

Implementation of changes to product information following European paediatric work sharing procedures

For submission of variations to include paediatric information in marketing authorisations following European work-sharing procedures.

- As type IB variations - under category C.I.3 (z) if wording is in line with work-sharing recommendations, only requires additional minor assessment and no new data submitted ([Article 5](#) (external link)).

- As type II variations - under category C.I.3 (b) if additional data that require assessment are submitted

Please also refer to '[Variations to licences](#)' (link) for further details on how to submit a variation application to the MHRA.

For further advice on implementing recommendations from European paediatric work-sharing procedures, please contact Dr Julia Dunne on 020 3080 6868 or send an email to specialpopulationsunit@mhra.gsi.gov.uk

Requests issued by the MHRA

| Drug substance | Date of request | Submission of variation deadline | Approval of variations deadline |
|--|------------------|----------------------------------|---------------------------------|
| Actonel (risedronate) (Art 46) | 02-03 May 2013 | 01 July 2013 | 31 July 2013 |
| Phytomenadione (Art 45) | 02 May 2013 | 01 July 2013 | 31 July 2013 |
| Testosterone (Art 45) | 30 April 2013 | 01 July 2013 | 31 July 2013 |
| Alfentanil (Art 45) | 29 April 2013 | 01 July 2013 | 31 July 2013 |
| Miconazole, Miconazole+zinc (Art 45) | 29 April 2013 | 04 June 2013 | 04 July 2013 |
| Dobutamine (Art 45) | 06 March 2013 | 04 June 2013 | 04 July 2013 |
| Ketoconazole (Art 45) | 26 April 2013 | 04 June 2013 | 04 July 2013 |
| Risperidone (Art 45) | 18 February 2013 | 01 May 2013 | 31 May 2013 |
| Bupivacaine, Bupivacaine + adrenaline (Art 45) | 04 January 2013 | 19 March 2013 | 18 April 2013 |
| Tobramycin (Art 46) | 04 January 2013 | 22 January 2013 | 21 February 2013 |
| Penicillamine (Art 45) | 26 November 2012 | 22 January 2013 | 21 February 2013 |

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| Dexamethasone (Art 45) | 26 November 2012 | 22 January 2013 | 21 February 2013 |
| Carbomer (Art 45) | 26 November 2012 | 27 December 2012 | 26 January 2013 |
| Rifampicin + Combi (Art 45) | 23 July 2012 | 11 October 2012 | 10 November 2012 |
| Tamsulosine (Art 46) | 13 - 16 July 2012 | 30 September 2012 | 30 October 2012 |
| Vecuronium (Art 45) | 13 July 2012 | 30 September 2012 | 30 October 2012 |
| Sucralfate (Art 45) | 13 July 2012 | 30 September 2012 | 30 October 2012 |
| Hydroxychloroquine (Art 45) | 13 July 2012 | 30 September 2012 | 02 October 2012 |
| Salbutamol (Art 45) | 08 June 2012 | 26 July 2012 | 25 August 2012 |
| Procarbazine (Art 45) | 03 May 2012 | 26 July 2012 | 25 August 2012 |
| Nifedipine (Art 45) | 03 May 2012 | 26 July 2012 | 25 August 2012 |
| Desogestrel / Desogestrel + Ethinylestradiol (Art 45) | 14 March 2012, 28 November 2012 | 5 June 2012, 22 January 2013 | 5 July 2012, 21 February 2012 |
| Lenograstim (Art 45) | 12 March 2012 | 30 May 2012 | 29 June 2012 |
| Ropivacain (Art 45) | 12 March 2012 | 30 May 2012 | 29 June 2012 |
| Colchicine (Art 45) | 13 March 2012 | 30 May 2012 | 29 June 2012 |
| Ramipril (art 45) | 2 March 2012 | 22 May 2012 | 22 June 2012 |
| Ifosfamide (+ combination) (Art 45) | 6 March 2012 | 22 May 2012 | 21 June 2012 |
| Minoxidil (Art 45) | 2 February 2012 | 30 April 2012 | 30 May 2012 |
| Phenoxymethylpenicillin (Art 45) | 2 February 2012 | 30 April 2012 | 30 May 2012 |
| Fenofibrate (Art 45) | 30 January 2012 | 30 April 2012 | 30 May 2012 |
| Quinapril | 30 September 2011 | 29 December 2011 | 28 January 2012 |
| Timolol | 30 September 2011 | 29 December 2011 | 28 January 2012 |
| Aciclovir | 16 August 2011 | 3 November 2011 | 3 December 2011 |

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| Xatral (Alfuzocin) (Art 46) | 11 July 2011 | 4 October 2011 | 3 December 2011 |
| Alendronic acid | 6-7 July 2011 | 4 October 2011 | 4 November 2011 |
| Flumazenil | 6 June 2011 | 4 September 2011 | 4 October 2011 |
| Clonidine | 26 May 2011 | 26 July 2011 | 25 August 2011 |
| Propranolol | 24 May 2011 | 26 July 2011 | 25 August 2011 |
| Clobazam | 19 May 2011 | 30 June 2011 | 30 July 2011 |
| Amiodarone | 27 April 2011 | 30 June 2011 | 30 July 2011 |
| Ethosuximide | 26 April 2011 | 30 June 2011 | 30 July 2011 |
| Metoclopramide | 21 April 2011 | 15 June 2011 | 15 July 2011 |
| Itraconazole | 15 April 2011 | 15 June 2011 | 15 July 2011 |
| Topiramate | 17 March 2011 | 5 May 2011 | 4 June 2011 |
| Bisacodyl | 7 March 2011 | 28 April 2011 | 28 May 2011 |
| Baclofen | 4 February 2011 | 14 April 2011 | 14 May 2011 |
| Fentanyl | 25 January 2011 | 14 April 2011 | 14 May 2011 |
| Salmeterol xinafoate, Fluticasone propionate (Seretide) (Art 46) | 17 January 2011 | 31 March 2011 | 30 April 2011 |
| Adartrel (Ropinirole) (Art 46) | 12 January 2011 | 31 March 2011 | 30 April 2011 |
| Esomeprazole (Nexium) (Art 46) | 12 January 2011 | 31 March 2011 | 30 April 2011 |
| Mepivacaine | 11 January 2011 | 15 March 2011 | 14 April 2011 |
| Metronidazole/Metronidazole + Spiramycin | 10 January 2011 | 15 March 2011 | 14 April 2011 |
| Remifentanil | 7 January 2011 | 15 March 2011 | 14 April 2011 |
| Diclofenac | 14 December 2010, 03 February 2011 | 31 January 2011, 14 April 2011 | 2 March 2011, 14 May 2011 |
| Clarithromycin | 7 December 2010 | 31 January 2011 | 2 March 2011 |
| Lansoprazole (Art 46) | 22 November 2010 | 15 January 2011 | 14 February 2011 |
| Oxybutinin | 16-17 November 2010 | 22 December 2010 | 21 January 2011 |

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| Risedronate | 16 November 2010, 09 December 2010 | 22 December 2010, 31 January 2011 | 21 January 2011, 2 March 2011 |
| Famciclovir | 16 November 2010 | 22 December 2010 | 21 January 2011 |
| Propofol | 12 November 2010 | 22 December 2010 | 21 January 2011 |
| Mirtazapine | 19 August 2010 | 1 November 2010 | 1 December 2010 |
| Phleum Pratense | 18 August 2010 | 15 October 2010 | 14 November 2010 |
| Amoxicillin | 6 August 2010 | 15 October 2010 | 15 November 2010 |
| Canis familiaris, Felis domesticus | 6 August 2010 | 15 October 2010 | 15 November 2010 |
| Dermatophagoides farinae, Dermatophagoides pteronyssinus | 3 August 2010 | 15 October 2010 | 15 November 2010 |
| Paclitaxel | 18 May 2010 | 30 July 2010 | 30 August 2010 |
| Amikacin | 17 May 2010 | 30 July 2010 | 30 August 2010 |
| Gentamicin sulphate | 17 May 2010 | 30 July 2010 | 30 August 2010 |
| Levothyroxine | 17 May 2010 | 30 July 2010 | 30 August 2010 |
| Tranexamic acid | 17 May 2010 | 30 June 2010 | 30 July 2010 |
| Felodipine | 14 May 2010 | 30 June 2010 | 30 July 2010 |
| Lisinopril | 14 May 2010; 13 January 2011 | 30 June 2010; 31 March 2011 | 30 July 2010; 30 April 2011 |
| Amlodipine | 14 May 2010, 18 August 2010 | 30 June 2010, 15 October 2010 | 30 July 2010, 14 November 2010 |
| Simvastatin (Article 45) | 8-15 December 2009; 19 February 2010, 14 January 2011 | 19 March 2010, 31 March 2011 | 19 March 2010, 30 April 2011 |
| Oxazepam | 21 December 2009 | 22 January 2010 | 1 February 2010 |
| Isotretinoin | 24 November 2009 | 22 January 2010 | 19 February 2010 |
| Ranitidine | 10-11 August 2009 | 16 October 2009 | 13 November |

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| | | | 2009 |
| Salmon calcitonin (Article 45) | 06 August 2009 | 9 October 2009 | 6 November 2009 |
| Fluvastatin | 23 July 2009 | 18 September 2009 | 16 October 2009 |
| Sumatriptan | 21 May 2009 | 17 July 2009 | 14 August 2009 |
| Fosinopril | 18 May 2009 | 10 July 2009 | 7 August 2009 |
| Budesonide (nebuliser suspension and inhalation powder only) | 23 March 2009 | 22 May 2009 | 19 June 2009 |
| Carboplatin | 16 March 2009 | 15 May 2009 | 12 June 2009 |
| Fluticasone (nasal spray formulations only) | 15-17 December 2008 | 06 February 2009 | 6 March 2009 |
| Gemcitabine | 24-26 November 2008 | 23 January 2009 | 20 February 2009 |
| Alendronate | 7-14 November 2008 | 9 January 2009 | 6 February 2009 |