European Medicines Agency
Evaluation of Medicines for Human Use

London, November 26th 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
NOVEMBER 2009 PLENARY MEETING
MONTHLY REPORT

The Committee for Medicinal Products for Human Use (CHMP) held its November plenary meeting on 16-19 November 2009.

The Committee welcomed Dr Mila Vlaskovska as the new Bulgarian member replacing Dr. Terziivanov, Dr Elena Masseva as the new Bulgarian alternate, replacing Dr Atansova, Dr. Kristiina Airola as the new Finnish Alternate, replacing Dr. Lapatto-Reiniluoto and Dr Daniela Melchiorri as the new Italian alternate, replacing Dr Addis. The Committee also welcomed Dr. Bert Leufkens, Netherlands, as the new CHMP co-opted member, replacing Dr. Persson in this role.

CENTRALISED PROCEDURE

Initial applications for marketing authorisation

The CHMP adopted three positive opinions by consensus on initial marketing authorisation applications.

New medicinal products

- **Elonva** (corifollitropin alfa), from N.V. Organon, intended for controlled ovarian stimulation for the development of multiple follicles in women participating in an Assisted Reproductive Technology program. The review of Elonva began on 24 December 2008 with an active review time of 205 days.
- **Urorec** and **Silodyx** (silodosin), from Recordati Ireland Ltd, intended for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). The review for Urorec began on 19 November 2008 with an active review time of 205 days. The review for Silodyx began on 26 July 2009 with an active review time of 85 days and was aligned with that of Urorec.

Negative opinions

The Committee adopted two negative opinions by consensus, recommending that the following medicines should not be granted a marketing authorisation:

- **Nenad (**lisuride), from Axxonis Pharma AG, intended for the treatment of the signs and symptoms of Restless Legs Syndrome.
- **Oncophage (**vitespen), from Antigenics Therapeutics Ltd. Oncophage is an autologous immunotherapy product, intended for the adjuvant treatment of renal cell carcinoma. Autologous immunotherapy products are produced by isolating tumour cells from an individual and processing these tumour cells into a formulation, which is then administered to the individual from whom the tumour cells were isolated to trigger an immune response against the tumour cells.

Question and-answer documents with more information about the reasons for these two refusals can be found here.

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Generic medicinal products

The Committee adopted four positive opinions by consensus for generic medicines:

- **Docetaxel TEVA** (docetaxel), from Teva Pharma B.V., a generic of Taxotere, which is authorised in the European Union for the treatment of breast cancer, non-small-cell lung cancer, prostate cancer, gastric adenocarcinoma and head and neck cancer.
- **Telmisartan Teva** (telmisartan), from Teva Pharma B.V., a generic of Micardis, which is authorised in the EU for the treatment of essential hypertension in adults.
- **Temozolomide Teva** (temozolomide), from Teva Pharma B.V., and **Temomedac** (temozolomide), from Alfred E. Tiefenbacher GmbH & Co. KG, generics of Temodal, which is authorised in the EU for treatment of glioblastoma and malignant glioma.

Summaries of opinion for these medicinal products are available here. Further information will be included in the European Public Assessment Reports (EPARs) once the European Commission has granted final approval.

Post-authorisation procedures

Extensions of indication and other recommendations

The Committee gave one positive opinion by consensus for an application for extension of indication, adding a new treatment option, for the following medicine:

- **Thyrogen (**thyrotrophin alfa), from Genzyme B.V. The Committee recommended to extend the indication of the use of Thyrogen for ablation of thyroid remnant tissue to patients who have undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of distant metastatic thyroid cancer. Thyrogen is currently authorised for testing undertaken for the detection of thyroid remnants and well-differentiated thyroid cancer in post-thyroidectomy patients maintained on hormone suppression therapy.

Summaries of opinion for these extensions of indication are available here. Further information will be included in the EPARs once the European Commission has granted final approval.

Negative opinion for extension of indication

The Committee adopted a negative opinion by majority for **Avastin** (bevacizumab), from Roche Registration Ltd, recommending that the current indication should not be extended to include the use of the medicine alone or in combination with irinotecan in patients with glioblastoma (WHO Grade IV malignant glioma) after relapse. A question and answer document with more information about the reasons for the refusal is available.

Update on H1N1 pandemic vaccines

The efficacy and safety of H1N1 pandemic vaccines was reaffirmed. The European Medicines Agency has reviewed further data on the centrally authorised pandemic vaccines, **Celvapan, Focetria** and **Pandemrix**. The Agency has reaffirmed that all three vaccines have a positive balance of benefits and risks in the context of the current H1N1 influenza pandemic.

A separate press release is available here.

Within the context of the pandemic situation, the Medicial Products Agency (MPA - Swedish Agency) notified the EMEA under Article 83 of Regulation 726/2004 of its intention to initiate a compassionate use at National level for the intravenous use of **Relenza** (zanamivir) from Glaxo Group Ltd to treat severe influenza in critically ill patients in hospitals. The CHMP agreed to prepare an opinion on the condition for use, distribution and the patients targeted.

Removal of contraindications recommended

The Committee recommended that the contraindication for pregnant and breast-feeding women should be deleted from the product information for **Taxotere** (docetaxel) and **Docetaxel Winthrop** (docetaxel), both from Aventis Pharma S.A. Both medicines are authorised for the treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, and head and neck cancer.

Summaries of opinion for all the mentioned medicines, including their full indication, can be found here.

Withdrawals

The EMEA was formally notified by AstraZeneca of its decision to withdraw its application for a centralised marketing authorisation for the medicine **Zactima** (vandetanib), 100 mg film-coated tablets. Zactima was expected to be used in combination with chemotherapy, for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who have received prior anticancer therapy. A separate press release document and a question-and-answer document with more information are available.

The EMEA has been formally notified by Arpida Ltd in October 2009 of its decision to withdraw its application for a centralised marketing authorisation for the medicine **Mersarex** (iclaprim), 12.8 mg/ml concentrate for solution for infusion. Mersarex was expected to be used for the treatment of complicated skin and soft tissue infection. An additional question-and-answer document is now available.

The EMEA has been formally notified by Otsuka Pharmaceutical Europe Ltd. of its decision to withdraw its application for an extension of indication for **Abilify** (aripiprazole). Abilify was expected to treat major depressive episodes as adjunctive treatment in patients who have had an inadequate response to at least one antidepressant monotherapy.

Re-examination procedures concluded (new applications) under Article 9(2) of Regulation (EC) No. 726/2004

The Committee concluded the re-examination by consensus of previously adopted opinions for two medicines for which an application for a new marketing authorisation was submitted:

- **Gemesis (**bercaplermin), from Biomimetic Therapeutics Ltd, the CHMP confirmed its previous negative opinion and adopted a final negative opinion, recommending that the medicine should not be granted a marketing authorisation. The medicine was intended for the treatment of periodontally related defects.
- **Milnacipran Pierre Fabre Medicament** (milnacipran) and **Impulsor** (milnacipran), from Pierre Fabre Médicament, the CHMP confirmed its previous negative opinion and adopted a final negative opinion, recommending that the medicine should not be granted a marketing authorisation. The medicine was intended for the treatment of fibromyalgia syndrome.

Re-examination procedures concluded (Type II variations) under Article 6(9) of Regulation (EC) No. 1085/2003

The Committee concluded a re-examination by majority of its previous negative opinion on an application for an extension of indication for **Erbitux** (cetuximab), from Merck KgaA, confirming its negative opinion that the indication of Erbitux should not be extended to add the first line treatment of patients with epidermal growth factor receptor (EGFR) expressing advanced or metastatic non-small cell lung cancer in combination with platinum-based chemotherapy.

More information about these re-examination procedures is available in separate question-and-answer documents available here.

OTHER INFORMATION ON THE CENTRALISED PROCEDURE

Lists of Questions

The Committee adopted six Lists of Questions on initial applications (including one under the mandatory scope and five under the optional scope) and one List of Questions on a "line extension" application (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 October 2009 is provided in **Annex 3.**

REFERRAL PROCEDURES

Referral procedures concluded

Finalising a review of **gadolinium-containing contrast agents** under Article 20 of Regulation (EC) No 726/2004, the Committee made a set of recommendations aimed at minimising the risk of nephrogenic systemic fibrosis (NSF) with these agents in patients at risk of developing the condition.

Gadolinium-containing contrast agents are used in patients undergoing magnetic resonance imaging (MRI) or magnetic resonance angiography (MRA) scans. The CHMP reviewed these agents because of the association between the use of gadolinium-containing contrast agents and NSF, a rare, serious and sometimes life-threatening condition that is characterised by formation of connective tissues in the skin, joints, muscles and internal organs, in patients with severe kidney problems. More information about the review is available in a separate press release and a question-and-answer document.

The CHMP concluded a referral arbitration procedure following a disagreement among EU Member States regarding the authorisation of **Pantoprazole Bluefish** 20&40 mg gastro-resistant tablets (pantoprazole sodium sesquihydrate), from Bluefish Pharmaceuticals AB, and **Pantoprazole Olinka** and associated names, 20 and 40 mg, gastro-resistant tablets (pantoprazole sodium sesquihydrate), from Olinka (UK) Ltd. These medicines are indicated for treatment of gastric and duodenal ulcer, reflux oesophagitis (treatment and prevention of relapse), treatment of non-erosive gastroesophageal reflux disease (GERD), prevention of non steroid anti-inflammatory drugs (NSAIDs) related ulcers, Zollinger-Ellison-Syndrome and eradication of H. pylori. The procedure was initiated because of concerns regarding the bioequivalence study comparing these generic medicines to the reference medicine Pantecta. The Committee concluded that the benefits of these medicines outweigh its risks and that a marketing authorisation can be granted in Sweden. The referral procedure was initiated under Article 29 of Directive 2001/83/EC as amended. A question-and-answer document with further information is now available.

Harmonisation referral concluded

The Committee recommended harmonisation of the prescribing information for **Lescol** (fluvastatin) and associated names, from Novartis group of companies and associated companies. Lescol is used to treat adults with primary hypercholesterolaemia or mixed dyslipidaemia, as an adjunct to diet, when response to diet and other non-pharmacological treatments is inadequate and for secondary prevention of major adverse cardiac events in adults with coronary heart disease after percutaneous coronary interventions. The review was initiated because of differences in the Summaries of Product Characteristics (SPCs), labelling and package leaflets in the countries where the product is marketed. The review was carried out under Article 30 of Directive 2001/83/EC as amended. A question-and-answer document with further information is now available.

Referral procedures started

The CHMP started a referral procedure under Article 107 (2) of Directive 2001/83/EC, as amended for anti-obesity medicines containing **sibutramine**, because preliminary data suggest a possible increased risk of serious cardiovascular events. The data raising the concern come from the SCOUT study (Sibutramine Cardiovascular OUTcome Trial), which investigates long-term cardiovascular effects of sibutramine treatment in a population with high cardiovascular risk. The review was triggered by Germany. As part of this procedure the CHMP will assess the impact of the new data on the benefit-risk balance of these medicines and make a recommendation whether their marketing authorisations should be maintained, changed, suspended or revoked.

The CHMP started two referral procedures under Article 29 of Directive 2001/83/EC, as amended for:

- **Ethirfin and associated names** prolonged release, hard capsules, due to concerns on the dissolution with alcohol of these products, which may cause dose dumping and potential overdose. This procedure was initiated by Denmark because of disagreements regarding the quality aspects of these medicinal products
- **Clopidogrel Teva** 75mg, film-coated tablets and Clopidogrel Orion 75mg, film-coated tablets. This procedure was initiated by Germany because of disagreements regarding the quality aspects of these medicinal products.

These types of procedures are initiated by one or more Member States in cases where an agreement cannot be reached in the context of the mutual recognition procedure or the decentralised procedure.

The CHMP started a referral procedure under Article 6(12) of Regulation (EC) 1084/2003, as amended for **Genotropin and associated names**, from Pfizer ApS, a growth hormone replacement therapy. Procedures under article 6(12) are initiated in cases of disagreement between Member States in the context of the mutual recognition procedure in relation to applications to change the marketing authorisation. In this particular case the procedure was initiated because of disagreements between Member States regarding the addition of “growth disturbance in children with severe forms of juvenile chronic idiopathic arthritis, requiring long term systemic glucocorticoid treatment, for improvement of growth and body composition” as a new indication.

The CHMP started a referral procedure under Article 30 of Directive 2001/83/EC as amended for **Atacand Plus and associated names** (candesartan cilexetil/hydrochlorothiazide), from AstraZeneca group of companies and associated companies, used in the treatment of high blood pressure (hypertension). This type of procedure is initiated with a view to harmonising product information for medicinal products authorised at Member State level.

MUTUAL-RECOGNITION AND DECENTRALISED PROCEDURES - HUMAN

The CHMP noted the report from the 45th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 16-17 November 2009. For further details, please see the relevant press release on the CMD(h) 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 26-28 October 2009. For further details, please see **Annex 4**.

Documents prepared by the CHMP Working Parties adopted during the November 2009 CHMP meeting are listed in **Annex 5**.

UPCOMING MEETINGS FOLLOWING THE OCTOBER 2009 CHMP PLENARY MEETING

- The 61st meeting of the CHMP will be held at the Agency on 14-17 December 2009.
- The next Name Review Group meeting will be held at the Agency on 24 November 2009.
- The 46th CMD(h) will be held at the Agency on 14-15 December 2009.

ORGANISATIONAL MATTERS

The main topics addressed during the November 2009 CHMP meeting related to:

- Discussions on future Working Party restructure in order to adapt to evolving regulatory environment. This work will be undertaken by the CHMP together with the Agency's support over 2010. An action plan will be developed in the future with an appropriate timetable.
- The agreement to set up a Pandemic Pharmacovigilance Rapid Response Expert Group.
- The adoption of a revised core group of the Clinical Neuroscience group (SAG CNS).
- Preliminary discussion for having a structured way forward to include patients' views in CHMP's benefit/risk considerations and development of criteria to identify when patients should be involved in CHMP's discussions, and to define the most suitable format of the consultation.
- Proposals for participation of patients in the Pharmacovigilance Working Party (PhVWP) following the pilot phase from April to June 2009.

PROCEDURAL ANNOUNCEMENT

Submission of full data on module 3 of dossiers of biological substances of non-recombinant origin

The European Directorate for the Quality of Medicines (EDQM) published on 22.10.09 its decision to exclude from the scope of the Certification Procedure, the products that have been classified as "other biological substances" by the CMD(h). (See EDQM website link: click here)

A list of these 'other biological' substances are available on the website of the Heads of Medicines Agencies: click here.

Further to this publication by EDQM, the CHMP has agreed on the following **recommendation**:

Applicants are requested to submit full data on the Module 3 for new applications for Marketing Authorisation through the centralised procedure for medicinal products containing these biological substances. Existing certificates of suitability (CEPs) for these substances can be included in the dossiers but should not be used as replacement of the relevant data in the corresponding sections of Module 3.

The reasoning behind this decision is that for biologicals the characterisation and determination of the quality of these products requires not only a combination of physico-chemical and biological testing, but also extensive knowledge over the production process and its control.

Applicants are also reminded that Active Substance Master Files (ASMFs) are not applicable to biological medicinal products (See CHMP monthly report October 2004).

A similar recommendation has been adopted by CMD(h) for applications submitted through the decentralised or mutual recognition procedures.

Transitional provisions for implementation of Variation Regulation (EC) No 1234/2008:

Further to discussions between the EMEA, European Commission and the CMD(h), the following practical guidance on the transitional provision and entry into force of the Variation Regulation, as set out in Articles 27.2 and 28 of Regulation (EC) No 1234/2008, will apply to submissions in the Centralised Procedure:

- Applications for variations and/or extensions will be processed according to the current Variation Regulation (EC) No 1085/2003 or new Variation Regulation (EC) No 1234/2008, based on the date of submission of the application (i.e. date of receipt by the EMEA);

- Marketing Authorisation Holders intending to submit applications for variations and/or extensions according to Variation Regulation (EC) No 1234/2008 for a start of procedure in January 2010 are therefore advised to submit their application after 1st January 2010 and at the latest by the recommended submission dates published on the EMEA website; the submission dates for Type II variations (60 day procedure) and for extension applications have been revised to allow Marketing Authorisation Holders the possibility to submit variations/extensions according to the new Variation Regulation for a start of procedure in January 2010;
  See http://www.emea.europa.eu/htms/human/submission/submission.htm

- Marketing Authorisation Holders intending to submit applications for variations and/or extensions according to Variation Regulation (EC) No 1085/2003 are advised to submit their application at the latest by 23rd December 2009.

- For additional guidance on the submission of Type IA and IB variations in December 2009, please refer to the Monthly Report of the October CHMP meeting.
  See: http://www.emea.europa.eu/pdfs/human/press/pr/67435609en.pdf

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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 NOVEMBER 2009

PRE-AUTHORISATION: MARKETING AUTHORISATION APPLICATIONS

Activity	2009								1995 onwards
	Optional Scope				Mandatory scope			Total	Overall total
	NAS	Significant innovation	Interest of Patients	Generics	Biotech	Indications	Orphans		
Applications for MA submitted	23	4	0	38	7	4	9	85	883
Positive opinions	22	10	0	49	13	3	6	103	595
Negative opinions[1]	0	3	0	0	2	0	2	7	28
Withdrawals prior to opinion	4	0	0	1	3	2	3	13	152
Marketing authorisation granted by the Commission	17	10	0	29	13	4	9	82	567

PRE-AUTHORISATION: SCIENTIFIC SERVICES

Activity (submissions)	2009	1995 onwards
Compassionate use applications	0	0
Art. 58 applications	0	4
Consultation for medical devices[2]	1	6
PMF (Click here for a list of PMF certifications)	1	14
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

OUTCOME OF THE NOVEMBER 2009 CHMP MEETING IN RELATION TO ACCELERATED ASSESSMENT PROCEDURES

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

ANNEX 2 TO CHMP MONTHLY REPORT NOVEMBER 2009

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

Activity	2009	Overall total 1995 onwards
Type I Variations (positive notifications)	1060	7430
Type II Variations (positive opinions)	1006	5549
Type II Variations (negative opinions)	3	19
Annex II Applications (positive opinions)	48	231
Annual Re-assessments (positive opinions)	14	-
Opinions for renewals of conditional MA's (positive opinions)	3	9
5-year Renewals (positive opinions)	56	-

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
4 Extension of indication	2 Positive opinions 1 Negative opinion 1 Withdrawal prior to opinion
33 SPC changes	32 Positive opinions 1 Withdrawal prior to opinion
52 Quality changes	52 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
N/A	N/A	N/A

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**
Azopt (brinzolamide) Alcon Laboratories (UK) Ltd.	Positive Opinion adopted	Unlimited validity
Orfadin (nitisinone) Swedish Orphan International AB	Positive Opinion adopted	Unlimited validity
Truvada (emtricitabine / tenofovir disoproxil fumarate) Gilead Sciences International Ltd.	Positive Opinion adopted	Unlimited validity

ANNEX 3 TO CHMP MONTHLY REPORT NOVEMBER 2009

MEDICINAL PRODUCTS GRANTED A COMMUNITY MARKETING AUTHORISATION UNDER THE CENTRALISED PROCEDURE SINCE THE OCTOBER 2009 CHMP MONTHLY REPORT

Invented Name	Imprida HCT
INN	amlodipine besylate / valsartan / hydrochlorothiazide
Marketing Authorisation Holder	Novartis Europharm Limited
Proposed ATC code	C09DX01
Indication	Treatment of essential hypertension as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of amlodipine, valsartan and hydrochlorothiazide (HCT), taken either as three single-component formulations or as a dual-component and a single-component formulation.
CHMP Opinion date	23.07.2009
Marketing Authorisation Date	15.10.2009

Invented Name	Exforge HCT
INN	amlodipine besylate / valsartan / hydrochlorothiazide
Marketing Authorisation Holder	Novartis Europharm Limited
Proposed ATC code	C09DX01
Indication	Treatment of essential hypertension as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of amlodipine, valsartan and hydrochlorothiazide (HCT), taken either as three single-component formulations or as a dual-component and a single-component formulation.
CHMP Opinion date	23.07.2009
Marketing Authorisation Date	16.10.2009

Invented Name	Alendronate Sodium and Colecalciferol, MSD
INN	alendronic acid / colecalciferol
Marketing Authorisation Holder	Merck Sharp & Dohme Ltd.
Proposed ATC code	M05BB03
Indication	Treatment of postmenopausal osteoporosis in patients at risk of vitamin D insufficiency. Alendronate Sodium and Colecalciferl, MSD reduces the risk of vertebral and hip fractures.
CHMP Opinion date	23.07.2009
Marketing Authorisation Date	16.10.2009

Invented Name	Clopidogrel MYLAN Pharma
INN	clopidogrel
Marketing Authorisation Holder	Mylan S.A.S.
Proposed ATC code	B01AC04
Indication	Clopidogrel is indicated in adults for the prevention of atherothrombotic events in: • Patients suffering from myocardial infarction (from a few days until less than 35 days), ischaemic stroke (from 7 days until less than 6 months) or established peripheral arterial disease.
CHMP Opinion date	23.07.2009
Marketing Authorisation Date	16.10.2009

Invented Name	Pandemic Influenza Vaccine H5N1 Baxter
INN	Pandemic influenza vaccine (H5N1 whole virion, Vero cell derived, inactivated)
Marketing Authorisation Holder	Baxter AG
Proposed ATC code	J07BB01
Indication	Prophylaxis of influenza in an officially declared pandemic situation. Pandemic influenza vaccine should be used in accordance with official guidance. Pandemic Influenza Vaccine H5N1 Baxter has been evaluated in adults 18-59 years of age and in elderly 60 years of age and above.
CHMP Opinion date	23.07.2009
Marketing Authorisation Date	16.10.2009

Invented Name	Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals
INN	Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) A/VietNam/1194/2004 NIBRG-14
Marketing Authorisation Holder	GlaxoSmithKline Biologicals S.A.
Proposed ATC code	J07BB02
Indication	Prophylaxis of influenza in an officially declared pandemic situation. Pandemic influenza vaccine should be used in accordance with official guidance
CHMP Opinion date	23.07.2009
Marketing Authorisation Date	19.10.2009

Invented Name	Foclivia
INN	A/Viet Nam/1194/2004 (H5N1) virus surface inactivated antigen
Marketing Authorisation Holder	Novartis Vaccines and Diagnostics S.r.l.
Proposed ATC code	J07BB02
Indication	Prophylaxis of influenza in an officially declared pandemic situation. Pandemic influenza vaccine should be used in accordance with Official Guidance
CHMP Opinion date	23.07.2009
Marketing Authorisation Date	19.10.2009

Invented Name	Biopoin
INN	Epoetin theta
Marketing Authorisation Holder	CT Arzneimittel GmbH
Proposed ATC code	B03XA01
Indication	• Treatment of symptomatic anaemia associated with chronic renal failure in adult patients. • Treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy.
CHMP Opinion date	23.07.2009
Marketing Authorisation Date	23.10.2009

Invented Name	Arcalyst
INN	rilonacept
Marketing Authorisation Holder	Regeneron UK Limited
Proposed ATC code	L04AC04
Indication	Arcalyst is indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) with severe symptoms, including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS), in adults and children aged 12 years and older.
CHMP Opinion date	23.07.2009
Marketing Authorisation Date	23.10.2009

Invented Name	Irbesartan Teva
INN	irbesartan
Marketing Authorisation Holder	Teva Pharma B.V.
Proposed ATC code	C09C A04
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.
CHMP Opinion date	23.07.2009
Marketing Authorisation Date	23.10.2009

Invented Name	Ilaris
INN	canakinumab
Marketing Authorisation Holder	Novartis Europharm Limited
Proposed ATC code	L04AC08
Indication	Ilaris is indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in adults, adolescents and children aged 4 years and older with body weight above 15 kg, including: – Muckle-Wells Syndrome (MWS), – Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA), Severe forms of Familial Cold Autoinflammatory Syndrome (FCAS) / Familial Cold Urticaria (FCU) presenting with signs and symptoms beyond cold-induced urticarial skin rash.
CHMP Opinion date	23.07.2009
Marketing Authorisation Date	23.10.2009

Invented Name	Lamivudine Teva
INN	lamivudine
Marketing Authorisation Holder	TEVA Pharma B.V
Proposed ATC code	J05AF05
Indication	Lamivudine Teva is indicated for the treatment of chronic hepatitis B in adults with: • compensated liver disease with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active liver inflammation and / or fibrosis. • decompensated liver disease.
CHMP Opinion date	23.07.2009
Marketing Authorisation Date	23.10.2009

Invented Name	Eporatio
INN	epoetin theta
Marketing Authorisation Holder	Ratiopharm GmbH
Proposed ATC code	B03XA01
Indication	• Treatment of symptomatic anaemia associated with chronic renal failure in adult patients. • Treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy.
CHMP Opinion date	23.07.2009
Marketing Authorisation Date	29.10.2009

Invented Name	Repaglinide Krka
INN	repaglinide
Marketing Authorisation Holder	Krka, d.d., Novo mesto
Proposed ATC code	A10B X02
Indication	Repaglinide is indicated in patients with Type 2 diabetes (Non Insulin-Dependent Diabetes Mellitus (NIDDM)) whose hyperglycaemia can no longer be controlled satisfactorily by diet, weight reduction and exercise. Treatment should be initiated as an adjunct to diet and exercise to lower the blood glucose in relation to meals.
CHMP Opinion date	23.07.2009
Marketing Authorisation Date	04.11.2009

Invented Name	Copalia HCT
INN	Amlodipine besylate/valsartan/hydrochlorothiazide
Marketing Authorisation Holder	Novartis Europharm Limited
Proposed ATC code	C09DX01
Indication	Treatment of essential hypertension as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of amlodipine, valsartan and hydrochlorothiazide (HCT), taken either as three single-component formulations or as a dual-component and a single-component formulation.
CHMP Opinion date	23.07.2009
Marketing Authorisation Date	04.11.2009

Invented Name	Dafiro HCT
INN	Amlodipine besylate / valsartan / hydrochlorothiazide
Marketing Authorisation Holder	Novartis Europharm Limited
Proposed ATC code	C09DX01
Indication	Treatment of essential hypertension as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of amlodipine, valsartan and hydrochlorothiazide (HCT), taken either as three single-component formulations or as a dual-component and a single-component formulation.
CHMP Opinion date	23.07.2009
Marketing Authorisation Date	04.11.2009

ANNEX 4 TO CHMP MONTHLY REPORT NOVEMBER 2009

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

	1995 - 2008	2009	Overall Total
Scientific Advice	887	**225**	**1112**
Follow-up to Scientific Advice	171	**55**	**226**
Protocol Assistance	198	**41**	**239**
Follow-up to Protocol Assistance	90	**18**	**108**
	1346	**339**	**1685**

OUTCOME OF THE NOVEMBER 2009 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	
Chemical	Treatment of Type 1 Diabetes.			x				x	
Biological	Treatment of exocrine pancreatic insufficiency.	x						x	
Chemical	Treatment of Gaucher disease.				x			x	
Biological	Treatment of type 2 diabetes mellitus.			x				x	
Biological	Treatment of type 2 diabetes mellitus.	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 obesity.	x				x		x	
Biological	Treatment of type 1 diabetes mellitus.			x				x	
Advanced Therapy	Treatment of Crohn's disease.	x				x	x		
Chemical	Treatment of Metastatic Breast cancer.	x						x	
Chemical	Treatment of Chronic Graft versus Host Disease.	x					x	x	
Chemical	Treatment of colon cancer, colorectal cancer, gastric cancer and breast cancer.			x				x	
Biological	Treatment of castration-resistant prostate cancer.	x						x	
Biological	Treatment of relapsed refractory Multiple Myeloma.				x			x	
Biological	Treatment of Peripheral T-cell Lymphoma.	x					x	x	
Chemical	Treatment of non-small cell lung cancer.			x				x	
Biological	Treatment of metastatic castration-resistant prostate cancer.	x						x	
Chemical	Treatment of Juvenile Idiopathic Arthritis.	x				x	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 breast cancer.	x						x	
Biological	Treatment of neutropenia.	x				x	x	x	
Chemical and Biological	Treatment metastatic breast cancer.	x					x	x	
Biological	Treatment of Cryopyrin-Associated Periodic Syndromes.		x					x	
Chemical	Treatment of ovarian cancer.	x					x	x	
Biological	Treatment of systemic lupus erythematosus.	x				x	x	x	
Biological	Treatment of dermatomyositis and polymyositis.	x					x	x	
Biological	Treatment of metastatic breast cancer.	x				x			
Chemical	Treatment of Onchocerciasis.			x		x		x	
Biological	Prophylaxis of bleeding in haemophilia B patients.		x			x	x	x	x
Biological	Prophylaxis of bleeding in haemophilia A patients.		x			x	x	x	x
Chemical	Treatment of Acute Coronary Syndrome.	x				x	x	x	
Chemical	Prevention of myocardial infarction, stroke or unstable angina.			x			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 acute illness due to influenza A infection.	x					x	x	
Biological	Prevention of pulmonary tuberculosis.	x				x	x	x	
Biological	Prevention against malaria disease due to P. falciparum and against infection with hepatitis B virus.			x		x	x	x	
Chemical	Treatment of Pseudomonas aeruginosa lung infection in cystic fibrosis.		x					x	x
Chemical	Treatment of osteoporosis.	x					x	x	
Chemical	Treatment of acute pain and fever.	x					x	x	
Chemical	Treatment of (male) osteoporosis.			x			x		
Chemical	Treatment of Leber's Hereditary Optic Neuropathy.		x					x	
Biological	Treatment of relapsing multiple sclerosis.	x				x	x	x	
Chemical	Treatment of peripheral neuropathic pain.			x				x	
Chemical	Treatment of schizophrenia.	x					x	x	
Chemical	Treatment of major depressive disorder.			x				x	

Substance	Intended indications(s)	Type of Request				Topic			
		New		Follow-up		Pharma ceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Advanced Therapy	Treatment of corneal lesions, with associated corneal (limbal) stem cell deficiency, due to ocular burn.				x			x	
Chemical	Treatment of Age Related Macular Degeneration	x					x		
Chemical	Treatment of acromegaly.	x					x	x	
Chemical	Treatment of acromegaly.		x				x	x	x
Chemical	Treatment of hyperphosphataemia.	x						x	
Advanced Therapy	Treatment of cartilage defects and Osteochondritis Dissecans.			x				x	
Chemical	Diagnostic for detecting gastrinoma in Zollinger-Ellison syndrome.	x						x	
Biological	Active immunisation for the prevention of invasive meningococcal disease caused by N. meningitidis serogroup B.			x				x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 28 Scientific Advice letters, 6 Protocol Assistance letters, 14 Follow-up Scientific Advice and 3 Follow-up Protocol Assistance letters were adopted at the 16-19 November 2009 CHMP meeting.

New requests for Scientific Advice Procedures

The Committee accepted 41 new Requests for which the procedure started at the SAWP meeting held on 26-29 October 2009. The new requests are divided as follows: 21 Initial Scientific Advice, 10 Follow-up Scientific Advice, 8 Initial Protocol Assistance and 2 Follow-up Protocol Assistance.

DOCUMENTS PREPARED BY THE CHMP WORKING PARTIES ADOPTED DURING THE NOVEMBER 2009 CHMP MEETING

EFFICACY WORKING PARTY (EWP)

Reference number	Document	Status[3]
EMEA/CHMP/EWP/192217/2009	Guideline on validation of bioanalytical methods	Adopted for 6-month public consultation
EMEA/CHMP/EWP/604040/2009	Concept Paper on the need for a guideline on the Clinical Investigation of Medicinal Products Intended for Treatment of Systemic and Cutaneous Lupus Erythematosus	Adopted for 3-month public consultation

CHMP WORKING GROUP WITH HEALTH CARE PROFESSIONALS (HCPWG)

Reference number	Document	Status
EMEA/533986/2009	HCPWP Work Plan for 2010	Adopted

[3] 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).