



IRISH MEDICINES BOARD

# Fees For Variations under the new Regulation

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*Information Day on the New Variations Regulation, 22<sup>nd</sup> Jan 2010*

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Director of Finance and  
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# Fees For Type 1a Annual Notification

	2009	2010
National first 2 in range	€365	€0
Natl 3 <sup>rd</sup> and subsequent	€184	€0
MR/ DCP inc first 2 in range	€315	€0
MR/ DCP 3 <sup>rd</sup> and subsequent	€184	€0
Outgoing Supplement	€365	€0



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# Fees For Type 1a Immediate Notification

	2009	2010
National first 2 in range	€365	€0
Natl 3 <sup>rd</sup> and subsequent	€184	€0
MR/ DCP inc first 2 in range	€315	€0
MR/ DCP 3 <sup>rd</sup> and subsequent	€184	€0
Outgoing supplement	€365	€0



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# Fees For Type 1b Variation

	2009	2010
National first 2 in range	€495	€520
Natl 3 <sup>rd</sup> and subsequent	€248	€260
MR/ DCP inc first 2 in range	€422	€422
MR/ DCP 3 <sup>rd</sup> and subsequent	€218	€218
Outgoing supplement	€365	€383



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# Fees For Type II standard Variation

	2009	2010
National first 2 in range	€633	€633
Natl 3 <sup>rd</sup> and subsequent	€316	€316
MR/ DCP inc first 2 in range	€422	€422
MR/ DCP 3 <sup>rd</sup> and subsequent	€218	€218
Outgoing supplement	€422	€422



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# Fees For Type II complex Variation

	2009	2010
National first 2 in range	€3,251	€3,251
Natl 3 <sup>rd</sup> and subsequent	€633	€633
MR/ DCP inc first 2 in range	€2,246	€2,246
MR/ DCP 3 <sup>rd</sup> and subsequent	€422	€422
Outgoing supplement	€656	€656



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# Grouped Variations

- The fee is the same as if the variations has been submitted individually



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# Maintenance Fees

Rate	Human Medicines	Veterinary Medicines
Standard	€50	€13
Reduced (For the first 10 authorisations)	€60	€70
Dormant	€91	€91



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# Dormant Marketing Authorisations

- A reduced rate of €491 per authorisation per annum (the same full rate charged in 2009) where the authorisation is deemed Dormant (even when the number of instances exceeds ten)
- *N.B.:*
  - *Where an MA Holder has less than 10 dormant authorisations, these will be charged at the Dormant rate, the balance up to 10 at the Reduced rate and all other authorisations charged at the Standard rate;*
  - *Where an MA Holder has more than 10 dormant authorisations, these will be charged at the Dormant rate, and all other authorisations charged at the Standard rate.*



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Any Questions.....



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