

Medicinal Products for Human Use

Explanatory notes:
- 1 point is 5 Eur

Type of application	National procedure	RS as CMS (MRP)	RS as CMS (DCP)	RS as RMS (MRP)	RS as RMS (DCP)
Art. 8(3), Art. 10b of Directive 2001/83/EC	1000 points basic fee (1 strength associated with 1 pharmaceutical form) + 200 points for each additional strength and/or pharmaceutical form	420 points basic fee (1 strength associated with 1 pharmaceutical form) + 100 points for each additional strength and/or pharmaceutical form	450 points basic fee (1 strength associated with 1 pharmaceutical form) + 100 points for each additional strength and/or pharmaceutical form	6000 points basic fee (1 strength associated with 1 pharmaceutical form) + 1750 points for each additional strength and/or pharmaceutical form	7000 points basic fee (1 strength associated with 1 pharmaceutical form) + 1750 points for each additional strength and/or pharmaceutical form
Art. 10a of Directive 2001/83/EC - in line with Community herbal monograph	800 points basic fee (1 strength associated with 1 pharmaceutical form) + 200 points for each additional strength and/or pharmaceutical form 500 points basic fee + 200 points for each additional strength and/or pharmaceutical form	380 points basic fee (1 strength associated with 1 pharmaceutical form) + 100 points for each additional strength and/or pharmaceutical form	420 points basic fee (1 strength associated with 1 pharmaceutical form) + 100 points for each additional strength and/or pharmaceutical form	5000 points basic fee (1 strength associated with 1 pharmaceutical form) + 1750 points for each additional strength and/or pharmaceutical form	5500 points basic fee (1 strength associated with 1 pharmaceutical form) + 1750 points for each additional strength and/or pharmaceutical form

Art. 10(1), Art. 10(3), Art. 10(4) of Directive 2001/83/EC	700 points basic fee (1 strength associated with 1 pharmaceutical form) + 200 points for each additional strength and/or pharmaceutical form	360 points basic fee (1 strength associated with 1 pharmaceutical form) + 100 points for each additional strength and/or pharmaceutical form	380 points basic fee (1 strength associated with 1 pharmaceutical form) + 100 points for each additional strength and/or pharmaceutical form	5000 points basic fee (1 strength associated with 1 pharmaceutical form) + 1750 points for each additional strength and/or pharmaceutical form	5800 points basic fee (1 strength associated with 1 pharmaceutical form) + 1750 points for each additional strength and/or pharmaceutical form
Art. 10c of Directive 2001/83/EC	200 basic fee (1 strength associated with 1 pharmaceutical form) + 200 points for each additional strength and/or pharmaceutical form	200 points basic fee (1 strength associated with 1 pharmaceutical form) + 100 points for each additional strength and/or pharmaceutical form	200 points basic fee (1 strength associated with 1 pharmaceutical form) + 100 points for each additional strength and/or pharmaceutical form	3500 points basic fee (1 strength associated with 1 pharmaceutical form) + 1750 points for each additional strength and/or pharmaceutical form	4600 points basic fee (1 strength associated with 1 pharmaceutical form) + 1750 points for each additional strength and/or pharmaceutical form
Line Extension (Annex I to Commission Regulation (EC) 1234/2008)	600 points basic fee (1 strength associated with 1 pharmaceutical form) + 200 points for each additional strength and/or pharmaceutical form	250 points basic fee (1 strength associated with 1 pharmaceutical form) + 100 points for each additional strength and/or pharmaceutical form	280 points basic fee (1 strength associated with 1 pharmaceutical form) + 100 points for each additional strength and/or pharmaceutical form	3000 points basic fee (1 strength associated with 1 pharmaceutical form) + 1750 points for each additional strength and/or pharmaceutical form	3000 points basic fee (1 strength associated with 1 pharmaceutical form) + 1750 points for each additional strength and/or pharmaceutical form

Type of application	National procedure	RS as CMS (MRP)	RS as RMS (DCP)
Type IA Variation (Art. 2 of Commission Regulation (EC))	50 points basic fee*	50 points basic fee *	400 points basic fee *

1234/2008)			
Type IB Variation (Art. 2 of Commission Regulation (EC) 1234/2008)	110 points basic fee*	110 points basic fee *	800 points basic fee *
Type II Variation (in accordance with Art. 2 of Commission Regulation (EC) 1234/2008)	180 points basic fee *	140 points basic fee *	1300 points basic fee *
Grouped Variation (Art. 7(2), point (a) and in conjunction with Art. 8 of Commission Regulation (EC) 1234/2008) - annual variations	50 points basic fee For each additional variation 75% of basic fee	50 points basic fee For each additional variation 75% of basic fee	50 points basic fee For each additional variation 75% of basic fee
Grouped Variation (Art. 7(2), point (a) of Commission Regulation (EC) 1234/2008) - type IA/IA_{IN}	50 points basic fee For each additional variation 75% of basic fee but not more than 400 points	50 points basic fee For each additional variation 75% of basic fee but not more than 400 points	400 points basic fee For each additional variation 75% of basic fee but not more than 2000 points
Grouped Variation (Art. 7(2), point (b) of Commission Regulation (EC) 1234/2008) - Line Extension as the main variation	100 % basic fee for the main variation 75% of basic fee for each additional variation but not more than 1000 points	100 % basic fee for the main variation 75% of basic fee for each additional variation but not more than 800 points	100 % basic fee for the main variation 75% of basic fee for each additional variation but not more than 5000 points
Grouped Variation (Art. 7(2), point (b) of Commission Regulation (EC) 1234/2008) – type II or type IB as the main variation	100 % basic fee for the main variation 75% of basic fee for each additional variation but not more than 600 points	100 % basic fee for the main variation 75% of basic fee for each additional variation but not more than 550 points	100 % basic fee for the main variation 75% of basic fee for each additional variation but not more than 3000 points

Exemption: variation to change the name and/or address of the MAH or variation to changes to an existing pharmacovigilance system as described in the DDPS	Up to 20 medicinal products: 100 points More than 20 medicinal products: 200 points More than 50 medicinal products: 400 points	Up to 20 medicinal products: 100 points More than 20 medicinal products: 200 points More than 50 medicinal products: 400 points	Up to 20 medicinal products: 100 points More than 20 medicinal products: 200 points More than 50 medicinal products: 400 points
Exemption: variation to change (invented) name of the medicinal product in one or more MS (including in Slovenia)	/	110 points basic fee	800 points basic fee
Worksharing procedures (Art. 20 of Commission Regulation (EC) 1234/2008)	/	1 st MA 100 % fee (in case of grouped variations taking into account the provisions for calculation fees for grouped variations) Each additional MA 75 % fee of 1 st MA	1 st MA 100 % fee (in case of grouped variations taking into account the provisions for calculation fees for grouped variations) Each additional MA 75 % fee of 1 st MA
Notification for product information amendment (Art. 61(3) of Directive 2001/83/EC)	20 points basic fee +20 points for each additional strength and/or pharmaceutical form	20 points basic fee +20 points for each additional strength and/or pharmaceutical form	20 points basic fee +20 points for each additional strength and/or pharmaceutical form
Review of educational material (Art. 8 and 127a of Directive 2001/83/EC)	70 points basic fee*		

* no fee for additional strength and/or pharmaceutical form in the same application

Type of application	National procedure	RS as CMS (MRP/DCP)	RS as RMS (MRP/DP)
Renewal	300 points basic fee (1 strength associated with 1 pharmaceutical form) + 50 points for each additional strength and/or pharmaceutical form	250 points basic fee (1 strength associated with 1 pharmaceutical form) + 50 points for each additional strength and/or pharmaceutical form	2350 points basic fee (1 strength associated with 1 pharmaceutical form) + 500 points for each additional strength and/or pharmaceutical form
PSUR assessment-(Art. 102 and 104 of Directive 2001/83/EC)	300 points	50 points	2350 points

Type of application	National procedure
Transfer of MA	50 points basic fee (1 strength associated with 1 pharmaceutical form) + 50 points for each additional strength and/or pharmaceutical form but not more than 200 points
Cessation of validity of MA	20 points basic fee (1 strength associated with 1 pharmaceutical form)

Type of application	
Scientific advice (basic advice on documentation preparation)	100 points
Scientific advice (complex advice on documentation preparation)	300 points
Scientific advice (advice on content of documentation)	700 points

Type of application	National procedure
List of the mutually interchangeable medicinal products	100 points
Change of classification of OTC medicinal product concerning the place of dispensing	100 points
Classification of product as medicinal product	60 points

Type of application	National procedure
Authorisation of clinical trial*	250 points
Notification of clinical trial*	150 points
Notification of substantial amendment of clinical trial	50 points
Authorisation of non-commercial clinical trial*	120 points
Notification of non-commercial clinical trial*	80 points
Notification of substantial amendment of non-commercial clinical trial	40 point

**Fee relating to the procedure of notification or approval of clinical trial in paediatric population and in orphan medications in amount of half the value of the fee*

Additional provisions for traditional herbal and homeopathic medicinal products

1. Traditional herbal medicinal products

Type of application	National procedure	RS as CMS (MRP/DP)	RS as RMS (MRP)	RS as RMS (DP)
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Art. 16a of Directive 2001/83/EC	400 points basic fee (1 strength associated with 1 pharmaceutical form) – if the Community herbal monograph does not exist or if additional data are supplied 300 points basic fee (1 strength associated with 1 pharmaceutical form) – in line with the Community herbal monograph + 100 points for each additional strength and/or pharmaceutical form	250 points basic fee (1 strength associated with 1 pharmaceutical form) + 100 points for each additional strength and/or pharmaceutical form	4000 points basic fee (1 strength associated with 1 pharmaceutical form) + 1750 points for each additional strength and/or pharmaceutical form	4500 points basic fee (1 strength associated with 1 pharmaceutical form) + 1750 points for each additional strength and/or pharmaceutical form
Line Extension (Annex I to Commission Regulation (EC) 1234/2008)	200 points basic fee (1 strength associated with 1 pharmaceutical form)	160 points basic fee (1 strength associated with 1 pharmaceutical form)	2000 points basic fee (1 strength associated with 1 pharmaceutical form)	2000 points basic fee (1 strength associated with 1 pharmaceutical form)

Type of application	National procedure	RS as CMS (MRP/DP)	RS as RMS (MRP/DP)
Type IA, IB, II Variation	70 % of the fees for variations stated above	70 % of the fees for variations stated above	70 % of the fees for variations stated above
Renewal	200 points basic fee (1 strength associated with 1 pharmaceutical form) + 50 points for each additional strength and/or pharmaceutical form	160 points basic fee (1 strength associated with 1 pharmaceutical form) + 50 points for each additional strength and/or pharmaceutical form	2000 points basic fee (1 strength associated with 1 pharmaceutical form) + 500 points for each additional strength and/or pharmaceutical form

2. Homeopathic medicinal products

Type of application	National procedure	RS as CMS (MRP/DP)	RS as RMS (MRP)	RS as RMS (DP)
Art. 14 of Directive 2001/83/EC	<p>100 points basic fee (for homeopathic medicines with 1 homeopathic principle, associated with 1 pharmaceutical form)</p> <p>300 points basic fee (for homeopathic medicines with 2 to 3 homeopathic principles, associated with 1 pharmaceutical form)</p> <p>400 points basic fee (for homeopathic medicines with more than 3 homeopathic principles associated with 1 pharmaceutical form)</p> <p>+ 60 points for each additional pharmaceutical form</p>	<p>50 points basic fee (for homeopathic medicines with up to 3 homeopathic principles, associated with 1 pharmaceutical form)</p> <p>60 points basic fee (for homeopathic medicines with more than 3 homeopathic principles associated with 1 pharmaceutical form)</p> <p>+ 20 points for each additional pharmaceutical form</p>	<p>4000 points basic fee (for homeopathic medicines with up to 3 homeopathic principles, associated with 1 pharmaceutical form)</p> <p>4400 points basic fee (for homeopathic medicines with more than 3 homeopathic principles associated with 1 pharmaceutical form)</p> <p>+ 1750 points for each additional pharmaceutical form</p>	<p>4000 points basic fee (for homeopathic medicines with up to 3 homeopathic principles, associated with 1 pharmaceutical form)</p> <p>4400 points basic fee (for homeopathic medicines with more than 3 homeopathic principles associated with 1 pharmaceutical form)</p> <p>+ 1750 points for each additional pharmaceutical form</p>

Type of application	National procedure	RS as CMS (MRP/DP)	RS as RMS (MRP/DP)
Type IA, IB, II Variation	30 points basic fee	30 points basic fee	1000 points basic fee
Renewal	30 points basic fee for each pharmaceutical form	30 points basic fee for each pharmaceutical form	1000 points basic fee for each pharmaceutical form

