

## 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	500 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	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

Type of application	National procedure	RS as CMS (MRP)	RS as CMS (DCP)	RS as RMS (MRP)	RS as RMS (DCP)
Art. 10a of Directive 2001/83/EC	450 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	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), Article 10(3)	400 points basic fee (1 strength associated with 1 pharmaceutical form)  + 100 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
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Type of application	National procedure	RS as CMS (MRP)	RS as CMS (DCP)	RS as RMS (MRP)	RS as RMS (DCP)
Art. 10c of Directive 2001/83/EC	200 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	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

Type of application	National procedure	RS as CMS (MRP)	RS as CMS (DCP)	RS as RMS (MRP)	RS as RMS (DCP)
Line Extension (in accordance with Annex II)	320 points basic fee (1 strength associated with 1 pharmaceutical form)	250 points basic fee (1 strength associated with 1 pharmaceutical form)	280 points basic fee (1 strength associated with 1 pharmaceutical form)	3000 points basic fee (1 strength associated with 1 pharmaceutical form)	3000 points basic fee (1 strength associated with 1 pharmaceutical form)

to Commission Regulation (EC) 1084/2003	+ 100 points for each additional strength and/or pharmaceutical form	+ 100 points for each additional strength and/or pharmaceutical form	+ 100 points for each additional strength and/or pharmaceutical form	+ 1750 points for each additional strength and/or pharmaceutical form	+ 1750 points for each additional strength and/or pharmaceutical form
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Type of application	National procedure	RS as CMS (MRP)	RS as RMS (DCP)
Type IA Variation ( in accordance with Article 2 to Commission Regulation (EC) 1234/2008)	50 points basic fee (1 strength associated with 1 pharmaceutical form)  + 20 points for each additional strength and/or pharmaceutical form	50 points basic fee (1 strength associated with 1 pharmaceutical form)  + 20 points for each additional strength and/or pharmaceutical form.	660 points basic fee (1 strength associated with 1 pharmaceutical form)  + 250 points for each additional strength and/or pharmaceutical form
Type IB Variation ( in accordance with Article 2 to Commission Regulation (EC) 1234/2008)	70 points basic fee (1 strength associated with 1 pharmaceutical form)  + 20 points for each additional strength and/or pharmaceutical form.	70 points basic fee (1 strength associated with 1 pharmaceutical form)  + 20 points for each additional strength and/or pharmaceutical form.	750 points basic fee (1 strength associated with 1 pharmaceutical form)  + 250 points for each additional strength and/or pharmaceutical form
Type II Variation ( in accordance with Article 2 to Commission Regulation (EC) 1234/2008)	110 points basic fee (1 strength associated with 1 pharmaceutical form)  + 30 points for each additional strength and/or pharmaceutical form	90 points basic fee (1 strength associated with 1 pharmaceutical form)  + 30 points for each additional strength and/or pharmaceutical form	1100 points basic fee (1 strength associated with 1 pharmaceutical form)  + 400 points for each additional strength and/or pharmaceutical form

Type of application	National procedure	RS as CMS (MRP)	RS as RMS (DCP)
Submission of Variation due to changes in product information following the assessment of PSUR in EU “work sharing” procedure (in accordance with Article 3 of Commission Regulation (EC) 1234/2008)	70 points basic fee and for each additional strength and/or pharmaceutical form	70 points basic fee and for each additional strength and/or pharmaceutical form	70 points basic fee and for each additional strength and/or pharmaceutical form
Submission of the product information in accordance with EU work sharing procedure on Article 45/46 of Regulation (EC) 1901/2006 in the assessment of paediatric data	70 points basic fee and for each additional strength and/or pharmaceutical form	70 points basic fee and for each additional strength and/or pharmaceutical form	70 points basic fee and for each additional strength and/or pharmaceutical form
Submission of Variation due to changes in product information following assessment at Pharmacovigilance Working Party (in accordance with Article 3 of Commission Regulation (EC) 1234/2008)	70 points basic fee and for each additional strength and/or pharmaceutical form	70 points basic fee and for each additional strength and/or pharmaceutical form	70 points basic fee and for each additional strength and/or pharmaceutical form
Review of educational material with regard to the safe and effective use of Medicinal products (in accordance with Article 127a of Directive (EC))	70 points basic fee and for each additional strength and/or pharmaceutical form	70 points basic fee and for each additional strength and/or pharmaceutical form	70 points basic fee and for each additional strength and/or pharmaceutical form

2001/83)			
Submission of the product information in accordance with Commission Decision after Community referral	70 points basic fee and for each additional strength and/or pharmaceutical form	70 points basic fee and for each additional strength and/or pharmaceutical form	70 points basic fee and for each additional strength and/or pharmaceutical form
Notification for product information amendment in accordance with Article 61(3) of Directive (EC) 2001/83)	20 points basic fee and for each additional strength and/or pharmaceutical form	20 points basic fee and for each additional strength and/or pharmaceutical form	20 points basic fee and for each additional strength and/or pharmaceutical form

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

## 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)
<p>Art. 16a of Directive 2001/83/EC</p> <p>and</p> <p>Art. 36 of Medical Products Act</p>	<p>300 points basic fee (1 strength associated with 1 pharmaceutical form) – if the Community monograph exist</p> <p>240 points basic fee (1 strength associated with 1 pharmaceutical form) - if the Community monograph does not exist</p> <p>+ 100 points for each additional strength and/or pharmaceutical form</p>	<p>200 points basic fee (1 strength associated with 1 pharmaceutical form)</p> <p>+ 100 points for each additional strength and/or pharmaceutical form</p>	<p>4000 points basic fee (1 strength associated with 1 pharmaceutical form)</p> <p>+ 1750 points for each additional strength and/or pharmaceutical form</p>	<p>4500 points basic fee (1 strength associated with 1 pharmaceutical form)</p> <p>+ 1750 points for each additional strength and/or pharmaceutical form</p>
<p>Line Extension (in accordance with Annex II to Commission Regulation (EC) 1084/2003</p>	<p>200 points basic fee (1 strength associated with 1 pharmaceutical form)</p>	<p>160 points basic fee (1 strength associated with 1 pharmaceutical form)</p>	<p>2000 points basic fee (1 strength associated with 1 pharmaceutical form)</p>	<p>2000 points basic fee (1 strength associated with 1 pharmaceutical form)</p>

Type of application	National procedure	RS as CMS (MRP/DP)	RS as RMS (MRP/DP)
Type IA Variation	50 points basic fee (1 strength associated with 1 pharmaceutical form)  + 20 points for each additional strength and/or pharmaceutical form	50 points basic fee (1 strength associated with 1 pharmaceutical form)  + 20 points for each additional strength and/or pharmaceutical form	660 points basic fee (1 strength associated with 1 pharmaceutical form)  + 250 points for each additional strength and/or pharmaceutical form
Type IB Variation	70 points basic fee (1 strength associated with 1 pharmaceutical form)  + 20 points for each additional strength and/or pharmaceutical form.	70 points basic fee (1 strength associated with 1 pharmaceutical form)  + 20 points for each additional strength and/or pharmaceutical form.	750 points basic fee (1 strength associated with 1 pharmaceutical form)  + 250 points for each additional strength and/or pharmaceutical form
Type II Variation	110 points basic fee (1 strength associated with 1 pharmaceutical form)  + 30 points for each additional strength and/or pharmaceutical form	90 points basic fee (1 strength associated with 1 pharmaceutical form)  + 30 points for each additional strength and/or pharmaceutical form	1100 points basic fee (1 strength associated with 1 pharmaceutical form)  + 400 points for each additional strength and/or pharmaceutical form
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 and Art. 14 of Medical Products Act	<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 and IB Variation	<p>30 points basic fee (for homeopathic medicines with up to 3 homeopathic principles, associated with 1 pharmaceutical form)</p> <p>30 points basic fee (for homeopathic medicines with more than 3 homeopathic principles associated with 1 pharmaceutical form)</p>	<p>30 points basic fee (for homeopathic medicines with up to 3 homeopathic principles, associated with 1 pharmaceutical form)</p> <p>30 points basic fee (for homeopathic medicines with more than 3 homeopathic principles associated with 1 pharmaceutical form)</p>	<p>1000 points basic fee (for homeopathic medicines with up to 3 homeopathic principles, associated with 1 pharmaceutical form)</p> <p>1000 points basic fee (for homeopathic medicines with more than 3 homeopathic principles associated with 1 pharmaceutical form)</p>
Type II Variation	<p>30 points basic fee (for homeopathic medicines with up to 3 homeopathic principles, associated with 1 pharmaceutical form)</p> <p>30 points basic fee (for homeopathic medicines with more than 3 homeopathic principles associated with 1 pharmaceutical form)</p>	<p>30 points basic fee (for homeopathic medicines with up to 3 homeopathic principles, associated with 1 pharmaceutical form)</p> <p>30 points basic fee (for homeopathic medicines with more than 3 homeopathic principles associated with 1 pharmaceutical form)</p>	<p>1000 points basic fee (for homeopathic medicines with up to 3 homeopathic principles, associated with 1 pharmaceutical form)</p> <p>1000 points basic fee (for homeopathic medicines with more than 3 homeopathic principles associated with 1 pharmaceutical form)</p>

Type of application	National procedure	RS as CMS (MRP/DP)	RS as RMS (MRP/DP)
Renewal	<p>30 points basic fee (for homeopathic medicines with up to 3 homeopathic principles, associated with 1 pharmaceutical form)</p> <p>30 points basic fee (for homeopathic medicines with more than 3 homeopathic principles associated with 1 pharmaceutical form)</p>	<p>30 points basic fee (for homeopathic medicines with up to 3 homeopathic principles, associated with 1 pharmaceutical form)</p> <p>30 points basic fee (for homeopathic medicines with more than 3 homeopathic principles associated with 1 pharmaceutical form)</p>	<p>1000 points basic fee (for homeopathic medicines with up to 3 homeopathic principles, associated with 1 pharmaceutical form)</p> <p>1000 points basic fee (for homeopathic medicines with more than 3 homeopathic principles associated with 1 pharmaceutical form)</p>