25 February 2011
EMA/CHMP/141522/2011

Monthly Report

Committee for Medicinal Products for Human Use (CHMP)

14 – 17 February 2011

Update on the review on narcolepsy and the possible association with Pandemrix

The Committee reviewed[1] further data from Finland on the suspected link between narcolepsy in children and adolescents and Pandemrix (influenza vaccine (H1N1)v (split virion, inactivated, adjuvanted)), from GlaxoSmithKline Biologicals S.A. The Committee concluded that the new evidence added to the concern arising from case reports in Finland and Sweden, but that the data were still insufficient to establish a causal relationship between Pandemrix and narcolepsy. Further analyses and study results are awaited to clarify the observations in Finland.

More information about this review is available in a separate press release on the Agency's website.

Centralised procedure

Initial applications for marketing authorisation

New medicinal products

The Committee adopted three positive opinions by consensus recommending the granting of marketing authorisations for the following new medicines:

- **Hizentra** (human normal immunoglobulin), from CSL Behring GmbH, intended for replacement therapy in adults and children in primary immunodeficiency syndromes, and in myeloma or chronic lymphatic leukaemia patients with severe secondary hypogammaglobulinaemia and recurrent infections. The review for Hizentra began on 24 March 2010 with an active review time of 210 days.

[1] The review of Pandemrix and the occurrence of cases of narcolepsy is being conducted in the context of a formal review, initiated at the request of the European Commission under Article 20 of Regulation (EC) No 726/2004, on 27 August 2010.

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- **Methylthioninium chloride Proveblue** (methylthioninium chloride), from Provepharm S.A.S., intended for acute symptomatic treatment of methaemoglobinaemia induced by medicinal and chemical products. The review for Methylthioninium chloride Proveblue began on 30 December 2009 with an active review time of 210 days. Provepharm S.A.S. has been assigned SME (small and medium-sized enterprise) status by the European Medicines Agency.
- **Rasilamlo** (aliskiren/amlodipine), from Novartis Europharm Ltd, intended for the treatment of essential hypertension in adult patients whose blood pressure is not adequately controlled with aliskiren or amlodipine used alone. The review for Rasilamlo began on 23 December 2009 with an active review time of 208 days.

The summaries of opinion for all medicines, including their full therapeutic indications, can be found here.

Positive opinion for informed consent application adopted

The Committee adopted a positive opinion by consensus recommending the granting of a marketing authorisation for **Sprimeo HCT** (aliskiren/hydrochlorothiazide), from Novartis Europharm Ltd, intended for the treatment of adult patients with essential hypertension. The review for Sprimeo HCT began on 19 December 2010 with an active review time of 60 days. This application was an informed consent application referring to the dossier of the authorised medicine Rasilez HCT.

Positive opinion for generic medicines adopted

The Committee adopted positive opinions by consensus recommending the granting of a marketing authorisation for the generic medicines **Ibandronic Acid Sandoz** (ibandronic acid), from Sandoz Pharmaceuticals GmbH, and for **Ibandronic Acid HEXAL** (ibandronic acid), from Hexal AG, intended for the prevention of skeletal events in patients with breast cancer and bone metastases. Ibandronic Acid Sandoz and Ibandronic Acid HEXAL are generics of Bondronat.

Withdrawals

On 3 January 2011, Sun Pharmaceutical Industries Europe B.V. officially notified the CHMP that it wishes to withdraw its application for a marketing authorisation for **Topotecan SUN** (topotecan), intended to be used for the treatment of metastatic cancer of the ovary, small cell lung cancer and cervical cancer. Topotecan SUN was developed as a generic medicine of Hycamtin. At the time of the withdrawal it was under review by the CHMP. A separate question-and-answer document and press release with more information are available.

On 8 February 2011, Merck Serono Europe Limited officially notified the CHMP that it wishes to withdraw its application for a marketing authorisation for **Movectro** (cladribine), intended to be used for the treatment of relapsing-remitting multiple sclerosis. The application for the marketing authorisation for Movectro was submitted to the Agency on 06 July 2009. On 23 September 2010, the CHMP adopted a negative opinion, recommending the refusal of the marketing authorisation for Movectro. On the request of the company, the CHMP re-examined its initial opinion and confirmed the refusal of the marketing authorisation on 20 January 2011. At the time of withdrawal, the final CHMP recommendation for the refusal of the marketing authorisation was pending European Commission (EC) decision. A separate question-and-answer document and press release with more information are available.

Post-authorisation procedures

Extensions of indications and other recommendations

The Committee adopted a positive opinion by consensus for an application for extension of the therapeutic indications, adding a new treatment option for a medicine that is already authorised in the European Union (EU), for **Humira** (adalimumab), from Abbott Laboratories Ltd, to include treatment of juvenile idiopathic arthritis in patients aged 4 to 12 years.

The summaries of opinions for the mentioned medicines, including the full indications, can be found here.

Restrictions on use of Zerit

The Committee recommended by consensus that in view of the side effects seen with **Zerit** (stavudine), from Bristol-Myers Squibb Pharma EEIG, the therapeutic indications should be restricted. The Committee recommended that, for both adults and children, the medicine should be used for as short a time as possible and only when there are no appropriate alternatives.

Zerit is used in combination with other antiviral medicines to treat adults and children who are infected with human immunodeficiency virus (HIV).

More information about this review is available in a separate question-and-answer document on the Agency's website.

Restrictions on use of Tygacil

The Committee recommended by consensus that the product information for **Tygacil** (tigecycline), from Wyeth Europa Ltd, should be amended to ensure that the medicine is used appropriately, by making prescribers aware that the medicine has been associated with an increased mortality in clinical studies.

The medicine should only be used in its approved therapeutic indications, namely in the treatment of complicated skin and soft tissue infections and complicated intra-abdominal infections, and only when other antibiotics are not suitable.

More information about this review is available in a separate question-and-answer document on the Agency's website.

New contraindication for Brinavess

The Committee recommended by consensus an update to the contraindications of **Brinavess** (vernakalant), from Merck Sharp & Dohme Ltd, following review of a case of severe hypotension and cardiogenic shock in a patient who was enrolled in an ongoing clinical trial. The new contraindication extends the time during which patients who received Brinavess should not be given any intravenous anti-arrhythmic medicine (class I and III) to 4 hours after administration.

The CHMP agreed a letter to be sent to healthcare professionals reminding them that any patient receiving Brinavess should be frequently monitored during administration of the medicine and up to two hours after the start of infusion until clinical and ECG parameters have stabilised, and that patients must not be given any i.v. anti-arrhythmic medicines (class I or class III) within 4 hours prior to and up to 4 hours after vernakalant administration.

Brinavess is indicated for rapid conversion of recent onset atrial fibrillation to sinus rhythm in adults.

The summary of opinion for the above mentioned medicine, including the full contraindication, can be found here.

Additional safety information

Following the assessment of the 4th Periodic Safety Update Reports and of safety reviews conducted at its request, the CHMP adopted a positive opinion by consensus recommending a variation to the terms of the marketing authorisation for the medicinal product **Thalidomide Celgene** (thalidomide) from Celgene Europe Ltd, with respect to the risk of myocardial infarction and arterial thromboembolic events. Patients treated with thalidomide have an increased risk of venous thromboembolism (such as deep vein thrombosis and pulmonary embolism) and arterial thromboembolism (such as myocardial infarction and cerebrovascular event). Action should be taken to try to minimize all modifiable risk factors (e.g. smoking, hypertension and hyperlipidaemia). The Committee agreed on a Direct Healthcare Professional Communication (DHPC).

The CHMP further adopted positive opinions by consensus recommending variations to the terms of the marketing authorisations for the medicinal products **Rotarix** (rotavirus vaccine, live) from GlaxoSmithKline Biologicals S.A. and **RotaTeq** (rotavirus vaccine, live) from Sanofi Pasteur MSD, SNC, to include the following key wording elements on intussusception in section 4.4 of the SmPCs of rotavirus vaccines: "No increased risk of intussusception was observed in clinical trials following administration of the products when compared with placebo. However, a small increased risk of intussusception in the 31-day period mostly within 7 days following the administration of the first dose can not be excluded. Therefore, as a precaution, healthcare professionals should follow-up on any symptoms indicative of intussusception (severe abdominal pain, persistent vomiting, bloody stools, abdominal bloating and/or high fever). Parents/guardians should be advised to promptly report such symptoms." In addition, section 4.8 was updated to include intussusception as an adverse reaction identified through post-marketing surveillance.

Other information on the centralised procedure

Supply shortage of Simponi

The Committee has been informed of a manufacturing problem with **Simponi** (golimumab) pre-filled pens, from Janssen Biologics B.V., which will lead to a temporary shortage of this presentation of the medicine in some European Union (EU) Member States. To deal with the shortage, the Committee is recommending that affected patients should be switched to the other presentation of Simponi, the pre-filled syringe, or to alternative treatments as advised by their doctors.

Simponi is a medicine for the treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis.

More information about this review is available in a separate question-and-answer document on the Agency's website.

Lists of Questions

The Committee adopted nine Lists of Questions on initial applications (including one under the mandatory scope and eight under the optional scope as per Regulation (EC) No. 726/2004), together with one List of Questions on a "line extension" application (in accordance with Annex I of Commission Regulation (EC) No. 1234/2008).

Detailed information on the centralised procedure

Monthly figures related to the centralised procedure activities are published independently on the Agency's website within two weeks following the end of the CHMP meeting and can be found here. The overview of opinions for annual re-assessments and renewals is provided in **Annex 1**. The list of medicinal products for which marketing authorisations have been granted by the European Commission since the CHMP plenary meeting in January is provided in **Annex 2**.

Name Review Group (NRG)

Statistical information on the outcome of the checking of acceptability of proposed invented names for medicinal products processed through the centralised procedure is provided in **Annex 3**.

Referral procedures

Arbitration concluded

The Committee completed an arbitration procedure[2] initiated by the Netherlands because of disagreement among EU Member States regarding the authorisation of the generic docetaxel-containing medicine **Docetaxel Teva Generics**, from Teva Generics B.V. This medicine is intended for the treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, and head and neck cancer. This procedure was initiated because of concerns that bioequivalence studies with Docetaxel Teva Generics had not been performed. The Committee concluded that additional data was not needed and that the benefit-risk balance of this medicine is positive. The CHMP therefore recommended that marketing authorisations should be granted in the Netherlands as well as in all the concerned Member States.

A question-and-answer document with more information about this arbitration procedure is available on the Agency's website.

Review of buflomedil-containing medicines started

The Committee has begun looking at the high risk of cardiac and nervous toxicity, especially following accidental or voluntary overdose, in patients taking **buflomedil-containing medicines** for the treatment of symptoms of peripheral arterial occlusive disease[3].

This follows the suspension of the marketing authorisation of these medicines in France, based on the review of all available safety information.

The CHMP will now review all available data thoroughly, including published data, non-clinical and clinical data, post-marketing reports and pharmacoepidemiological studies, and will assess their impact on the balance of the risks and benefits of these medicines.

Review of pholcodine-containing medicines started

The Committee has begun looking at the potential link between the use of **pholcodine-containing medicines** and anaphylactic reactions in patients subsequently exposed to neuromuscular blocking agents (NMBA) used in anaesthesia.

[2] The review of Docetaxel Teva Generics was conducted under Article 29 of Directive 2001/83/EC.
[3] The review of buflomedil-containing medicines is being conducted under Article 107 of Directive 2001/83/EC, as amended.

This follows the publication of studies suggesting that pholcodine induces immunologic stimulation in exposed individuals, and that in some Member States where pholcodine is no longer marketed, a decrease in reports of NMBA-related anaphylaxis has been observed.

Pholcodine-containing medicines are used to treat cough in children and adults.

The CHMP will now review[4] all available data thoroughly, including published data, non-clinical and clinical data, post-marketing reports and pharmacoepidemiological studies, and will assess their impact on the balance of risks and benefits of these medicines.

Mutual-recognition and decentralised procedures - Human

The CHMP noted the report from the 59th CMDh (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 14-15 February 2011. For further details, please see the relevant press release on the CMDh website under the heading Press Releases: http://www.hma.eu/

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 31 January – 2 February 2011. For further details, please see **Annex 4**.

Documents adopted during the February 2011 CHMP meeting are listed in **Annex 5**.

Upcoming meetings following the February 2010 CHMP plenary meeting

- The 75th meeting of the CHMP will be held at the Agency on 14-17 March 2011.
- The next Name Review Group meeting will be held at the Agency on 22 March 2011.
- The 60th CMDh (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the Agency on 14-15 March 2011.

Organisational matters

The main topics addressed during the February 2011 CHMP meeting related to:

- The re-election of Mr Robert Hemmings as CHMP Co-opted member and Prof Jean-Hugues Trovin as Chair of the Biologics Working Party. Dr Anneliese Hilger was elected as Chair of the Blood Product Working Party and Dr Elmer Schabel was endorsed as Chair of the Gastroenterology Drafting Group.
- The appointment of Dr Kolbein Gudmundsson as the new Icelandic Member replacing Dr Sif Ormarsdóttir and the appointment of Dr Miroslav Salavec as the new Czech alternate, replacing Dr Katerina Kubackova in this role.
- The adoption of the geriatric medicines strategy. The strategy sets out the Agency's vision for the development of medicines for the elderly by building on its existing activities. In particular, the Agency aims to ensure that the medicines used by older people are of high quality and are studied appropriately in the older population, both before and after authorisation, and to improve the

[4] The review of pholcodine-containing medicines is being conducted under Article 31 of Directive 2001/83/EC, as amended.

availability of information for older people on the use of medicines. Further information on medicines for older people can be found on the Agency's website.

- Discussion on quality of opinions of the scientific Committees with regard to conformity with the regulatory framework and the enforceability of recommended obligations. The possibilities to include requests for outstanding data in the Annex II, in the Risk Management Plan (RMP) or in the CHMP Assessment Report were outlined. Further discussion on this issue is envisaged.

Procedural Announcement

Pre-accession linguistic check for Croatian underway

The European Medicines Agency, together with the Croatian national competent authorities, has started a pre-accession linguistic checking process for product information in the Croatian language.

This procedure aims to facilitate the phasing-in of Commission Decisions on centrally authorised medicines once Croatia joins the European Union (EU). This is to avoid delays in the supply of medicinal products in Croatia and to prevent the circulation of products with Croatian translations of sub-standard quality, which could lead to public health concerns. The pre-accession check also aims to avoid peaks of activity for regulators and industry around the time of accession.

Croatia is currently due to join the EU on 1 June 2012. All marketing-authorisation holders are strongly encouraged to start translating their product information into Croatian as early as possible and to submit it for checking. This will avoid difficulties in marketing their products once Croatia has joined the EU.

All product information templates have now been translated into Croatian and are available, together with the relevant reference documents, separately for human medicines and for veterinary medicines. A timetable of dates for sending translated documents for checking is also available. The first sending slot is scheduled for 1 March 2011.

Further information can be found here.

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

Annex 1 to CHMP Monthly Report February 2011

Opinions for annual re-assessment applications		
Name of medicinal product (INN) MAH	**Outcome**	**Comments**
Ceplene (histamine dihydrochloride), Epicept GmbH	Positive opinion	Marketing Authorisation remains under exceptional circumstances
Yondelis (trabectedin), Pharma Mar S.A.	Positive opinion	Marketing Authorisation remains under exceptional circumstances
Xagrid (anagrelide), Shire Pharmaceutical Contracts Limited	Positive opinion	Marketing Authorisation remains under exceptional circumstances

Opinion for renewals of conditional Marketing Authorisation		
Name of medicinal product (INN) MAH	**Outcome**	**Comments**
Votrient (pazopanib), Glaxo Group Ltd.	Positive Opinion	Marketing Authorisation remains under conditional approval

Opinions for 5-Year Renewal applications		
Name of medicinal product (INN) MAH	**Outcome**	**Comments**
Valtropin (somatropin), BioPartners GmbH	Positive Opinion	Recommending additional renewal
Tygacil (tigecycline), Wyeth Europa Ltd	Positive Opinion	Recommending additional renewal
Zerit (stavudine), Bristol-Myers Squibb Pharma EEIG	Positive Opinion	Unlimited validity
Osigraft (eptotermin alfa), Howmedica International S. de R. L.	Positive Opinion	Unlimited validity
Preotact (parathyroid hormone (rdna)), Nycomed Danmark ApS	Positive Opinion	Unlimited validity

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Accelerated Assessment Procedures			
Substance	**Intended Indication(s)**	**Accelerated Assessment Requests**	
		Accepted	Rejected
N/A			

Annex 2 to CHMP Monthly Report February 2011

Medicinal products granted a community marketing authorisation under the centralised procedure since the January 2011 CHMP Monthly Report

Invented name	**FLUENZ**
INN	Influenza vaccine (live attenuated, nasal)
Marketing Authorisation Holder	MedImmune LLC
Proposed ATC code	J07BB03
Indication	Prophylaxis of influenza in individuals 24 months to less than 18 years of age. The use of FLUENZ should be based on official recommendations.
CHMP Opinion date	21/10/2010
Marketing Authorisation Date	27/01/2011

Invented name	**IASIBON**
INN	ibandronic acid
Marketing Authorisation Holder	Pharmathen S.A.
Proposed ATC code	M05BA06
Indication	Prevention of skeletal events (pathological fractures, bone complications requiring radiotherapy or surgery) in patients with breast cancer and bone metastases. Treatment of tumour-induced hypercalcaemia with or without metastases.
CHMP Opinion date	21/10/2010
Marketing Authorisation Date	21/01/2011

Annex 3 to CHMP Monthly Report February 2011

NAME REVIEW GROUP (NRG)

	NRG meeting 25 Jan 2011		NRG meeting 22 March 2011		NRG meeting 24 May 2011		NRG meeting 28 June 2011		NRG meeting 22 Sept 2011		NRG meeting 17 Nov 2011		2011	
	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected
Proposed invented names	***34***	**68**											**34**	**68**
Justification for retention of invented name *	***0***	***2***											**0**	**2**

*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.

	NRG meeting 25 Jan 2011		NRG meeting 22 March 2011		NRG meeting 24 May 2011		NRG meeting 28 June 2011		NRG meeting 22 Sept 2011		NRG meeting 17 Nov 2011		2011	
Objections	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected	Accepted	Rejected
Total number of objections raised	155	90											**155**	**90**
Criterion - Safety concerns														
Similarity with other Invented name	125	73											**125**	**73**
Conveys misleading therapeutic/pharmaceutical connotations	2	3											**2**	**3**
Misleading with respect to composition	3	1											**3**	**1**
Criterion - INN concerns														
Similarity with INN	8	6											**8**	**6**
Inclusion of INN stem	5	3											**5**	**3**
Criterion - Other public health concerns														
Unacceptable qualifiers	1	0											**1**	**0**
Conveys a promotional message	1	0											**1**	**0**
Appears offensive or has a bad connotation	1	0											**1**	**0**
Similarity between name of individual active substance and fixed combinations and/or between fixed combinations	0	0											**0**	**0**
Similarity between name of prodrug and related active substance	0	0											**0**	**0**

See *Guideline on the Acceptability of Names for Human Medicinal Products Processed through the Centralised Procedure (CPMP/328/98 Rev. 5)* for detailed explanations of criteria used.

Annex 4 to CHMP Monthly Report February 2011

Pre-authorisation: scientific advice and protocol assistance
EMA centralised procedures

	1995 - 2010	2011	Overall total
Scientific Advice	1368	43	1411
Follow-up to Scientific Advice	320	9	329
Protocol Assistance	297	8	305
Follow-up to Protocol Assistance	133	3	136
	2118	**63**	**2181**

FDA Parallel Scientific Advice	2006 - 2010	2011	Overall total
Completed	9	1	10
Ongoing	0	4	4
Foreseen	0	3	3
	9	**8**	**17**

Outcome of the February 2011 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 type 2 diabetes mellitus	*x*						*x*	
Biological	Treatment of diabetes mellitus	*x*				*x*	*x*	*x*	
Chemical	Treatment of Gaucher disease type 1				*x*			*x*	
Biological	Treatment of diabetes mellitus			*x*				*x*	
Biological	Treatment of idiopathic membranous glomerulonephropathy	*x*						*x*	
Advanced therapy	Treatment of ovarian cancer		*x*			*x*	*x*	*x*	*x*
Chemical	Treatment of Philadelphia chromosome positive acute lymphoblastic leukaemia		*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 differentiated thyroid cancer	*x*						*x*	
Biological	Treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, moderate to severe plaque psoriasis	*x*				*x*	*x*	*x*	
Biological	Treatment pancreatic cancer.		*x*					*x*	
Chemical	Treatment of differentiated thyroid cancer.	*x*						*x*	
Biological	Treatment of HER2-overexpressing breast cancer and Metastatic Gastric Cancer	*x*				*x*	*x*	*x*	
Biological	Treatment of HER2-overexpressing breast cancer and metastatic gastric cancer	*x*				*x*	*x*	*x*	
Biological	Treatment of HER2-overexpressing breast cancer and Metastatic Gastric Cancer			*x*				*x*	
Biological	Treatment of HER2-overexpressing breast cancer and metastatic gastric cancer	*x*				*x*	*x*	*x*	
Chemical	Treatment papillary or follicular thyroid cancer	*x*						*x*	
Biological	Treatment of non-Hodgkin's lymphoma, and rheumatoid arthritis	*x*				*x*	*x*	*x*	
Chemical	Treatment of advanced renal cell carcinoma				*x*			*x*	
Chemical	Reduction of risk of Stroke/Systemic Embolic Events	*x*				*x*			
Chemical	Iron replacement in chronic kidney disease patients	*x*				*x*	*x*	*x*	
Chemical	Treatment of hypercholesterolaemia and homozygous familial hypercholesterolaemia	*x*						*x*	
Chemical	Treatment of hypertension in children			*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 moderate to severe psoriasis vulgaris	*x*					*x*	*x*	
Chemical	Treatment of severe systemic and/or deep mycoses, visceral leishmaniasis and fungal infections in febrile neutropenia	*x*				*x*	*x*	*x*	
Biological	Protection against malaria disease due to P. falciparum and infection with hepatitis B virus			*x*				*x*	
Biological/ Advanced therapy	Reduction of clinically significant Cytomegalovirus viremia	*x*				*x*	*x*	*x*	
Chemical	Treatment of active and progressive psoriatic arthritis	*x*						*x*	
Chemical	Treatment of Alzheimer's disease	*x*				*x*	*x*	*x*	
Biological	Promotion of motor recovery after a stroke	*x*					*x*	*x*	
Chemical	Treatment of major depressive disorder			*x*				*x*	
Chemical	Treatment of schizophrenia	*x*						*x*	
Chemical	Treatment of Huntington's disease		*x*			*x*	*x*	*x*	*x*
Chemical/ Biological	Treatment of House dust mite-induced persistent asthma with rhinitis. Scientific Advice is sought on clinical development	*x*						*x*	
Biological	Treatment of neuroblastoma	*x*				*x*	*x*	*x*	

SA: scientific advice
PA: protocol assistance

The above-mentioned 23 Scientific Advice letters, 4 Protocol Assistance letters, 5 Follow-up Scientific Advice and 2 Follow-up Protocol Assistance letters were adopted at the 14 – 17 February 2011 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 37 new Requests for which the procedure started at the SAWP meeting held on 31 January – 2 February 2011. The new requests are divided as follows: 21 Initial Scientific Advice, 8 Follow-up Scientific Advice, 5 Initial Protocol Assistance and 3 Follow-up Protocol Assistance.

Annex 5 to CHMP Monthly Report February 2011

Documents adopted during the February 2011 CHMP meeting

Biologics Working Party (BWP)

Reference number	Document	Status[5]
EMA/CHMP/BWP/360642/2010	Guideline on the warning on transmissible agents in summary of product characteristics (SmPCs) and package leaflets for plasma-derived medicinal products	**2-month public consultation**
EMEA/CHMP/BWP/617111/2010	Concept paper on the revision of the guideline on similar biological medicinal products containing biotechnology derived proteins as active substance: Quality Issues	**3-month public consultation**
EMA/CHMP/BWP/776563/2010	Concept Paper on potency declaration / labelling for biological medicinal products modified proteins for which an International Standard exist for the non-modified product	**3-month public consultation**

Vaccine Working Party (VWP)

Reference number	Document	Status[5]
EMA/CHMP/VWP/696134/2010 Rev. 1	Updated VWP Work Programme 2011	**adopted**
EMA/86004/2011	Concept Paper On Guidance on the Non Clinical and Clinical Development of Medicinal Products for HIV Prevention including Oral and Topical Pre-Exposure Prophylaxis	**2-month public consultation**

Cardiovascular Working Party (CVS WP)

Reference number	Document	Status[5]
EMA/CHMP/68875/2011	Concept Paper on the need for a guideline on clinical investigation of medicinal products for prevention of stroke and systemic embolic events in patients with atrial fibrillation	**3-month public consultation**

[5] Adopted or release for consultation documents can be found at the European Medicines Agency website (under "Document library-Public Consultations" or under "Regulatory-Human Medicines").

Central Nervous System Working Party (CNS WP)

Reference number	Document	Status[5]
EMA/CHMP/40072/2010 Rev. 1	Draft Guideline on clinical investigation of medicinal products in the treatment of schizophrenia	**6-month public consultation**
EMA/607700/2010 Rev. 1	Guideline on medicinal products for the treatment of Insomnia • Comments received (EMA/16274/2009)	**adopted**

Oncology Working Party (OWP)

Reference number	Document	Status[5]
EMA/99797/2011 Rev. 1	Updated OWP Work Programme 2011	**adopted**

Pharmacokinetics Working Party (PKWP)

Reference number	Document	Status[5]
EMEA/CHMP/600958/2010	Appendix to the Guideline on Bioequivalence: Presentation of Biopharmaceutical and Bioanalytical Data in Application Dossiers (EMA/CHMP/EWP/82259/2010)	**3-month public consultation**