European Medicines Agency
Evaluation of Medicines for Human Use

28 September 2005
EMEA/CHMP/295298/2005

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SEPTEMBER 2005 PLENARY MEETING
MONTHLY REPORT

The Committee for Medicinal Products for Human Use (CHMP) held its September plenary meeting from 12 –15 September 2005.

Centralised procedure

Initial applications for marketing authorisation

The CHMP adopted positive opinions on four initial marketing authorisation applications at this meeting:

- **Macugen** (pegaptanib sodium), from Pfizer Ltd, for the treatment of the wet form of age-related macular degeneration (AMD), a condition that leads to vision loss resulting from damage to the central part of the retina. EMEA review began on 20 September 2004 with an active review time of 216 days.
- **Naglazyme** (galsulfase (recombinant human N-acetylgalactosamine-4-sulfatase)), from BioMarin Europe Ltd, for long-term enzyme replacement therapy in Mucopolysaccharidosis VI, an inherited enzyme deficiency resulting in greater than normal levels of mucopolysaccharides in body tissues. EMEA review began on 20 December 2004 with an active review time of 213 days. Naglazyme is the **twenty-third orphan medicinal product** to receive a positive CHMP opinion.
- **Proquad** (combined measles, mumps, rubella and varicella virus vaccine), from Sanofi Pasteur MSD, for simultaneous vaccination against measles, mumps, rubella and varicella in individuals from 12 months of age. EMEA review began on 18 October 2004 with an active review time of 209 days.
- **Yttriga** (yttrium), from AEA Technology OSA GmbH, for radiolabelling of carrier molecules, which have been specifically developed and authorised for radiolabelling with this radionuclide. EMEA review began on 17 May 2004 with an active review time of 209 days.

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

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Extensions of indication and other recommendations

- The Committee also adopted a positive opinion for the extension of indication for **Busilvex** (busulfan), from Pierre Fabre Médicament, to include the conditioning treatment of children prior to conventional haematopoietic progenitor cell transplantation. Busilvex is an orphan medicinal product and was first authorised in the European Union on 9 July 2003.

  A Summary of opinion for this medicinal product is available on the EMEA website: http://www.emea.eu.int. Further information will be included in the EPAR once the European Commission has granted final approval.

The Committee also adopted a positive opinion on a "line extension" application (Part B) (in accordance with Annex II of Commission Regulation (EC) No. 1085/2003).

Lists of Questions

The Committee adopted eight Lists of Questions on initial applications (1 Part A and 7 Part B) and three Lists of Questions on "line extensions" applications (Part B) (in accordance with Annex II of Commission Regulation (EC) No. 1085/2003).

Application for marketing authorisation for orphan medicinal product

Details of those orphan medicinal products that have been subject of a centralised application for marketing authorisation since the July 2005 CHMP are provided in **Annex 4**.

Post-Authorisation follow-up

- **Hexavac** (comb vaccine) from Pasteur Merieux MSD

  The EMEA is recommending, as a precautionary measure, the suspension of the marketing authorisation for Hexavac due to concerns about the long-term protection against hepatitis B. For further information, please refer to the Press Release and to the Questions and Answers document published on 20 September 2005 at the EMEA website:
  http://www.emea.eu.int/pdfs/human/press/pr/29736905en.pdf
  http://www.emea.eu.int/pdfs/human/press/pr/30488805en.pdf

Detailed information on the centralised procedure

An overview of centralised procedures since 1995 is given 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 July 2005 is provided in **Annex 2.** The post-authorisation centralised procedures finalised during this meeting are summarised in **Annex 3**.

Other procedures

- **Review of NSAIDs**

  The Committee continued its assessment of the available data on the cardiovascular, gastro-intestinal and skin safety of non-selective non-steroidal anti-inflammatory drugs (NSAIDs). It is expected that an overall view on the different safety aspects considered in this review will be reached during the Committee's October 2005 meeting.

Referral procedures

Finalised referral procedures

- The CHMP finalised a referral procedure for **Adartrel** (ropinirole), from Laboratoires GlaxoSmithKline, with the recommendation to approve the medicinal product for the treatment of moderate to severe idiopathic restless legs syndrome. The referral was initiated because of concerns regarding efficacy and long-term safety by Spain and The Netherlands under Article 29(2) of Directive 2001/83/EC as amended. After reviewing all available evidence the Committee concluded that the benefit-risk balance for Adartrel is positive and that a marketing authorisation should be granted.

- The CHMP recommended the harmonisation of the summaries of product characteristics (SPCs) of three generic medicinal products containing lanzoprazol. **Lanzoprazol AbZ** and **Lanzoprazol-CT** were reviewed because of differences in the posology section between the SPCs of the reference product and the SPCs of the generic products. The procedure was initiated by Germany under Article 29(2) of Directive 2001/83/EC as amended. The procedure for **Lanzoprazol-ratiopharm** was initiated on the same legal basis by Germany and Portugal because of differences in the posology and indication section of the SPCs.

Start of referral procedures

- The CHMP began a referral procedure for the generic product **Ceftriaxone Tyrol 1g and 2g** (ceftriaxone) from Sandoz Ltd, because of differences between the SPC of the reference product and the SPC of the generic product, concerning the dosing of newborn infants. The procedure was initiated by the United Kingdom under Article 29(2) of Directive 2001/83/EC as amended.

- The CHMP began a referral procedure for the generic product **Nifedipine Pharmamatch retard 30 and 60 mg (nifedipine),** from Pharmamatch BV. The procedure concerns differences between the SPC of the reference product and the SPC of the generic product relating to contraindications during pregnancy and lactation. It was initiated by the United Kingdom under Article 29 (2) of Directive 2001/83/EC as amended.

- The CHMP began a referral procedure for **Stamaril** and associated tradenames, from Sanofi Pasteur MSD, in order to harmonise the national SPCs, in particular the sections dealing with indications and safety aspects, across the European Union. The referral was made by the marketing authorisation holder under Article 30 of Directive 2001/83/EC as amended.

- The Committee began referral procedures for **Seretide Diskus, Viani Diskus, Seretide Evohaler and Viani Evohaler** from GlaxoSmithKline. These products are used in the treatment of asthma. The matter was referred to the CHMP by the marketing authorisation holder under Article 6(13) of Commission Regulation (EC) No 1084/2003. The Committee is requested to consider whether or not the proposed extension of indication should be granted.

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 30 August – 1 September 2005 For further details, please see **Annex 5**.

Documents prepared by the CHMP Working Parties adopted during the September 2005 CHMP meeting are listed in **Annex 6**.

Upcoming meetings following the September 2005 CHMP plenary meeting:

- The Informal CHMP meeting hosted by the UK Authorities will be held in Dorking on 2-4 October 2005.
- An Expert Workshop on Plasma-Derived and Urine-Derived medicinal products and vCJD Risk will be held at the EMEA on 6-7 October 2005.
- The 15th meeting of the CHMP will be held at the EMEA on 10 – 13 October 2005.
- The next Invented Name Review Group meeting will be held at the EMEA on 10 October 2005.
- The next Mutual Recognition Facilitation Group Meeting will be held at the EMEA on 10 –11 October 2005.
- The EMEA/EWP Workshop on validation of scales will be held at the EMEA on 21 October 2005.
- The EMEA /EFPIA info day 2005 will be held at the EMEA on the 21 October 2005 (registration through EFPIA).
- The EMEA/CHMP Biomarker Workshop (with academia and health professionals) in the development of new medicines will be held at the EMEA on 16 December 2005.

Organisational matters

The main topics addressed during the September 2005 CHMP meeting related to:

- The adoption of the revised Composition of the Blood Products Working Party.
- The adoption of the revised Composition of the Gene Therapy Working Party.
- The adoption of the Work Programme 2005-2006 of the Working Party on Cell Based Products.
- The adoption of the Composition of the Pharmacovigilance Working Party.
- The adoption of the Mandate, Objectives and Rules of Procedure of the Central Nervous System Scientific Advisory Group.
- The updated EMEA Policy and Procedure on the Handling of conflicts of interests further to one-year experience of the procedure. This updated EMEA Policy will be presented to the EMEA Management Board on 28-29 September 2005.

- The finalisation of the "Guideline on Similar Biological Medicinal Products".
  This Guideline is transmitted to the European Commission.

EMEA Implementation of the New EU Pharmaceutical Legislation

The seventh CHMP/EMEA Implementation Task Force (CEITAF) meeting took place on Monday 12 September 2005.

The following Guideline was adopted by the CHMP and will be published on the EMEA website:

- Renewals in the Centralised procedure
  The updated Guideline on renewals will also be transmitted to the European Commission for publication as part of the Notice To Applicants Volume 2C.

The following documents were agreed by the CHMP and will be transmitted to the European Commission:

- Scope mandatory indications:
  Guideline on therapeutic areas within the mandatory scope of the centralised procedure for the evaluation for marketing authorisation applications with reference to Article 3 and the Annex of Regulation (EC) No 726/2004.

- Guideline on reporting of suspected transmission of any infectious agent via a medicinal product.

Initial discussions took place on the following topics:

- Opinion on any scientific matter.

- Guidance for the incorporation of risk management concepts into CHMP Opinions and Assessment Reports.

- Generic applications (draft procedural Timetable and CHMP Assessment Report template).

PROCEDURAL ANNOUNCEMENT

- **Change in the method for payment of fees for Centralised Procedures**

  The European Medicines Agency (EMEA) will change the method for payment of fees for all centralised procedures submitted and validated on or after the 1st December 2005.
  For all such procedures the Applicant should not pay the corresponding fee in advance. Instead the EMEA will issue an invoice on the date of the notification of the administrative validation to the applicant and fees will be payable within 45 days of the date of the said notification. The invoice will be sent to the billing address indicated by the Applicant and will contain clear details of the product and procedures involved, the type of fee, the amount of the fee, the bank account to where the fee should be paid and the due date for payment. Where more than one procedure is processed in a given month a summary invoice or statement will be issued at the end of each month for payment within 30 days of the end of the month.
  In order to prepare for a smooth transition the EMEA will shortly be contacting all Applicants to confirm the billing addresses and to coordinate the application of any credits outstanding in their favour as of 30th November 2005.

- **Transitional phasing-in Guidance of the new legislation**

  The guidance document on Practical considerations on the phasing-in of the new legislation on new/ongoing applications and centrally authorized medicinal products has been published on the EMEA website:
  http://www.emea.eu.int/pdfs/human/euleg/24328005en.pdf

- **Guidance for the provision of data (excluding paediatric data) not yet submitted to the EMEA**

  To follow-up on a letter from the EMEA sent in February 2005 to all marketing authorisation holders (MAHs), as part of the EMEA exercise concerning their legal obligations to submit data, a document ”Guidance for the provision of data (excluding paediatric data) not yet submitted to the EMEA" has been adopted. This guidance document will be addressed to all MAHs and is available on the EMEA website http://www.emea.eu.int.

  This guidance only focuses on data (excluding paediatric data) for which no regulatory actions are deemed necessary by the MAH and gives details on the content, format and timelines of the data to be submitted. The submission of these data should be viewed as an information gathering baseline exercise in order to get an overview of data not yet submitted to the EMEA.
  Following the receipt of this guidance document, information from MAHs is expected to be received by the end of 1Q2006.

Mutual Recognition procedure

The CHMP noted the report from the Mutual Recognition Facilitation Group (MRFG) meeting held on 12-13 September 2005. For further details, please see **Annex 7**.

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

EMEA CENTRALISED PROCEDURES

	1995 - 2004	2005	Overall Total
Scientific Advice	433	76	509
Follow-up to Scientific Advice	71	15	86
Protocol Assistance	59	29	88
Follow-up to Protocol Assistance	12	9	21

	1995-2004			2005			Overall Total
	Part A	Part B	Total	Part A	Part B	Total	
Applications submitted	153	303	456	4	24	28	484
Consultation for Medical Device[1]	0	1	1	0	1	1	2
Withdrawals	22	62	84	0	3	3	87
Positive opinions[2]	107	197	304	4	14	18	322[3]
Negative opinions[4]	2	5	7	0	0	0	7[5]
Marketing authorisations granted by the Commission	98	190	288	3	8	11	299[6]

	1995-2004			2005			Overall Total
	Part A	Part B	Total	Part A	Part B	Total	
Variations type I	863	1937	2800	110	327	437	3237
Positive opinions, variations type II	758	886	1644	205	177	382	2026
Negative opinions, variations type II	1	6	7	0	0	0	7
Extensions (Annex II applications)	53	63	116	6	5	11	127

[1] 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 derivatives of human blood or plasma and Directive 2001/104/EC.
[2] 23 positive opinion corresponding to 23 Orphan Medicinal Products
[3] 322 positive opinions corresponding to 251 substances
[4] In case of appeal, the opinion will not be counted twice
[5] 7 negative opinions corresponding to 6 substances (2 of these negative opinions correspond to 2 Orphan Medicinal Products)
[6] 299 marketing authorisations corresponding to 230 substances

ANNEX 2 to CHMP Monthly Report September 2005

MEDICINAL PRODUCTS GRANTED A COMMUNITY MARKETING AUTHORISATION UNDER THE CENTRALISED PROCEDURE SINCE THE JULY 2005 CHMP MONTHLY REPORT

Invented Name	FOSAVANCE
INN	Alendronate sodium / Colecalciferol
Marketing Authorisation Holder	Merck Sharp & Dohme Ltd
Proposed ATC code	M05XX (pending)
Indication	Treatment of postmenopausal osteoporosis in patients at risk of vitamin D insufficiency. FOSAVANCE reduces the risk of vertebral and hip fractures.
CPMP Opinion date	26.05.05
Marketing Authorisation Date	24.08.05

OUTCOME OF THE SEPTEMBER 2005 CHMP MEETING IN RELATION TO CENTRALISED APPLICATIONS IN THE POST-AUTHORISATION PHASE

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
1 Extension of indication	1 Positive opinion
35 SPC changes	35 Positive opinions
39 Quality changes	39 Positive opinions

Opinion for Annual Re-Assessment application		
Name of Medicinal Product (INN)	**Outcome**	**Comments**
Cystagon (mercaptamine) Orphan Europe SARL	Positive Opinion	The authorisation will remain under exceptional circumstances

Opinions for Renewal applications		
Name of Medicinal Product (INN)	**Outcome**	**Comments**
Ovitrelle (choriogonadotropin alfa) Serono Europe Limited	Positive Opinion	---
Panretin (alitretinoin) Ligand Pharmaceuticals Ltd	Positive Opinion	---
Luveris (lutropin alfa) Serono Europe Limited	Positive Opinion	---
Betaferon (interferon beta –1b) Schering AG	Positive Opinion	---
NeoSpect (depreotide) Amersham Health AS	Positive Opinion	---

OVERVIEW OF DESIGNATED ORPHAN MEDICINAL PRODUCTS THAT HAVE BEEN THE SUBJECT OF A CENTRALISED APPLICATION FOR MARKETING AUTHORISATION: UPDATE SINCE THE JULY 2005 CHMP MEETING

Active substance	**Sponsor/applicant**	**EU Designation Number & Date of Orphan Designation**	**Designated Orphan Indication**
Betaine anhydrous (Cystadane)	Orphan Europe SARL	EU/3/01/045 09/07/2001	Treatment of homocystinuria
Dexrazoxane (Savene)	TopoTarget A/S	EU/3/01/059 19/09/2001	Treatment of anthracycline extravasations
Carboxypeptidase G2	Protherics PLC	EU/3/02/128 03/02/2003	Adjunctive treatment in patients at risk of methotrexate toxicity
Sitaxsentan sodium (Thelin)	Encysive (UK) Ltd	EU/3/04/234 21/10/2004	Treatment of pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension

OUTCOME OF THE SEPTEMBER 2005 CHMP MEETING IN RELATION TO SCIENTIFIC ADVICE PROCEDURES

Substance	Intended indications(s)	Type of Request				Topic			
		New		Follow-up		Pharma ceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Neutropenias			X				X	
Chemical	Atherothrombotic events	X						X	
Chemical	Major depressive episode and Bipolar I disorder	X						X	
Chemical	Vulvovaginal candidiasis	X						X	
Chemical	Venous thromboembolism			X				X	
Chemical	Congenital venous malformations				X		X		
Chemical	Inflammatory and neuropathic pain	X						X	
Chemical	Brain metastases in non-small cell lung cancer	X						X	
Chemical	Fungal infection in Haematopoietic stem transplant	X						X	
Biological	Angioedema				X			X	
Chemical	Osteoporosis	X						X	

Chemical	Stem cell transplantation				X			X	
Biological	Non-small cell lung cancer	X				X	X	X	
Chemical	Hyperphosphataemia and dyslipidaemia	X						X	
Chemical	Schizophrenia, Manic episode	X				X		X	
Chemical	Attention Deficit/Hyperactivity Disorder			X				X	
Chemical	Multiple sclerosis, Rheumatoid arthritis, renal cell carcinoma, metastatic breast cancer, mantle cell lymphoma	X				X		X	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 11 Scientific Advice letters, 3 Follow-up Scientific Advice letters and 3 Follow-up Protocol Assistance letters were adopted at the 12-15 September 2005 CHMP meeting.

The Committee accepted 10 Initial Scientific Advice Requests, 2 Follow-up Scientific Advice Requests, 6 Initial Protocol Assistance Requests, and 3 Follow-up Protocol Assistance Request started in September (30 August-1 September) 2005.

DOCUMENTS PREPARED BY THE CHMP WORKING PARTIES ADOPTED DURING THE SEPTEMBER 2005 CHMP MEETING

BIOLOGICS WORKING PARTY

Reference number	Document	Status
CHMP/BWP/188268/05	Guideline on validation of immunoassay for the detection of antibody to human immunodeficiency virus (Anti-HIV) in plasma pools	Released for 3 months consultation
CHMP/BWP/188270/05	Guideline on validation of immunoassay for the detection of Hepatitis B virus surface antigen (HbsAg) in plasma pools	Released for 3 months consultation
CHMP/BWP/229472/05 CPMP/BWP/243/96	Concept paper on the revision of the note for guidance on allergen products Production and quality issues	Released for 3 months consultation

EFFICACY WORKING PARTY

Reference number	Document	Status
EMEA/CPMP/EWP/504/ 97 Rev. 1	Guideline on clinical investigation of medicinal products in prevention and treatment of acute respiratory distress syndrome	Released for 6 months consultation
EMEA/CHMP/EWP/561/ 98 Rev 1	Guideline on clinical investigation of medicinal products for the treatment of multiple sclerosis	Released for 6 months consultation

SCIENTIFIC ADVISORY GROUP

Reference number	Document	Status
CHMP/211527/2005	Central Nervous System (CNS) SAG Mandate, Objectives and Rules of Procedure	Adopted

Report from the meeting held on 12 and 13 September 2005

General Issues

Guideline on the processing of renewals in the mutual recognition and decentralised procedures

The updated guideline on renewals in the mutual recognition and decentralised procedure has been finalised by the MRFG and is currently published on the website for consultation. In order to allow Interested Parties a 3-week consultation period, the MRFG has agreed to extend the deadline for comments, to be sent to the MRFG secretariat (sonia.ribeiro@emea.eu.int) coordinated where possible by trade associations, until 28 September 2005.

Questions and Answers on the implementation of the new legislation

A Q&A document outlining practical considerations on the implementation of the new legislation to medicinal products for human use authorised or applied for via the mutual recognition procedure or the new decentralised procedure has been agreed by the MRFG. The Q&A document will be published on the website and further Q&As will be added as they are developed.

MRFG/CMD(h) Concept paper – Achieving harmonised patient information

The MRFG has finalised the Concept paper - Achieving harmonised patient information, taking account of the comments received following the consultation procedure. The final Concept paper will be published on the website.

Decentralised procedure – Member States' Standard Operating Procedure

Following the agreement on the Flow Chart of the Decentralised procedure (see July MRFG press release), the MRFG has drafted a detailed procedural guidance to complement the flow-chart. The Decentralised procedure – Member States' Standard Operating Procedure will be published on the website, for information to Interested Parties. A short period will be given for comments, to be sent to the MRFG secretariat (sonia.ribeiro@emea.eu.int) coordinated where possible by trade associations, until 28 September 2005, ahead of final agreement at October MRFG.

Best Practice Guide for the Public Assessment Report in the Decentralised and Mutual Recognition Procedure

The MRFG has agreed a Best Practice Guide for the Public Assessment Report in the Decentralised and Mutual Recognition Procedure, to comply with the requirements set **out in Article 21(4) of Directive 2001/83/EC, as amended. The Best Practice Guide will be published on the website.**

Working group meeting on harmonisation of SPC's

In view of the role of the Coordination group to lay down a list of medicinal products for which a harmonised SPC should be drawn up, in accordance with Article 30(2) of Directive 2001/83/EC, as amended, a Working Group, with representatives from the CHMP, MRFG, EMEA and EC, met in September to have preparatory discussions in relation to the mandate for the new Group and the criteria for the selection of products for SPC harmonisation.

Information on MR procedures for new active substances

A mutual recognition procedure for a medicinal product containing treprostinil has been finalised on 10 August 2005. Please find below information on the Invented name, INN, MAH, Indication, Procedure number and Day 90.

Invented Name (RMS)	Remodulin 1 mg/ml, 2.5 mg/ml, 5 mg/ml, 10 mg/ml
INN	Treprostinil sodium
Marketing Authorisation Holder	United Therapeutics Corporation
Indication	Treatment of primary pulmonary arterial hypertension to improve exercise tolerance and symptoms of the disease in patients classified as NYHA Class III (New York Heart Association).
Procedure number	FR/H/0278/001-4
Day 90	10.08.2005

Updated monitoring

An abridged version of the report from the MRFG Plenary meeting is published initially including data for July. The updated monitoring will be published later in September and it will include the data for both July and August 2005.

Mutual Recognition Monitoring

The MRFG noted that **119** new mutual recognition procedures were finalised during the month of July 2005, as well as **333** type IA variations, **187** type IB variations and **131** type II variations.

The status as of 31st of July of procedures under mutual recognition is as follows:

Year	Procedures from New applications finalised	Procedures from New applications in process	Procedures from Type IA variations finalised	Procedures from Type IB variations finalised	Procedures from Type II variations finalised	Arbitrations referred to CHMP
2005	572	349	2224	1097	712	2 Var.

116 new procedures (regarding **305** products) started in July 2005. The categories of these procedures are as follows:

18 known active substances (already authorised in at least one member state), including **2** repeat use.

95 abridged applications including **38** multiple applications and **6** repeat use.

3 line extension applications including **1** repeat use.

The new procedures started related to **15** full dossiers, **88** generics, **3** bibliographic applications, **3** fixed combinations, and **7** for different use, route or dose.

The procedures consisted of **113** chemical substances, 1 herbal medicinal product, **1** biological-vaccine and **1** biological-other[1].

111 of these procedures were prescription-only medicinal products in the reference Member State and **5** procedure were classified as a Non-prescription (including OTC) medicinal product[2].

1. As considered by RMS.
2. In this category products are classified as prescription-only or Non-prescription (OTC) products when the RMS has approved them accordingly, although the legal status is not part of the Mutual Recognition Procedure.

Number of countries involved in the new applications procedures started in July 2005

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
AT (2)	8
AT (2)	4
CZ (3)	16
DE (1)	14
DE (1)	8
DK (2)	1
DK (1)	8
DK (1)	7
DK (2)	3
DK (2)	6
DK (2)	2
DK (2)	2
DK (2)	9
DK (2)	7
DK (2)	1
DK (2)	1
DK (2)	1
DK (4)	8
DK (2)	9
DK (2)	4
DK (2)	1

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DK (2)	5
DK (2)	1
DK (3)	1
DK (3)	1
DK (3)	3
DK (3)	1
DK (3)	1
DK (3)	1
DK (2)	11
DK (1)	4
DK (1)	14
DK (4)	2
DK (4)	6
DK (4)	1
DK (4)	8
DK (4)	1
DK (4)	1
DK (4)	1
DK (2)	1
DK (3)	1
DK (3)	1
ES (2)	8
FI (3)	8
FI (3)	2
FI (3)	1
FI (3)	10
FI (5)	1
FI (4)	1
FI (5)	1
FI (5)	1
FI (5)	11
FI (5)	4
FI (5)	12
FI (5)	2
FI (5)	2
FI (5)	3
FI (5)	10
FI (5)	1
FI (1)	1
FI (5)	4
FI (5)	10
FI (5)	4
FI (5)	1
FI (5)	1
FI (3)	4
FI (3)	1
FI (3)	1
FI (3)	1
FI (5)	4
FI (4)	5
FI (4)	4
FI (4)	19
FR (1)	8
FR (3)	4
FR (2)	26
NL (1)	9
NL (2)	17
NL (2)	6
NL (2)	1
NL (2)	1
NL (2)	1
NL (2)	1
NL (1)	1

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
NL (1)	1
NL (1)	4
NL (1)	1
NL (1)	7
NL (1)	9
NL (1)	1
NL (1)	1
NL (1)	1
NL (1)	1
NL (1)	7
NL (1)	1
NL (1)	1
NL (1)	6
NL (1)	2
NL (1)	9
PT (2)	1
SE (1)	4
SE (3)	3
SE (2)	1
SE (1)	2
SE (3)	2
SE (3)	7
SE (3)	2
SE (3)	6
SE (3)	1
SE (3)	1
SE (3)	1
UK (1)	8
UK (2)	1
UK (1)	2
UK (3)	7
UK (1)	12

All documents mentioned in this press release can be found at the MRFG website at the European Medicines Authorities Windows under the heading MRFG Guidance.

Information on the above mentioned issues can be obtained from the presiding chair of the MRFG:

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Or you could visit the ***MRFG web site*** *at the EUROPEAN NATIONAL MEDICINES AUTHORITIES WINDOW:*
http://heads.medagencies.org/