Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Annex A: Summary of fee changes

Decrease in fees

MHRA will 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.

Introduction of fees for online sellers of medicine

MHRA will 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 will charge 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 will 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.

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	4,758	**4,282**
- 2nd WAVE	3,963	**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	**2,288**
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 Reduced rate fee Lower fee	2,556 1,275 323	**2,428** **1,211** **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.