EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

Monthly Report

Committee for Medicinal Products for Human Use (CHMP)

11 – 14 April 2011

Interim measures for Pandemrix

The CHMP has recommended that the product information for Pandemrix[2] (Influenza vaccine (H1N1)) (split virion, inactivated, adjuvanted), from GlaxoSmithKline Biologicals S.A., should be amended to advise prescribers to take into account preliminary results from epidemiological studies on Pandemrix and narcolepsy, and to perform an individual benefit-risk assessment when considering the use of Pandemrix in children and adolescents. This is an interim measure pending the outcome of the European review expected to conclude in July 2011.

The CHMP reviewed all available data, including new findings from Sweden and France on the suspected link between narcolepsy in children and adolescents and Pandemrix. The CHMP concluded that, following the earlier results of an epidemiological study from Finland, the new evidence strengthened the signal in children and adolescents, but that the data had methodological limitations. The relationship between Pandemrix and narcolepsy is still under investigation.

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 two positive opinions by consensus recommending the granting of marketing authorisations for the following new medicines:

[1] The document has been revised to correct information on opinion for 5-year renewal application and accelerated assessment procedure contained in Annex 1 (page 8), designated orphan indication contained in Annex 3 (page 12), statistical figures contained in Annex 4 (page 13).
[2] The review of Pandemrix is being conducted in the context of a formal review under Article 20 of Regulation (EC) 726/2004, as amended.

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- **Bydureon** (exenatide), from Eli Lilly Nederland B.V., intended for the treatment of type-2 diabetes in adults. The review for Bydureon began on 24 March 2010 with an active review time of 183 days.
- **Nulojix** (belatacept), from Bristol-Myers Squibb Pharma EEIG, intended in combination with corticosteroids and a mycophenolic acid for prophylaxis of graft rejection in adults receiving a renal transplant. The review for Nulojix began on 24 February 2010 with an active review time of 210 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 **Leganto** (rotigotine), from Schwarz Pharma Ltd, intended for the symptomatic treatment of moderate to severe idiopathic restless legs syndrome in adults and idiopathic Parkinson's disease. The review for Leganto began on 13 February 2011 with an active review time of 60 days. This application was an informed consent application referring to the dossier of the authorised medicine Neupro.

Positive opinion for generic medicine adopted

The Committee adopted a positive opinion by consensus recommending the granting of a marketing authorisation for the generic medicine **Rivastigmine Actavis** (rivastigmine), from Actavis Group PTC ehf, intended for the symptomatic treatment of mild to moderately severe Alzheimer's dementia and mild to moderately severe dementia in patients with idiopathic Parkinson's disease. Rivastigmine Actavis is a generic of Exelon.

Withdrawals

On 15 March 2011, Reliance GeneMedix Plc officially notified the CHMP that it wished to withdraw its application for a marketing authorisation for **Epostim** (epoetin alfa), intended to be used to treat anaemia and stimulate red blood cell production. Epostim was developed as a 'biosimilar' medicine of Eprex. 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.

The European Medicines Agency has been formally notified by Novartis of its decision to withdraw its application for a centralised marketing authorisation for the medicine **Joicela** (lumiracoxib), 100 mg film-coated tablets. Joicela was intended to be used for symptomatic relief in the treatment of osteoarthritis of the knee and hip in patients who are non-carriers of the DQA1*0102 allele. The application for the marketing authorisation for Joicela was submitted to the Agency on 3 December 2009. At the time of the withdrawal it was under review by the CHMP. A separate press release with more information is available.

Post-authorisation procedures

Positive opinions for extensions of therapeutic indications adopted

The Committee adopted four positive opinions by consensus for applications for extensions of therapeutic indications, adding new treatment options for medicines that are already authorised in the EU, for:

- **Carbaglu** (carglumic acid), from Orphan Europe S.A.R.L., to include the treatment of hyperammonaemia due to isovaleric acidaemia, methylmalonic acidaemia and propionic acidaemia.
- **Pradaxa** (dagibatran), from Boehringer Ingelheim International GmbH, to include the prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation.
- **Ozurdex** (dexamethasone), from Allergan Pharmaceuticals Ireland, to include the treatment of adult patients with inflammation of the posterior segment of the eye presenting as non-infectious uveitis.
- **Simponi** (golimumab), from Janssen Biologics B.V., to include the reduction of the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of psoriatic arthritis.

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

Re-examination procedure on Avastin concluded

Following re-examination of its previous negative opinion, the Committee adopted a final positive opinion by majority, recommending that the therapeutic indications of **Avastin** (bevacizumab), from Roche Registration Ltd, should be extended to include first-line treatment in combination with capecitabine of patients with metastatic breast cancer in whom treatment with other chemotherapy options, including taxanes or anthracyclines, is not considered appropriate.

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

Additional safety information

The CHMP adopted a positive opinion by consensus recommending a variation to the terms of the marketing authorisation for the medicinal product **Neulasta** (pegfilgrastim) from Amgen Europe B.V. to include in section 4.8 of the SmPC hypersensitivity and update frequencies of adverse drug reactions in line with the current SmPC guidance.

The CHMP adopted by consensus an update of sections 4.4 and 4.8 of the SmPC of **Afinitor** (everolimus) from Novartis Europharm Ltd to include information on renal failure, proteinuria and pulmonary embolism events. Cases of renal failure (including acute renal failure), some with a fatal outcome, and proteinuria have been observed in patients treated with Afinitor. Therefore monitoring of renal function is recommended, particularly where patients have additional risk factors that may further impair renal function. Pulmonary embolism was also reported and was considered as an emerging safety observation.

In follow up to the assessment of the 5th and 6th Periodic Safety Update Reports for the medicinal product **Vectibix** (panitumumab) from Amgen Europe B.V., the CHMP adopted by consensus an update of sections 4.4 and 4.8 of the SmPC with the addition of keratitis and ulcerative keratitis. Patients who develop ocular toxicities while receiving Vectibix should be monitored for evidence of keratitis or ulcerative keratitis and therapy should be interrupted or discontinued if patients present with ulcerative keratitis, while continuation should be carefully considered with keratitis in the absence of corneal ulceration. Vectibix should be used cautiously in patients with a history of keratitis, ulcerative keratitis or severe dry eye. Use of contact lenses has also been associated with keratitis and ulceration of the cornea. The Committee agreed on a Direct Healthcare Professional Communication (DHPC). Finally, the CHMP considered that the above recommendations should be extended to the other EGFR inhibitors for which ocular toxicities have already been described.

The CHMP adopted a positive opinion by consensus recommending a variation to the terms of the marketing authorisation for the medicinal product **Viracept** (nelfinavir) from Roche Registration Ltd to include contraindications with regards to co-administration with alfuzosin and co-administration with sildenafil used in the treatment of pulmonary arterial hypertension, due to pharmacokinetic interactions. In addition, precautions concerning co-administration with sildenafil used in the treatment of erectile dysfunction, tadalafil, vardenafil, warfarin, colchicine, salmeterol and bosentan have been included in the product information.

The CHMP adopted a positive opinion by consensus recommending a variation to the terms of the marketing authorisation for the medicinal product **Tasigna** (nilotinib) from Novartis Europharm Ltd, with respect to the risk of Tumour Lysis Syndrome, further to a safety review conducted by the Marketing Authorisation Holder. Due to possible occurrence of Tumour Lysis Syndrome, correction of clinically significant dehydration and treatment of high uric acid levels are recommended prior to initiating therapy with Tasigna.

The CHMP adopted a positive opinion by consensus recommending a variation to the terms of the marketing authorisation for the medicinal product **Tysabri** (natalizumab) from Elan Pharma International Ltd with respect to the increased risk of developing PML in patients who have all three risk factors identified (more than 2 years of Tysabri therapy, prior immunosuppressant therapy and anti-JCV antibody positive) and that anti-JCV antibody testing may provide supportive information for risk stratification prior to or during treatment with Tysabri. The educational material has also been amended to reflect this information.

In addition, based upon the data that have become available since the granting of the initial Marketing Authorisation, the CHMP considers that the benefit-risk balance of Tysabri remains positive, but considers that its safety profile is to be closely monitored as currently available information from the post-marketing experience (ongoing observational trials, registries and ongoing clinical trials) does not provide a complete picture of evidence on how the risk factors could combine and interfere on the benefit-risk balance in long-term exposed patients.

Therefore, based on the safety profile of Tysabri, which requires the submission of 6-monthly PSURs, the CHMP concluded that the MAH should submit one additional renewal application in 5 years time.

Other information on the centralised procedure

Lists of Questions

The Committee adopted seven Lists of Questions on initial applications (including three under the mandatory scope and four under the optional scope as per Regulation (EC) No. 726/2004), together with two Lists of Questions on “line extension” applications (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 March is provided in **Annex 2**.

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 March 2011 CHMP plenary meeting are provided in **Annex 3**.

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 4**.

Referral procedures

Class review of bisphosphonates and atypical fractures concluded

The Committee concluded that rare atypical factures of the femur are a class effect of bisphosphonates[3].

The CHMP confirmed that the benefits of bisphosphonates in the treatment and prevention of bone disorders continue to outweigh their risks, but that a warning of the risk of atypical femoral fractures should be added to the prescribing information for all bisphosphonate-containing medicines in the EU. This extends to the whole bisphosphonate class the warning that had already been included in the product information for alendronate-containing medicines across Europe, following a review by the CHMP's Pharmacovigilance Working Party in 2008.

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

Lifting of suspension of Octagam recommended

The Committee recommended the lifting of the suspension of the marketing authorisations for Octagam[4] (human normal immunoglobulin 5% and 10%) and associated names, and the reintroduction of the medicine onto the market in the European Union. The lifting of the suspension is subject to changes to the manufacturing process.

Octagam is an intravenous solution used to strengthen the body's immune system to lower the risk of infection in patients with a weakened immune system.

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

Update on review of Baxter's dialysis solutions

While an in-depth review of the problem of the presence of endotoxins in Baxter's dialysis solutions[5] manufactured at the Castlebar plant in Ireland is ongoing, the Committee recommended that manufacturing sites located in Canada, Poland and Turkey be included into the existing marketing authorisations of Baxter's peritoneal dialysis solutions, in order to ensure the supply of endotoxin-free solutions in Europe.

[3] Bisphosphonates include alendronic acid, clodronic acid, etidronic acid, ibandronic acid, neridronic acid, pamidronic acid, risedronic acid, tiludronic acid and zoledronic acid. The review of centrally authorised bisphosphonates was conducted in the context of a formal review under Article 20 of Regulation (EC) 726/2004, as amended. The review of nationally authorised bisphosphonates was conducted in the context of a formal review under Article 31 of Directive 2001/83/EC, as amended.
[4] The review of Octagam was conducted in the context of a formal review under Article 31 of Directive 2001/83/EC, as amended.
[5] The referral for Baxter's dialysis solutions is being conducted under Article 31 of Directive 2001/83/EC, as amended.

The Committee will continue to investigate the root cause of the problem and the changes in the manufacturing process at Castlebar that are needed to ensure production of endotoxin-free products from this plant.

Review of Celecoxib started

The Committee has begun looking at the available data on the use of celecoxib[6] in the reduction of the number of adenomatous intestinal polyps in familial adenomatous polyposis, following Pfizer's voluntary withdrawal of the marketing authorisation of its celecoxib-containing orphan medicine, Onsenal, during the medicine's annual reassessment.

This review was initiated over the concern that other celecoxib-containing products may be used off-label in this indication.

The Committee will now review all available data thoroughly and will adopt an opinion on the matter.

Mutual-recognition and decentralised procedures - Human

The CHMP noted the report from the 61st CMDh (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 11 - 13 March 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 28 - 30 March 2011. For further details, please see **Annex 5**.

Upcoming meetings following the April 2011 CHMP plenary meeting

- The 77th meeting of the CHMP will be held at the Agency on 16-19 May 2011.
- The next Name Review Group meeting will be held at the Agency on 24 May 2011.
- The 62nd CMDh (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the Agency on 16-18 May 2011.

Organisational matters

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

- The re-election of Dr Beatriz Silva Lima as Chair and Dr Jan Willem van der Laan as Vice-Chair of the Safety Working Party.
- The re-election of Dr Sol Ruiz as Vice-Chair of the Biologics Working Party.

This month there was no CHMP Organisational Matters (ORGAM) meeting.

[6] The review of celecoxib is being conducted in the context of a formal review, initiated at the request of the European Commission under Article 5(3) of Regulation (EC) No 726/2004.

Procedural Announcement

Requirement reminder for all Marketing Authorisation Holders that have been granted a deferral in their agreed Paediatric investigational Plan

The Agency would like to remind the Marketing Authorisation Holders of the obligation to fulfil the requirement of Article 34(4) of Regulation (EC) No 1901/2006 ("Paediatric Regulation"), which states that an **Annual report on deferred measures** should be submitted, for authorised medicinal products if a deferral was granted for the completion of an agreed Paediatric Investigation Plan.

Annual reports should be submitted according to the guidance available on the EMA's website and using the template for annual report on a deferral.

Implementation of Type II variations not affecting the EU Marketing Authorisation Decision

Marketing Authorisation Holders are hereby informed that as of 1 May 2011 Type II variations that do not require a Commission decision amending the relevant marketing authorisation may be implemented after the marketing authorisation holder has been informed by the Agency.

For further information, please refer to the procedural note from the European Commission, delegating this task to the European Medicines Agency.

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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 April 2011

Opinions for annual re-assessment applications		
Name of medicinal product (INN) MAH	**Outcome**	**Comments**
N/A		

Opinion for renewals of conditional Marketing Authorisation		
Name of medicinal product (INN) MAH	**Outcome**	**Comments**
N/A		

Opinions for 5-Year Renewal applications		
Name of medicinal product (INN) MAH	**Outcome**	**Comments**
Tysabri (Natalizumab), Elan Pharma International Ltd.	Positive Opinion	Recommending additional renewal
Avaglim (Rosiglitazone / Glimepiride), Smithkline Beecham Ltd.	Negative Opinion	Not recommending the renewal
Ganfort (Bimatoprost / Timolol), Allergan Pharmaceuticals Ireland	Positive Opinion	Unlimited validity
Nexavar, **Orphan** (Sorafenib), Bayer Schering Pharma AG	Positive Opinion	Unlimited validity

Accelerated Assessment Procedures			
Substance	**Intended Indication(s)**	**Accelerated Assessment Requests**	
		Accepted	Rejected
Chemical	Treatment of melanoma	X	

Annex 2 to CHMP Monthly Report April 2011

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

Invented name	**Pravafenix**
INN	Fenofibrate / Pravastatin
Marketing Authorisation Holder	Laboratoires SMB s.a.
Proposed ATC code	C10BA03
Indication	Treatment of high CHD-risk adult patients with mixed dyslipidaemia characterised by high triglycerides and low HDL-cholesterol levels whose LDL-C levels are adequately controlled while on a treatment with pravastatin 40 mg monotherapy
CHMP Opinion date	20/01/2011
Marketing Authorisation Date	14/04/2011

Invented name	**Trobalt**
INN	Retigabine
Marketing Authorisation Holder	Glaxo Group Limited
Proposed ATC code	N03AX21
Indication	As adjunctive treatment of partial onset seizures with or without secondary generalisation in adults aged 18 years and above with epilepsy
CHMP Opinion date	20/01/2011
Marketing Authorisation Date	28/03/2011

Invented name	**Jevtana**
INN	Cabazitaxel
Marketing Authorisation Holder	Sanofi-Aventis
Proposed ATC code	not yet assigned
Indication	In combination with prednisone or prednisolone the medicine is indicated for the treatment of patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen
CHMP Opinion date	20/01/2011
Marketing Authorisation Date	17/03/2011

Invented name	**Halaven**
INN	Eribulin
Marketing Authorisation Holder	Eisai Europe Limited
Proposed ATC code	L01XX41
Indication	Treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least two chemotherapeutic regimens for advanced disease
CHMP Opinion date	20/01/2011
Marketing Authorisation Date	17/03/2011

Invented name	**Gilenya**
INN	Eribulin
Marketing Authorisation Holder	Novartis Europharm Limited
Proposed ATC code	L04AA27
Indication	Indicated as single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following adult patient groups: - Patients with high disease activity despite treatment with a beta-interferon. These patients may be defined as those who have failed to respond to a full and adequate course (normally at least one year of treatment) of beta-interferon. Patients should have had at least 1 relapse in the previous year while on therapy, and have at least 9 T2-hyperintense lesions in cranial MRI or at least 1 Gadolinium-enhancing lesion. A “non-responder” could also be defined as a patient with an unchanged or increased relapse rate or ongoing severe relapses, as compared to the previous year. OR - Patients with rapidly evolving severe relapsing remitting multiple sclerosis defined by 2 or more disabling relapses in one year, and with 1 or more Gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI.
CHMP Opinion date	20/01/2011
Marketing Authorisation Date	17/03/2011

Invented name	**Riprazo HCT**
INN	Aliskiren hemifumarate / Hydrochlorothiazide
Marketing Authorisation Holder	Novartis Europharm Limited
Proposed ATC code	C09XA52
Indication	Treatment of essential hypertension in adults
CHMP Opinion date	20/01/2011
Marketing Authorisation Date	13/04/2011

Annex 3 to CHMP Monthly Report April 2011

Overview of designated orphan medicinal products that have been the subject of a centralised application for marketing authorisation:

Update since the March 2011 CHMP meeting

Active substance	Invented name	Sponsor/applicant	EU designation number	Designated orphan indication
Eculizumab	Soliris	Alexion Europe SAS	EU/3/09/653	Treatment of atypical haemolytic uremic syndrome
[gly2]-recombinant human glucagon-like peptide	Revestive	Nycomed Danmark APS	EU/3/01/077	Treatment of short bowel syndrome

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Annex 4 to CHMP Monthly Report April 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	56	50									**90**	**118**
Justification for retention of invented name *	0	2	4	6									**4**	**8**

*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	102	91									**257**	**181**
Criterion - Safety concerns														
Similarity with other Invented name	125	73	82	74									**207**	**147**
Conveys misleading therapeutic/pharmaceutical connotations	2	3	0	1									**2**	**4**
Misleading with respect to composition	3	1	5	5									**8**	**6**
Criterion - INN concerns														
Similarity with INN	8	6	5	2									**13**	**8**
Inclusion of INN stem	5	3	3	2									**8**	**5**
Criterion - Other public health concerns														
Unacceptable qualifiers	1	0	3	2									**4**	**2**
Conveys a promotional message	1	0	2	5									**3**	**5**
Appears offensive or has a bad connotation	1	0	2	0									**3**	**0**
Similarity between name of individual active substance and fixed combinations and/or	0	0	0	0									**0**	**0**

	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	
between fixed combinations														
Similarity between name of prodrug and related active substance	0	0	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 5 to CHMP Monthly Report April 2011

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

	1995 - 2010	2011	Overall total
Scientific Advice	1368	78	1446
Follow-up to Scientific Advice	320	23	353
Protocol Assistance	297	20	317
Follow-up to Protocol Assistance	133	6	139
	2118	**127**	**2245**

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 April 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	Management and control of serum phosphorus and control in end-stage renal disease and management of hyperphosphataemia in chronic kidney disease and end-stage renal disease.	*x*				*x*	*x*	*x*	
Chemical	Treatment of type 2 diabetes Mellitus.			*x*				*x*	
Biological	Treatment of type 1 diabetes mellitus.			*x*			*x*	*x*	
Chemical	Treatment of diabetic gastroparesis.	*x*						*x*	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, psoriasis and Crohn´s disease.	*x*				*x*	*x*	*x*	
Chemical	Treatment of ovarian cancer, Kaposi's sarcoma, metastatic cancer.			*x*				*x*	
Chemical	Treatment of advanced ovarian cancer.	*x*				*x*	*x*		
Chemical	Treatment of advanced ovarian cancer.	*x*						*x*	
Chemical	Treatment of non-small cell lung cancer.	*x*						*x*	
Chemical	Treatment of B-RAF mutation positive advanced or metastatic melanoma.	*x*						*x*	
Biological	Treatment of locally advanced or metastatic non-small cell lung cancer.	*x*				*x*	*x*	*x*	
Chemical	Treatment of myelofibrosis.		*x*					*x*	
Advanced therapy	Treatment of prostate tumours.	*x*				*x*		*x*	
Biological	Treatment of moderate to severe active rheumatoid arthritis.	*x*				*x*	*x*	*x*	
Chemical	Treatment of moderate to severe rheumatoid arthritis.			*x*				*x*	
Chemical	Treatment of head and neck metastatic squamous cell carcinoma.	*x*						*x*	
Chemical	Prevention of kidney transplant rejection.	*x*						*x*	
Chemical	Treatment of thrombocytopenia.			*x*			*x*	*x*	
Chemical	Reduction of risk of stroke/systemic embolic events.			*x*				*x*	
Chemical	Treatment of polycythaemia vera.		*x*					*x*	*x*

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Advanced therapy	Treatment of acute myeloid leukaemia, acute lymphoblastic leukaemia, chronic myeloid leukaemia, myelodysplastic syndrome and Hodgkin's disease.		*x*			*x*	*x*	*x*	*x*
Biological	Treatment of IL-1beta driven inflammatory diseases in cardiovascular disease.			*x*				*x*	
Chemical	Treatment of complicated intra-abdominal infections.	*x*					*x*	*x*	
Chemical	Treatment of complicated urinary tract infections.	*x*					*x*	*x*	
Chemical	Treatment of complicated skin and soft tissues infections.	*x*					*x*	*x*	
Chemical	Prevention of post-surgical staphylococcal infections.	*x*					*x*	*x*	
Chemical	Treatment of Alzheimer's disease.	*x*					*x*		
Chemical	Intended for sedation for diagnostic and therapeutic procedures.	*x*						*x*	
Chemical	Treatment of moderate to severe chronic pain.	*x*				*x*	*x*	*x*	
Biological	Treatment of multiple sclerosis.			*x*				*x*	
Chemical	Treatment of schizophrenia.	*x*						*x*	
Chemical	Treatment of asthma.	*x*					*x*	*x*	
Advanced therapy	Treatment of limbal stem cell deficiency.			*x*				*x*	
Biological	Treatment of neurotrophic keratitis.	*x*					*x*		

SA: scientific advice
PA: protocol assistance

The above-mentioned 22 Scientific Advice letters, 3 Protocol Assistance letters, 9 Follow-up Scientific Advice and 0 Follow-up Protocol Assistance letters were adopted at the 11 – 14 April 2011 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 34 new Requests for which the procedure started at the SAWP meeting held on 28 – 30 March 2011. The new requests are divided as follows: 22 Initial Scientific Advice, 7 Follow-up Scientific Advice, 2 Initial Protocol Assistance and 3 Follow-up Protocol Assistance.