TYPE OF LICENCE	Current fee £	Proposed fee £
Herbal	80	**76**
Homoeopathic + Anthroposophic PLR's (per PLR)	80	**76**
Simplified Homoeopathic Registration	0	**0**
National Rules Homoeopathic Authorisation	80	**76**
Manufacturer's Licence	493	**468**
Wholesale Dealer's Licence	303	**288**
Wholesale Dealer's Licence (reduced rate or GSL)	181	**172**
THMPD Registration	80	**76**

FEES FOR SAFETY AND QUALITY VETTING OF UNLICENSED IMPORTED MEDICINES

Number of notifications estimated for coming year	Current fee (Additional sum to be paid with annual periodic fee for Manufacturers Licence holders and wholesale dealer licence holders) £	Proposed fee £
1 – 20	130	**130**
21 – 100	519	**519**
21 – 1,000	2,077	**2,077**
1,001 – 5,000	10,383	**10,383**
5,001 – 20,000	25,957	**25,957**
20,001 – 50,000	51,914	**51,914**
50,001 – 100,000	103,828	**103,828**
100,001 +	155,742	**155,742**

CLINICAL TRIALS

Fee Description	Current fee £	Proposed fee £
Applications with an IMP Dossier	3,400	**3,060**
Applications without an IMP Dossier	250	**225**
CT Variations/Amendments	250	**225**

SUPPLIERS OF DEFINED SIMPLE APIs

Standard, rather than complex, fees will be charged as shown in the table below to new suppliers of defined simple Active Pharmaceutical Ingredients (APIs). These simple APIs – listed below - are substances widely employed as excipients, food additives, reagents in analytical or synthetic chemistry, etc. and are all subjects of Ph. Eur/BP monographs as a prerequisite.

	Current fee £	Current fee £	Proposed fee £	Proposed fee £
	Complex	**Standard**	**Complex**	**Standard**
1. Licence variations applications: Single applications				
Type II variation National/CMS	9,232	816	**8,309**	**734**
Type II variation RMS	16,007	989	**14,406**	**890**
2. Licence variations applications: Groups				
Type II variation group national/CMS	10,011	1,836	**9,010**	**1,652**
Type II variation group RMS/Reference Authority for worksharing	16,926	2,218	**15,233**	**1,996**
3. Initial MA applications				
Abridged national	28,492	10,447	**25,643**	**9,402**
Abridged DCP (where UK is RMS)	41,922	18,422	**35,634**	**15,659**
Abridged DCP (where UK is CMS)	27,511	10,087	**24,760**	**9,078**
Abridged incoming MR (where UK is CMS)	19,256	7,056	**17,330**	**6,350**

List of defined simple APIs to be charged a standard fee:

1. ALUMINIUM CHLORIDE
2. ALUMINIUM HYDROXIDE
3. ALUMINIUM SULPHATE
4. AMMONIA
5. AMMONIUM BICARBONATE
6. AMMONIUM CHLORIDE
7. ANHYDROUS GLUCOSE
8. ASCORBIC ACID
9. BENZOIC ACID
10. BENZOYL PEROXIDE
11. BENZYL ALCOHOL
12. BENZYL BENZOATE
13. BISMUTH SUBGALLATE
14. CALAMINE
15. CALCIUM ACETATE
16. CALCIUM CARBONATE
17. CALCIUM CHLORIDE
18. CALCIUM GLUCONATE
19. CALCIUM GLYCEROPHOSPHATE

20. CALCIUM PHOSPHATE
21. CHARCOAL
22. CHLOROBUTANOL
23. CHLOROCRESOL
24. CITRIC ACID
25. COCONUT OIL
26. DIMETICONE
27. ETHANOL
28. FERRIC CHLORIDE
29. FERROUS FUMARATE
30. FERROUS GLUCONATE
31. FERROUS SULPHATE
32. FORMALDEHYDE
33. GLUCOSE
34. GLYCEROL
35. GLYCINE
36. HYDROGEN PEROXIDE
37. IODINE
38. ISOPROPYL ALCOHOL
39. ISOPROPYL MYRISTATE
40. KAOLIN
41. LACTIC ACID
42. LACTOSE
43. LACTULOSE
44. LITHIUM CARBONATE
45. LITHIUM CITRATE
46. MAGNESIUM ACETATE
47. MAGNESIUM CARBONATE
48. MAGNESIUM CHLORIDE
49. MAGNESIUM HYDROXIDE
50. MAGNESIUM OXIDE
51. MAGNESIUM SULPHATE
52. MAGNESIUM TRISILICATE
53. MALIC ACID
54. MANGANESE SULPHATE
55. OLEIC ACID
56. PARAFFIN
57. PHENOL
58. POTASSIUM ACETATE
59. POTASSIUM BICARBONATE
60. POTASSIUM CHLORIDE
61. POTASSIUM CITRATE
62. POTASSIUM DIHYDROGEN PHOSPHATE
63. POTASSIUM HYDROGEN TARTRATE
64. POTASSIUM HYDROXIDE
65. POTASSIUM IODATE
66. POTASSIUM IODIDE
67. POTASSIUM NITRATE
68. SODIUM FLUORIDE
69. SODIUM HYDROXIDE
70. SODIUM IODIDE
71. SODIUM LACTATE
72. SODIUM SULPHATE
73. SUCROSE
74. TAR

75. TARTARIC ACID
76. UNDECENOIC ACID
77. UREA
78. WOOL ALCOHOLS
79. WOOL FAT
80. ZINC CHLORIDE
81. ZINC OXIDE
82. ZINC SULPHATE
83. ZINC UNDECENOATE

* NB Dried/Anhydrous, Hydrate/Hydrous, Activated, Strong, Light, Heavy and Coloured forms for these APIs are not cited in this list. These specific forms, where relevant, are stated in the title of the Ph. Eur. /BP monographs

CURRENT FEES FOR FALSIFIED MEDICINES DIRECTIVE

Fee Description	Current fee £	Proposed fee £
Broker Fees		
Application for registration as a Broker	1,803	**1,803**
Assessment of the Initial Application	1,354	**1,354**
Additional fee if the risk assessment of the initial application triggers an inspection	582	**582**
Assessment of the Annual Compliance Report	257	**257**
Notification of Changes	257	**257**
Inspection fee	1,936	**1,936**
Persons Appointed appeals procedure fee	10,000	**10,000**
Active Substance Manufacturers		
Application for registration	3,143	**3,143**
Assessment of Initial Application	1,863	**1,863**
Additional fee for the first day of an inspection if triggered following risk-assessment of the application	792	**792**
Assessment of the Annual Compliance Report	257	**257**
Notification of Changes	257	**257**
Inspection days	2,655	**2,655**
Active Substance Importer/Distributor		
Application for registration	1,803	**1,803**
Assessment of Initial Application - Active Substance Importer / Distributor	1,354	**1,354**
Additional fee for the first day of inspection if triggered following risk-assessment of the application.	582	**582**
Assessment of the Annual Compliance Report - Active Substance Importer / Distributor	257	**257**
Notification of Changes	257	**257**

Standard daily rate for Inspection	1,936	**1,936**
Persons Appointed appeals procedure fee	10,000	**10,000**

NEW FEES RESULTING FROM IMPLEMENTATION OF THE FALSIFIED MEDICINES DIRECTIVE (2011/62/EU)

Fee Description	**Current fee £**	**Proposed fee £**
FMD LOGO		
Initial application fee	None	**100**
Annual service fee	None	**97**

Note:

1. A one-off supplement fee, equivalent to the cost of the initial application fee, will be added to the annual service fee for all those on-line sellers who registered before 1st April 2016.

ANNEX C

RESPONSE TO CONSULTATION LETTER (MLX 389)

MHRA FEES FOR 2016/2017

Please complete the proforma below and return to: consultations@mhra.gsi.gov.uk by **19/11/2015**.

Name: ……

Company Name: ……

……

General comments

Specific questions:

MEDICINES LICENSING FEES

The current fees structure is over-recovering the cost of the work in several areas and these new fees seek to address that by bringing them more accurately into line with costs, thus reducing them in certain areas.

1. Do you agree or disagree with the proposed fee reductions in Annexes A & B?

NEW FEE FOR ONLINE SELLERS OF MEDICINE

The MHRA must recover the costs of the new registration scheme and logo system for UK-based online sellers of human medicine, introduced as a result of the EU Falsified Medicines Directive. The Agency proposes to introduce an application fee of £100, and an ongoing annual service fee of £97. We also propose charging sellers who did not pay an initial application fee (i.e. those who registered before 1 April 2016) a one-off supplement to the annual service fee, equal to the cost of the application fee. This would ensure that costs are attributed fairly across retailers using the service.

The Agency estimates the number of on-line traders who will register with the FMD Logo scheme in 2015/2016 will be approximately 4000. The fees will have a greater impact on small traders, however the Agency believes this to be unavoidable and the fees are set at the minimum level possible to ensure cost recovery.

2. Are the proposed fee levels tolerable, or will they cause a significant impact on your business's finances?
    a. Are you a small/micro business?

3. Do you have any data or information that will improve the registration volumes estimates?

4. Do you have any data to inform our assumption on how many businesses will register beyond year one?