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Press Office

Start of community reviews

CHMP meeting of 12-15 March 2012

Table 1. Start of reviews for centrally authorised medicines

Name	INN	Type of procedure	Scope
M-M-RVAXPRO	Measles, mumps and rubella vaccine (live)	Article 20 of Regulation (EC) 726/2004	Procedure triggered by the European Commission requesting the review of the benefit-risk balance of M-M-RVAXPRO in pregnant women and in subjects with immune deficiencies. In view of current available data, including recent publications, the Committee is requested to assess whether in some cases the benefit of vaccination of the above mentioned populations may outweigh the risks.
Proquad	Measles, mumps, rubella and	Article 20 of Regulation (EC)	Procedure triggered by the European

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Name	INN	Type of procedure	Scope
	varicella vaccine (live)	726/2004	Commission requesting the review of the benefit-risk balance of Proquad in pregnant women and in subjects with immune deficiencies. In view of current available data, including recent publications, the Committee is requested to assess whether in some cases the benefit of vaccination of the above mentioned populations may outweigh the risks.
Zostavax	Zoster vaccine (live)	Article 20 of Regulation (EC) 726/2004	Procedure triggered by the European Commission requesting the review of the benefit-risk balance of Zostavax in pregnant women and in subjects with immune deficiencies. In view of current available data, including recent publications, the Committee is requested to assess whether in some cases the benefit of vaccination of the above mentioned populations may outweigh the risks.

Table 2. Start of reviews for non-centrally authorised medicines

Name	INN	Type of procedure	Scope
Monovalent and multivalent measles, mumps, rubella and varicella vaccines	Measles, mumps, rubella and varicella vaccine (live)(monovalent and multivalent measles, mumps, rubella and varicella vaccines)	Article 31 of Directive 2001/83/EC, as amended	Procedure triggered by Belgium requesting the review of the benefit-risk balance of all monovalent and multivalent measles, mumps, rubella and varicella vaccines in pregnant women and in subjects with immune deficiencies. In view of current

Name	INN	Type of procedure	Scope
			available data, including recent publications, the Committee is requested to assess whether in some cases the benefit of vaccination of the above mentioned populations may outweigh the risks.

Table 3. Start of arbitration procedure

Name	INN	Type of procedure	Scope
Mifepristone Linepharma	mifepristone	Article 29(4) of Directive 2001/83/EC, as amended	The Committee started a referral procedure for Mifepristone Linepharma and associated names. The procedure was initiated by Sweden because of disagreements regarding the demonstration of therapeutic equivalence with the originator product.
Mometasone Furoate Sandoz	Mometasone furoate	Article 29(4) of Directive 2001/83/EC, as amended	The Committee started a referral procedure for Mometasone Furoate Sandoz and associated names. The procedure was initiated by the Netherlands because of disagreements regarding the demonstration of therapeutic equivalence with the originator product.
Yvidually/Flexyess	Ethinylestradiol 0.02 mg (as betadex clathrate), drospirenon 3 mg	Article 29(4) of Directive 2001/83/EC, as amended	The Committee started a referral procedure for Yvidually/Flexyess and associated names. The procedure was initiated by the Netherlands because of disagreements regarding the benefit-risk ratio, in particular the contraceptive efficacy of the proposed dosing scheme.