European Medicines Agency
Evaluation of Medicines for Human Use

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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
JANUARY 2007 PLENARY MEETING
MONTHLY REPORT

The Committee for Medicinal Products for Human Use (CHMP) held its January plenary meeting from 22-24 January 2007.

The Chairman on behalf of the Committee, extended a welcome to Dr. Terziivanov, the new CHMP member from Bulgaria and Dr. Anuceanu, the new CHMP member from Romania, who were joining the CHMP following the accession of Bulgaria and Romania to the the EU on the 1st January 2007.

Centralised procedure

Initial applications for marketing authorisation

The CHMP adopted a positive opinion by majority on two initial marketing authorisation applications at this meeting:

- **Januvia** (sitagliptin) and **Xelevia** (sitagliptin), from Merck Sharp & Dohme. Both products are intended for the treatment of type-II diabetes mellitus in combination with either metformin or, in certain patients, a PPARγ agonist (i.e. thiazolidinedione) to improve glycaemic control when diet and exercise plus the agent in monotherapy do not provide adequate glycaemic control. EMEA review for Januvia began on 29 March 2006 and for Xelevia on 17 September 2006, with active review times of 202 and 85 days respectively.

Summaries of opinion for these medicinal products are available on the EMEA website http://www.emea.europa.eu/htms/human/opinion/opinion.htm. Further information will be included in the European Public Assessment Report (EPAR) once the European Commission has granted final approval.

Extensions of indication and other recommendations

The Committee adopted two positive opinions by consensus on the extension of indication of medicinal products that are already authorised in the European Union:

- **Prevenar** (pneumococcal conjugate vaccine), from Wyeth-Lederle Vaccines S.A., to include active immunisation of infants and young children from 2 months to 5 years of age against otitis media (middle ear infection) caused by *Streptococcus pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F and 23. Prevenar was first granted a marketing authorisation in the European Union on 2 February 2001 and is currently approved for active immunisation of children from 2 months to 5 years of age against sepsis, meningitis, bacteraemic pneumonia and bacteraemia caused by the same serotypes.

- **Xyrem** (sodium oxybate), from UCB Pharma Ltd, to extend the indication to the treatment of narcolepsy with cataplexy in adult patients. Narcolepsy is the inability to regulate sleep-wake cycles normally. Cataplexy is the sudden loss of voluntary muscle tone and is one of the symptoms of narcolepsy. Xyrem is an orphan medicinal product. It was first granted a marketing authorisation in the European Union on 13 October 2005 and is currently approved for the treatment of cataplexy in adult patients with narcolepsy.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Summaries of opinions for these two products are available and can be found here.

Lists of Questions

The Committee adopted 7 Lists of Questions on initial applications (one under the mandatory scope and five under the optional scope) and one Lists of Questions on "line extensions" applications (in accordance with Annex II of Commission Regulation (EC) No. 1085/2003.

Detailed information on the centralised procedure

An overview of centralised procedures since 1995 is given in **Annex 1**. The post-authorisation centralised procedures finalised during this meeting are summarised in **Annex 2**. The list of medicinal products for which marketing authorisations have been granted by the European Commission since the CHMP plenary meeting in December 2006 is provided in **Annex 3.**

Applications for marketing authorisation for orphan medicinal products

Details of those orphan medicinal products that have been subject of a centralised application for marketing authorisation since the December 2006 CHMP plenary meeting are provided in **Annex 4**.

Referral procedures

Referral procedures concluded

- The Committee concluded a referral procedure for **Ciprofloxacin Nycomed Hikma 200 mg/ 100 ml solution for infusion** (ciprofloxacine lactate), from Hikma Farmaceutica (Portugal) LDA. The CHMP recommended by consensus the harmonisation of the dosing recommendation for the treatment of complicated urinary tract infections, and of the maximum daily dose for adults in approved indications, across the European Union.

- The Committee concluded a referral procedure for **Alendronat Hexal 10 mg tablets** (alendronate), from Hexal A/S, Sweden. The CHMP recommended by consensus to approve the treatment of osteoporosis in men at increased risk of fracture.

Both procedures were initiated under Article 29 of Directive 2001/83/EC as amended because of disagreements between the Member States in the context of the mutual recognition procedure.

Referral procedures started

- The Committee started a referral procedure for **Fentanyl-ratiopharm 25/50/75/100 µg/h Matrixpflaster** (fentanyl) and **Fentanyl-ratiopharm 25/50/75/100 µg/h TTS** (fentanyl), from Ratiopharm GmbH, because of disagreement regarding the scope of the proposed indication, the contraindications and the demonstration of bioequivalence with the originator product. Both products are intended for use in the management of severe chronic pain. The procedures were initiated under Article 29 of Directive 2001/83/EC as amended.

Mutual Recognition procedure and Decentralised procedures-Human

The CHMP noted the report from the 14th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 22-23 January 2007. For further details, please see the relevant press release on the CMD(h) website under the heading Press Releases: http://heads.medagencies.org/

CHMP Working Parties

The CHMP was informed of the outcome of the discussions of the Scientific Advice Working Party (SAWP) meeting, which was held on 10-12 January 2007. For further details, please see **Annex 5**.

Documents prepared by the CHMP Working Parties adopted during the January CHMP meeting are listed in **Annex 6**.

Name Review Group (NRG)

The NRG finalised its discussion of revision 5 of the Guideline on the Acceptability of Invented names for Human medicinal products processed through the Centralised procedure (CHMP/328/98).

The Guideline will be released for 3-months consultation after finalisation of the written procedure by the CHMP.

In an effort to further increase transparency in relation to the activities of the NRG, it was decided that in addition to providing statistical information on the outcome of the checking of acceptability of proposed invented names for medicinal products processed through the centralised procedure, to also include information as to the type of objections raised in the CHMP Monthly report as of January 2007. For further details, please see **Annex 7**.

As part of the EMEA initiatives to prepare for the accession of Bulgaria and Romania to the European Union, the invented names of all centrally authorised products were checked by the new Member States for potential confusion with medicinal products authorised on their market. The NRG reviewed the objections received and endorsed, in accordance with the Guideline on the acceptability of invented names for human medicinal products processed through the Centralised procedure (CHMP/328/98 rev 4), potential risks of confusion between two invented names of centrally authorised products and those of medicinal products currently authorised in Bulgaria and Romania. The companies concerned will be contacted with the intention to seek resolution of any concerns identified.

Upcoming meetings following the January 2007 CHMP plenary meeting:

- The 30th meeting of the CHMP will be held at the EMEA on 19-22 February 2007.
- The next Invented Name Review Group meeting will be held at the EMEA on 19 February 2007.
- The 15th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the EMEA on 19-21 February 2007.

Organisational matters

The main topics addressed during the January 2007 CHMP meeting related to:

- The action plan for development of a CHMP Guideline for Phase I Clinical Trials with high-risk medicinal products. A draft of this guideline is scheduled to be released for public consultation in March 2007.
- Discussion on models and methods that could be used for assessing the benefit risk of a given medicinal product. A report will be released for public consultation in the near future.
- Discussion on the establishment of EU Regulatory System Crisis Management Plan covering both centrally and non-centrally authorised products for human use.
- Discussion with regards to research areas that could benefit from European Commission funding as part of the 2007 Work Programme for the Health Theme of the 7th Framework Programme.
- Discussion on the first phase of Rapporteurship appointment and the planning estimates of forthcoming applications.
- Follow-on discussion with regard to the publication of information related to negative opinions and refusals of applications.

- The nomination of Dr Koch, Dr. Hemmings and Dr. Mittmann as new members of the Scientific Advice Working Party.
- The nomination of Dr. Auriche as a new member of the Gene Therapy Working Party.

Noël Wathion
Head of Unit
Post-Authorisation Evaluation of Medicines for Human Use, Tel. (+44-20) 74 18 85 92

This CHMP Monthly Report and other documents are available on the Internet at the following address:
http://www.emea.europa.eu

ANNEX 1 TO CHMP MONTHLY REPORT JANUARY 2007

PRE-AUTHORISATION: MARKETING AUTHORISATION APPLICATIONS

Activity	2007								1995 onwards
	Optional Scope				Mandatory scope			Total	Overall total
	NAS	Significant innovation	Interest of Patients	Generics	Biotech	Indications	Orphans		
Applications for MA submitted	1	0	0	0	1	1	0	3	578
Positive opinions	0	0	0	0	0	2	0	2	381
Negative opinions[1]	0	0	0	0	0	0	0	0	12
Withdrawals prior to opinion	0	0	0	0	0	0	0	0	103
Marketing authorisation granted by the Commission	8	0	0	0	1	0	1	10	361

PRE-AUTHORISATION: SCIENTIFIC SERVICES

Activity (submissions)	2007	1995 onwards
Compassionate use applications	0	0
Art. 58 applications	0	3
Consultation for medical devices[2]	0	3[3]
PMF (Click here for a list of PMF certifications)	1	10[4]
VAMF	0	0

[1] In case of Re-examination under Art. 9(2) of Regulation (EC) No. 726/2004, the opinion will not be counted twice.
[2] Consultation in accordance with Council Directive 93/42/EEC concerning medical devices as amended by Directive 2000/70/EC as regards medical devices incorporating stable derivates of human blood or plasma and Directive 2001/104/EC
[3] From the October 2005 CHMP Monthly Report there was a small numerical error in the number of submissions for consultation for medical device (5 instead of the correct number 3) which was carried over in the Annex I of the subsequent CHMP Monthly Reports. This error is rectified in this Monthly Report.
[4] From the October 2006 CHMP Monthly Report there was a small numerical error in the number of PMF Certification (10 instead of 9) which was carried over in the Annex I of the subsequent CHMP Monthly Reports. This error is rectified in this Monthly Report.

OUTCOME OF THE JANUARY 2007 CHMP MEETING IN RELATION TO ACCELERATED ASSESMENT PROCEDURES

Substance	Intended indications(s)	Accelerated Assessment Requests	
		Accepted	Rejected
Biological	N/A	N/A	N/A
Chemical	N/A	N/A	N/A

POST-AUTHORISATION: TYPE I AND II VARIATIONS, ANNEX II, RENEWALS AND ANNUAL RE-ASSESSMENT APPLICATIONS

Activity	2007	Overall total 1995 onwards
Type I Variations (positive notifications)	47	4236
Type II Variations (positive opinions)	72	2934
Type II Variations (negative opinions)	0	8
Annex II Applications (positive opinions)	0	142
Annual Re-assessment (positive opinions)	3	-
Opinion for renewals of conditional MA's (positive opinions)	0	0
5 Year Renewals (positive opinions)	2	-

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
2 Extensions of indication	2 Positive opinions
48 SPC changes	48 Positive opinions
22 Quality changes	22 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Aptivus (tipranavir) Boehringer Ingelheim	Positive Opinion	The Marketing Authorisation will remain under exceptional circumstances.
Revatio (sildenafil citrate) Pfizer Limited	Positive Opinion	The Marketing Authorisation will remain under exceptional circumstances.
Ventavis (iloprost) Schering AG	Positive Opinion	The Marketing Authorisation will remain under exceptional circumstances.

Opinion for renewals of conditional MA's		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
N/A	N/A	N/A

Opinions for 5 Year Renewal applications		
Name of Medicinal Product (INN) **MAH**	**Outcome**	**Comments**
Invanz (ertapenem), Merck Sharp & Dohme	Positive Opinion adopted	The Committee agreed that a further 5-year renewal would be required
Kineret (anakinra) Amgen Europe	Positive Opinion adopted	Unlimited validity

ANNEX 3 TO CHMP MONTHLY REPORT JANUARY 2007

MEDICINAL PRODUCTS GRANTED A COMMUNITY MARKETING AUTHORISATION UNDER THE CENTRALISED PROCEDURE SINCE THE DECEMBER 2006 CHMP MONTHLY REPORT

Invented Name	Inovelon
INN	rufinamide
Marketing Authorisation Holder	Eisai Limited
Proposed ATC code	N03AF03
Indication	Inovelon is indicated as adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome in patients 4 years and older.
CHMP Opinion date	16.11.2006
Marketing Authorisation Date	16.01.2007

Invented Name	Lucentis
INN	ranibizumab
Marketing Authorisation Holder	Novartis Europharm Limited
Proposed ATC code	S01LA04
Indication	Lucentis is indicated for the treatment of neovascular (wet) age-related macular degeneration (AMD).
CHMP Opinion date	16.11.2006
Marketing Authorisation Date	22.01.2007

Invented Name	Exforge
INN	amlodipine / valsartan
Marketing Authorisation Holder	Novartis Europharm Ltd
Proposed ATC code	C09DB01
Indication	Exforge is indicated in patients whose blood pressure is not adequately controlled on amlodipine or valsartan monotherapy.
CHMP Opinion date	16.11.2006
Marketing Authorisation Date	17.01.2007

Invented Name	Copalia
INN	amlodipine / valsartan
Marketing Authorisation Holder	Novartis Europharm Ltd
Proposed ATC code	C09DB01
Indication	Copalia is indicated in patients whose blood pressure is not adequately controlled on amlodipine or valsartan monotherapy.
CHMP Opinion date	16.11.2006
Marketing Authorisation Date	16.01.2007

Invented Name	Imprida
INN	amlodipine / valsartan
Marketing Authorisation Holder	Novartis Europharm Ltd
Proposed ATC code	C09DB01
Indication	Imprida is indicated in patients whose blood pressure is not adequately controlled on amlodipine or valsartan monotherapy.
CHMP Opinion date	16.11.2006
Marketing Authorisation Date	17.01.2007

Invented Name	Dafiro
INN	amlodipine / valsartan
Marketing Authorisation Holder	Novartis Europharm Ltd
Proposed ATC code	C09DB01
Indication	Dafiro is indicated in patients whose blood pressure is not adequately controlled on amlodipine or valsartan monotherapy.
CHMP Opinion date	16.11.2006
Marketing Authorisation Date	16.01.2007

Invented Name	Irbesartan Hydrochlorothiazid Winthrope
INN	irbesartan / hydrochlorothiazide
Marketing Authorisation Holder	Sanofi Pharma Bristol-Myers Squibb SNC
Proposed ATC code	C09DA04
Indication	Treatment of essential hypertension. This fixed dose combination is indicated in patients whose blood pressure is not adequately controlled on irbesartan or hydrochlorothiazide alone.
CHMP Opinion date	16.11.2006
Marketing Authorisation Date	19.01.2007

Invented Name	Irbesartan Hydrochlorothiazid BMS
INN	irbesartan / hydrochlorothiazide
Marketing Authorisation Holder	Bristol-Myers Squibb Pharma EEIG
Proposed ATC code	C09DA04
Indication	Treatment of essential hypertension. This fixed dose combination is indicated in patients whose blood pressure is not adequately controlled on irbesartan or hydrochlorothiazide alone.
CHMP Opinion date	16.11.2006
Marketing Authorisation Date	19.01.2007

Invented Name	Irbesartan Winthrope
INN	irbesartan
Marketing Authorisation Holder	Sanofi Pharma Bristol-Myers Squibb SNC
Proposed ATC code	C09CA04
Indication	Treatment of essential hypertension. Treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive medicinal product regimen (see section 5.1).
CHMP Opinion date	16.11.2006
Marketing Authorisation Date	19.01.2007

Invented Name	Irbesartan BMS
INN	irbesartan
Marketing Authorisation Holder	Bristol-Myers Squibb Pharma EEIG
Proposed ATC code	C09CA04
Indication	Treatment of essential hypertension. Treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive medicinal product regimen (see section 5.1).
CHMP Opinion date	16.11.2006
Marketing Authorisation Date	19.01.2007

OVERVIEW OF DESIGNATED ORPHAN MEDICINAL PRODUCTS THAT HAVE BEEN THE SUBJECT OF A CENTRALISED APPLICATION FOR MARKETING AUTHORISATION: UPDATE SINCE THE DECEMBER 2006 COMP MEETING

Active substance	**Sponsor/applicant**	**EU Designation Number & Date of Orphan Designation**	**Designated Orphan Indication**
gusperimus trihydrochloride (Spanidin)	Euro Nippon Kayaku GmbH	EU/3/01/034 29/03/2001	Treatment of Wegener's granulomatosis

PRE-AUTHORISATION: SCIENTIFIC ADVICE AND PROTOCOL ASSISTANCE EMEA CENTRALISED PROCEDURES

	1995 - 2006	2007	Overall Total
Scientific Advice	718	18	736
Follow-up to Scientific Advice	127	1	128
Protocol Assistance	157	3	160
Follow-up to Protocol Assistance	40	2	42
	1042	**24**	**1006**

OUTCOME OF THE JANUARY 2007 CHMP MEETING IN RELATION TO SCIENTIFIC ADVICE PROCEDURES

Final Scientific Advice Procedures

Substance	Intended indications(s)	Type of Request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Treatment of motion sickness and post-operative nausea and vomiting	x				X	X	x	
Biological	Treatment of diabetes	x				x			
Biological	Treatment of mucopolysaccharidosis I				x			x	
Biological	Treatment of diabetes	x					X	x	
Chemical	Treatment of Non Small Cell Lung cancer.	x						x	
Chemical	Treatment of Non Small Cell Lung cancer.	x						x	
Biological	Prevention of post-transplant infections and disease relapse after hematopoietic cell transplantation				x	x		x	x
Chemical	Treatment of cachexia associated with cancer	x						x	
Biological	Treatment of multiple sclerosis	x					x	x	
Chemical	Treatment of multiple myeloma		x					x	

Substance	Intended indications(s)	Type of Request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Treatment of superficial vein thrombophlebitis	x					x		
Biological	Treatment of hereditary Factor XIII deficiency		x				x	x	x
Chemical	Treatment of chronic thromboembolic pulmonary hypertension and pulmonary arterial hypertension	x				x		x	
Chemical	Prophylaxis and treatment of venous thromboembolic events	x						x	
Chemical	Prophylaxis and treatment of atrial fibrillation	x						x	
Chemical	Treatment of thromboembolic disease	x					x		
Chemical	Treatment of psoriasis	x						x	
Chemical	Treatment of invasive zygomycosis and aspergillosis	x						x	
Chemical	Treatment of acute gout	x						x	
Chemical	Treatment of Parkinson's disease	x				x			
Chemical	Treatment of aggression in patients with dementia	x						x	
Chemical	Treatment of Parkinson's disease			x				x	
Chemical	Prevention of bronchopulmonary dysplasia in premature neonates		x				x		
Biological	Treatment of adult and paediatric growth hormone deficiency	x				x			

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 18 Scientific Advice letters, 3 Protocol Assistance letters, 1 Follow-up Scientific Advice letters and 2 Follow-up Protocol Assistance letters were adopted at the 22-24 January 2007 CHMP meeting.

New requests for Scientific Advice Procedures

The Committee accepted 10 Initial Scientific Advice Requests, 2 Follow-up Scientific Advice Requests, 8 Initial Protocol Assistance Requests and 2 Follow-up Protocol Assistance Requests started at the meeting that took place on 10-12 January 2007.

DOCUMENTS PREPARED BY THE CHMP WORKING PARTIES ADOPTED DURING THE JANUARY 2007 CHMP MEETING

BLOOD PRODUCTS WORKING PARTY

Reference number	Document	Status[5]
CHMP/BPWP/122007/ 2005	Revision of Guideline on core SPC for human plasma fibrogen products	Adopted for 6 months consultation

VACCINE WORKING PARTY

Reference number	Document	Status
CHMP/VWP/19541/2007	CHMP Position Paper on Thiomersal Implementation of the Warning Statement Relating to Sensitisation	Adopted
CHMP/VWP/263499/2006	Guideline on influenza vaccines prepared from viruses with the potential to cause a pandemic and intended for use outside of the core dossier context	Adopted

WORKING PARTY ON SIMILAR BIOLOGICALS MEDICINAL PRODUCTS

Reference number	Document	Status
CHMP/BMWP/14327/ 2006	Guideline on immunogenicity assessment of biotechnology-derived therapeutic proteins	Adopted for 6 months public consultation
CHMP/BMWP/101695/ 2006	Guideline on comparability of biotechnology-derived medicinal products after a change in the manufacturing process - non-clinical and clinical issues	Adopted for 3 months public consultation
CHMP/BMWP/496286/ 2006	Concept paper on similar biological medicinal products containing low molecular weight heparins - (non) clinical issues	Adopted for 3 months public consultation

WORKING PARTY ON CELL-BASED PRODUCTS

Reference number	Document	Status
CHMP/410869/2006	CPWP/BWP Guideline on human cell-based medicinal products	Adopted for 6 months public consultation

[5] Adopted or release for consultation documents can be found at the EMEA website (under "What's new-recent publications" or under Human Medicines-Guidance documents").

QUALITY WORKING PARTY

Reference number	Document	Status
EMEA/INS/6909/2007	Revised Mandate for EMEA PAT Team - Note to CHMP	Adopted

SAFETY WORKING PARTY

Reference number	Document	Status
EMEA/510840/2006	Final draft Guideline on the specification limits for residues of metal catalysts	Adopted for 3 months public consultation

EFFICACY WORKING PARTY

Reference number	Document	Status
CPMP/EWP/788/01 Rev 1	Guideline on Clinical Investigation of Medicinal Products for the Treatment of Migraine	Adopted
CHMP/EWP/21477/2007	Overview of Comments Received	Adopted
CPMP/EWP/252/03 Rev. 1	Guideline on Clinical Medicinal Products intended for the Treatment of Neuropathic Pain	Adopted
CHMP/EWP/21568/2007	Overview of Comments Received	Adopted
CHMP/EWP/7799/2007	Concept Paper on the development of a CHMP Guideline on Extrapolation Results in Clinical Studies in the EU-Population	Adopted for 3 months public consultation
CHMP/EWP/263148/2006	Concept Paper on the development of a CHMP Guideline on Clinical Investigation of Immunosuppressants for Solid Organ Transplantation	Adopted for 3 months public consultation
CHMP/EWP/89249/2004	Guideline on the Clinical on the Clinical Investigation of the Pharmacokinetics of Therapeutics Proteins	Adopted
CHMP/EWP/198957/2004	Overview of Comments Received	Adopted

PAEDIATRIC WORKING PARTY

Reference number	Document	Status
EMEA/13306/2007	Assessment of Paediatric Needs in Nephrology	Adopted for 6 months public consultation

ANNEX 7 TO CHMP MONTHLY REPORT JANUARY 2007

INVENTED NAME REVIEW GROUP (NRG)

	January 2007			2007	
	Accepted	Rejected	Pending	Accepted	Rejected
Proposed invented names	16	13	0	16	13
Justification for retention of invented name *	3	0	0	3	0

*In case of objections to the proposed invented name(s), the applicant may justify the retention of the proposed invented name using the relevant justification form available on the EMEA website.

	January 2007		2007	
	Accepted	Rejected	Accepted	Rejected
Total number of objections raised	34	16	34	16
Criterion - Safety concerns				
Similarity with other Invented name	26	14	26	14
Conveys misleading therapeutic/pharmaceutical connotations	2	0	2	0
Misleading with respect to composition	0	0	0	0
Criterion - INN concerns				
Similarity with INN	0	0	0	0
Inclusion of INN stem	0	0	0	0
Criterion - Other public health concerns				
Unacceptable qualifiers	0	1	0	1
Conveys a promotional message	5	1	5	1
Appears offensive or has a bad connotation	0	0	0	0
Similarity between name of individual active substance and fixed combinations and/or between fixed combinations	1	0	1	0
Similarity between name of prodrug and related active substance	0	0	0	0

See *Guideline on the Acceptability of Invented names for human medicinal products processed through the Centralised procedure (CPMP/328/98)* for detailed explanations of criteria used.