The European Agency for the Evaluation of Medicinal Products
Evaluation of Medicines for Human Use

5 November 2003
EMEA/CPMP/4482/03/Rev 2

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS
SEPTEMBER 2003 PLENARY MEETING
MONTHLY REPORT

The Committee for Proprietary Medicinal Products (CPMP) held its 96th plenary meeting from 23-25 September 2003.

The CPMP Chairman, on behalf of the Committee, thanked Prof. R. Bass for his work for the CPMP and extended a welcome to Prof. T. Ott, who was attending the CPMP for the first time as CPMP Member. Also, the CPMP Chairman, on behalf of the Committee, thanked Dr P. Arlett for his work for the CPMP and extended a welcome to Dr F. Rotblat, who replaced him.

The CPMP Chairman, Dr D. Brasseur, also welcomed Prof. Raul Kiivet from Estonia, who was attending the CPMP for the first time.

Product related issues

Centralised procedures

The CPMP adopted one opinion on an initial marketing authorisation application at this meeting:

- A positive opinion on the marketing authorisation application for **Zevalin** (ibritumomab tiuxetan), from Schering AG, which is intended for the treatment of non-Hodgkin's lymphoma. EMEA review began on 24 March 2003 and the opinion was adopted on 25 September 2003, with an active review time of 115 days.
  A summary of this opinion is available on the EMEA web site: http://www.emea.eu.int.

The Committee also gave one positive opinion on a new indication for an already authorised medicinal product:

- Extension of the indication for **Enbrel** (etanercept), from Wyeth Europe Ltd, to include the treatment of severe ankylosing spondylitis in adults. Enbrel is currently indicated for the treatment of rheumatoid arthritis and psoriatic arthritis in adults and for juvenile chronic arthritis. Enbrel was first authorised in the European Union in February 2000.
  Further information will be included in the public assessment report (EPAR) once the European Commission has taken its decision.

The Committee also adopted three opinions for 3 "line extension" applications (in accordance with Annex II of Commission Regulation (EC) No. 542/95, as amended) (1 Part B and 2 Part A), 2 Lists of Questions on initial Marketing Authorisation applications (1 Part B and 1 Part A) and 3 Lists of Questions on "line extension" applications (in accordance with Annex II of Commission Regulation (EC) No. 542/95, as amended) (3 Part B).

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 CPMP plenary meeting in July 2003 is provided in **Annex 2**. The post-authorisation centralised procedures finalised during this meeting are summarised in **Annex 3**.

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Referrals

Referral under Article 7(5) of Commission Regulation (EC) No 541/95

- A referral for Arbitration under Article 7(5) of Commission Regulation (EC) No 541/95, as amended was initiated by France on a medicinal product containing donepezil (Aricept from EISAI S.A.S.) The referral relates to an application under the Mutual Recognition procedure for a new indication ("type II variation") for vascular dementia. A Rapporteur and Co-Rapporteur were appointed and the review procedure has been started.

The Committee finalised a Community-wide review for:

- **Laurina and associated names** (containing desogestrel and ethinyl estradiol). These combined oral contraceptives are currently licensed in a number of Member States. The arbitration referral related to proposed changes to the wording of the product information. The CPMP concluded that the data were not sufficient to support the requested product safety claims, but agreed to changes in the warnings and statements about venous and arterial thromboembolism to bring the product information in line with the September 2001 CPMP position on combined oral contraceptives. The referral was made by Germany under Article 7(5) of the Variations Regulation (Commission Regulation (EC) No 541/95) in November 2002.

Referral under Article 29(2) of Directive 2001/83/EC (previously Article 10(2) of CD 75/319/EEC)

- The CPMP began a Community-wide for generic products containing Amlodopine maleate. The arbitration referral was initiated by Germany and related to public health concerns over potential differences in the quality profile between the generic products and innovator product. The application is currently under review in the Mutual Recognition procedure. The arbitration referral is made under Article 29 of the Community Code on human medicines. A Rapporteur and Co-Rapporteur were appointed and the review procedure has started.

Referral under Article 30 of Directive 2001/83/EC (previously Article 11 of CD 75/319/EEC)

The Committee finalised a Community-wide review for:

- **Zestril** and associated names (lisinopril). The product is already authorised in all the EU Member States and Norway. The CPMP recommended harmonisation of the authorised indications of these products as follows: treatment of hypertension, treatment of symptomatic heart failure, short-term (6 months) treatment of haemodynamically stable patients within 24 hours of an acute myocardial infarction, treatment of renal disease in hypertensive patients with type 2 diabetes mellitus and incipient nephropathy. The review was initiated by The Netherlands under Article 30 of the Community Code on human medicines in July 2002.

Referral under Article 31 of Directive 2001/83/EC (previously Article 12 of CD 75/319/EEC)

The Committee finalised a Community-wide review for:

- **Gatifloxacin**-containing medicinal products. These products are either already authorised or awaiting authorisation in a number of EU Member States and Iceland. The referral related to safety and efficacy concerns of the products. The CPMP concluded that there was a positive balance of benefits and risks for these products in the treatment of community-acquired pneumonia (mild to moderate) and in the treatment of complicated urinary tract infections (excluding prostatitis and epididymitis). The review was initiated by Belgium under Article 31 of the Community Code on human medicines in April 2002

Invented Name Review Group

The Invented Name review Group held its 41st meeting on 22 September 2003, and the conclusions of the group were subsequently adopted by the CPMP. Since the July 2003 NRG meeting, observers form Acceding Countries have attended the meeting.

The procedure for checking the acceptability of Invented Names of Human Medicinal products and the submission forms for new proposed Invented Names are now published on the EMEA website (see procedural announcement below).

The next meeting of the Invented Name review Group will take place on 20 October 2003.

Non-product related issues

CPMP Working Parties and Ad Hoc Groups

The CPMP was informed of the outcome of the discussions of the Scientific Advice Working Group (SAWG) meeting, which was held on 8 - 9 September 2003. For further details, please see **Annex 4**.

Documents prepared by the CPMP Working Parties and Ad Hoc Groups adopted during the September 2003 CPMP meeting are listed in **Annex 5**.

The Ad Hoc Expert Group on Pharmacogenetics (Chairperson Dr E. Abadie) will hold its next meeting on 15 October 2003.

The Report from the Ad hoc meeting of CPMP Gene Therapy Expert Group held on 26-27 June 2003 has been published in the EMEA Web Site:

http://www.emea.eu.int/pdfs/human/genetherapy/538203en.pdf.

Upcoming meetings following the September 2003 CPMP plenary meeting:

-An EMEA-EFPIA Joint Seminar was held on 26 September 2003 in London. This seminar was entitled: "Countdown to the new Europe: The practical implications of EU Enlargement for Regulatory Affairs professionals".

-The next Informal CPMP meeting under the Italian EU Presidency will be held in Rome on 13-14 October 2003.

-An EMEA-EFPIA Info Day will be held at the EMEA on 24 October 2003.

Organisational Matters

The 26th CPMP Organisational Matters meeting took place on Monday 22 September 2003, chaired by Dr D. Brasseur. Topics addressed during the meeting related to:

- Discussion on issues related to Working Parties

  In view of substantial workload related to product specific issues and in order to ensure the optimum conduct of the plenary CPMP meeting, it was agreed that in future there will be no scheduled discussion of issues related to Working Parties (WPs) during the CPMP meeting (other than the Scientific Advice Working Group, and product related issues from the Pharmacovigilance Working Party, the Biotechnology Working Party and the Vaccines Expert Group). It is intended that all Working Parties' documents [Concept Papers, Guidelines (for release for consultation or adoption by the CPMP), Points to Consider etc] should be presented during the monthly ORGAM meetings and then be adopted during the voting slots of the plenary CPMP meeting. Items for discussion (i.e. specific or controversial issues/documents of general CPMP interest) can be identified by the WP Chairperson in liaison with the EMEA WP Secretariat in advance of the ORGAM meeting.

- Procedural Guidance documents on the Plasma and Vaccine Antigen Master File respectively and Scientific Guidance on Vaccine Antigen Master File were discussed at ORGAM (These documents are due to be adopted by CPMP in October 2003).
- The main elements of the draft EMEA Post-Authorisation Guidance, including comments received from interested parties during the consultation phase, were discussed by the Group. The revised EMEA Post-Authorisation Guidance was subsequently adopted by the CPMP and is available on the EMEA website http://www.emea.eu.int/htms/human/postguidance/index.htm.
- The Group discussed the consultation procedure of the Scientific Advice Working Group by the CPMP, in the framework of specific obligations or follow-up measures (protocol for preclinical or clinical studies). An agreement has been reached that the CPMP may request a "protocol consultation" to the SAWG in case of any outstanding issues identified by the Rapporteur after assessment of such protocols.
- A proposed framework for discussions at CPMP level on (possible) Public Health Concerns related to medicinal products for human use was presented.
- The Group discussed the outcome of Performance Indicators for the centralised procedure (initial applications).

The next CPMP Organisational Matters meeting is scheduled to take place on Monday 20 October 2003.

Procedural announcement

- In view of the EU Enlargement that will come into force as of the 1 May 2004, Marketing Authorisation Holders are encouraged to provide Module 1 and 2 of their initial Marketing Authorisation applications and Variation Applications for new clinical indications to the currently nominated observers of the 10 Accession Countries (an updated list of the nominated observers is provided in **Annex 6**).

  In addition, the CPMP Rapporteurs' Assessment Reports for the same applications will be sent to the nominated observers in order to facilitate a smooth transition for the 10 Accession Countries joining the EU into the ongoing evaluation work of the CPMP.

- A revision of the format and content of the CPMP Monthly Report / CPMP Press Release will be considered for implementation in the near future.

- The procedure for checking acceptability of invented names of human medicinal products is now published on the EMEA website in the pre-submission guidance: http://www.emea.eu.int/htms/human/presub/q04.htm

  Two submission forms, for new proposed invented names (http://www.emea.eu.int/htms/human/presub/Proposed%20IN%20submission%20form.doc) and, when applicable, **for justification** of a previously not accepted invented name (http://www.emea.eu.int/htms/human/presub/IN%20justification%20form.doc), should be used and sent electronically to the e-mail address NRG@emea.eu.int.

  Any query related to Invented Names for upcoming/on-going or already centrally authorised medicinal products for human use, can also be sent to this e-mail address.

Mutual Recognition procedure

The CPMP noted the report from the Mutual Recognition Facilitation Group (MRFG) meeting held on 22 September 2003. For further details, please see **Annex 7.**

The 97th plenary meeting of the CPMP will be held from 21-23 October 2003.

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

EMEA CENTRALISED PROCEDURES

	1995 - 2002	2003	Overall Total
Scientific Advice	302	49	351
Follow-up to Scientific Advice	50	8	58
Protocol Assistance	13	10	23
Follow-up to Protocol Assistance	4	2	6

	1995-2002			2003			
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Applications submitted	127	239	366	6	24	30	396
Consultation for Medical Device[1]	0	1	1	0	0	0	1
Withdrawals	20	53	73	1	2	3	76
Positive CPMP opinions[2]	92	155	247	6	9	15	262[3]
Negative CPMP opinions[4]	1	4	5	1	1	2	7[5]
Marketing authorisations granted by the Commission	88	146	234	3	12	15	249[6]

	1995-2002			2003			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Variations type I	585	1132	1717	133	290	423	2140
Positive opinions, variations type II	405	511	916	132	131	263	1179
Negative opinions, variations type II	1	6	7	0	0	0	7
Extensions (Annex II applications)	44	44	88	5	8	13	101

[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] 13 positive opinion corresponding to 13 Orphan Medicinal Products
[3] 262 positive opinions corresponding to 199 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] 249 marketing authorisations corresponding to 187 substances

ANNEX 2 to CPMP Monthly Report September 2003

MEDICINAL PRODUCTS GRANTED A COMMUNITY MARKETING AUTHORISATION UNDER THE CENTRALISED PROCEDURE SINCE JULY 2003 CPMP MONTHLY REPORT

Invented Name	Trudexa
INN	adalimumab
Marketing Authorisation Holder	Abbott Laboratories
ATC code	L04AA
Indication	Treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drugs including methotrexate has been inadequate
CPMP Opinion date	22.05.2003

Invented Name	Humira
INN	adalimumab
Marketing Authorisation Holder	Abbott Laboratories
ATC code	L04AA
Indication	Treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drugs including methotrexate has been inadequate
CPMP Opinion date	22.05.2003

Invented Name	Ventavis
INN	iloprost
Marketing Authorisation Holder	Schering AG
ATC code	B01AC
Indication	Treatment of patients with primary pulmonary hypertension or secondary hypertension due to connective tissue disease.
CPMP Opinion date	22.05.2003

OUTCOME OF THE SEPTEMBER 2003 CPMP 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
21 SPC changes	21 Positive opinions
36 Quality changes	36 Positive opinions

Opinion for Annual Re-Assessment applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Avonex (interferon beta-1a) Biogen France S.A	Positive opinion	Marketing Authorisation to remain under exceptional circumstances
Cystagon (mercaptamine) Orphan Europe SARL	Positive opinion	Marketing Authorisation to remain under exceptional circumstances
MabCampath (alemtuzumab) Millenium & Ilex UK Ltd	Positive opinion	Marketing Authorisation to remain under exceptional circumstances

Opinions for Renewal applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Karvezide (irbesartan hydrochlorothiazide) Bristol Myers Squibb Pharma EEIG	Positive opinion	---
CoAprovel (irbesartan hydrochlorothiazide) Sanofi Pharma Bristol Myers Squibb SNC	Positive opinion	---
Micardis (telmisartan) Boehringer Ingelheim International GmbH	Positive opinion	---
Pritor (telmisartan) GlaxoSmithKline	Positive opinion	---
Kinzalmono (telmisartan) Bayer AG	Positive opinion	---

OUTCOME OF THE SEPTEMBER 2003 CPMP MEETING IN RELATION TO SCIENTIFIC ADVICE PROCEDURES

Substance	Intended indications(s)	Type of Request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Mucopolysaccharidosis I		X					X	
Chemical	Atrial fibrillation	X						X	
Chemical	Pseudomonas aeruginosa lung infection in cystic fibrosis				X			X	
Biological	Acute lung injury		X					X	
Biological	Measles, mumps, rubella vaccine	X				X			
Chemical	Atopic dermatitis	X						X	

SA: Scientific Advice

PA: Protocol Assistance

In September 2003, the above-mentioned 3 Scientific Advice letters, 2 Protocol Assistance letters and 1 Follow-up Protocol Assistance letter were adopted.
The Committee accepted 6 Initial Scientific Advice Requests, 1 Follow-up Scientific Advice Request, 2 Initial Protocol Assistance Requests and 1 Follow-up Protocol Assistance Request.

DOCUMENTS PREPARED BY THE CPMP WORKING PARTIES AND AD-HOC GROUPS ADOPTED DURING THE SEPTEMBER 2003 CPMP MEETING

EFFICACY WORKING PARTY

Reference number	Document	Status
CPMP/EWP/2455/02 draft 7	Note for Guidance on allergic conjunctivitis and rhinitis	**Released for 6 months consultation**
CPMP/EWP/4284/02	Note for Guidance on clinical investigation of medicinal products for treatment of Generalised Anxiety Disorder	**Released for 6 months consultation**
CPMP/EWP/4280/02	Note for Guidance on clinical investigation of medicinal products for the treatment of Panic Disorder	**Released for 6 months consultation**
CPMP/EWP/4279/02	Note for Guidance on clinical investigation of medicinal products for the treatment of Obsessive Compulsive Disorder	**Released for 6 months consultation**
CPMP/EWP/3635/03	Concept Paper on clinical investigation of medicinal products for the treatment of social anxiety disorder (social phobia)	**Adopted**
CPMP/EWP/2455/02	Note for Guidance on the Clinical development of Medicinal Products for the treatment of Allergic Rhino-conjunctivitis	**Released for 6 months consultation**

ANNEX 6 to CPMP Monthly Report September 2003

MEMBER NOMINATIONS FROM CANDIDATE COUNTRIES

COUNTRY	MEMBER	ADDRESS	TELEPHONE / FAX	E-MAIL
Cyprus	Panayiota Kokkinou	Ministry of Health (Cyprus) 7 Larnacos Avenue CY - 1475 Lefkosia, Nicosia Cyprus	Telephone: + 357 22 40 71 03 Fax: + 357 22 40 71 49	Rocphc3@cytanet.com.cy
Latvia	Prof Juris Pokratnieks	State Agency of Medicines Jersikas iela 15 Riga, IV LV - 1003 Latvia	Mobile: +371 924 52 44 Fax: +371 707 8428	Pokrot@latnet.lv
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Estonia	Dr Raul Kiivet (Alternate member Dr Alar Irs)	State Agency of Medicines Ravila 19 Tartu 50411 Estonia	Dr Kiivet Telephone: +37 27 374 140 (or 191) Fax: +37 27 374 142	sam@sam.ee Alar.Irs@sam.ee

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			Dr Irs Telephone: + 37 27 37 41 40 Fax: +37 27 37 41 42	
Czech Republic	Prof. Milan Smid	State Institute for Drug Control Srobarova 48 100 41 Prague 10 Czech Republic	Telephone: +420 272 185 835 Fax: +420 272 739 995	smid@sukl.cz
Poland	To be confirmed	Drug Institute/Bureau of Drug and Medical Materials Registration 30/34 Chelmska str. PL-00-725 Warsaw Poland	Telephone: +48 22 8514381 Fax: +48 22 8515243	firstname.surname@urpl.gov.pl
Lithuania	Vladas Volbekas	Drug Registration Commission State Medicines Control Agency in Lithuania Traku 14 LT - 2001 Vilnius Lithuania	Telephone / Fax number: +370 37 22 28 23	volbekas@kaunas.omnitel.net
Slovenia	Dr Vesna Koblar	Agency for Medicinal Products Kersnikova UL.2 SI - 1000 Ljubljana Slovenia	Telephone: + 386 1 478 62 43 Fax: + 386 1 478 62 60	Vesna.Koblar@gov.si

The European Agency for the Evaluation of Medicinal Products
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ANNEX 7 to CPMP Monthly Report September 2003

Report from the meeting held on 22 September 2003

General Issues

Position Paper on Repeat Use of the MRP
The final revised "Position Paper on Repeat Use of the MRP" was adopted at the September meeting and will be published on the Website. The document now contains a paragraph on "Special case – simplified CADREAC procedure".

Best Practice Guides for the Submission and Processing of Variations in the Mutual Recognition Procedures
The revised version of the "Best Practice Guides for the Submission and Processing of Variations in the Mutual Recognition Procedures" has been published on the MRFG website.

The BPGs are applicable only as of 1st October 2003 with the entry into force of the new Variation Regulation (EC) 1084/2003. All information about the numbering system for the new Variation procedures can be found in this document.

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Mutual Recognition Monitoring

The MRFG noted that **69** new mutual recognition procedures were finalised during the months of July and August 2003, as well as **628** type I and **185** type II variations.

The status as of 31 August 2003 of procedures under mutual recognition is as follows:

Year	Procedures from New applications finalised	Procedures from New applications in process	Procedures from Type I variations finalised	Procedures from Type I variations pending	Procedures from Type II variations finalised	Procedures from Type II variations pending	Arbitrations referred to CPMP
2003	267	190	1834	376	487	220	2 N.A. and 2 Variations

150 new procedures (regarding **402** products) started in July and August 2003. The categories of these procedures are as follows:

3 new active substances consisted of 2 chemical substances and 1 biological vaccine.

16 known active substances (already authorised in at least one member state), including **2** multiple and **2** repeat uses.

123 abridged applications; including **36** multiple applications and **1** repeat use.

8 line extension application and

The new procedures started related to **17** full dossiers, **99** generics, **6** bibliographic applications, **1** informed consent, 1 fixed combination and **26** other.

The procedures consisted of **145** chemical substances, **2** biological-vaccine and **2** biological blood product and **1** other[1] .

142 of these procedures were prescription-only medicinal products in the reference Member State and **8** were Non-prescription (including OTC) medicinal products[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 and August 2003

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
AT (3)	6
AT (2)	12
DE (1)	6
DE (1)	4
DE (1)	12
DE (1)	14
DE (2)	2
DE (4)	2
DE (8)	1
DE (4)	4
DK (2)	1
DK (2)	10
DK (1)	5
DK (2)	1
DK (2)	1
DK (2)	1

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DK (3)	8
DK (2)	1
DK (3)	1
DK (1)	3
DK (2)	2
DK (3)	2
DK (3)	1
DK (3)	1
DK (4)	10
DK (4)	2
DK (4)	1
DK (4)	1
DK (4)	1
DK (4)	1
DK (4)	1
DK (4)	3
DK (4)	3
DK (1)	6
DK (2)	1
DK (2)	1
DK (2)	1
DK (2)	1
DK (2)	1
DK (2)	1
DK (2)	1
DK (2)	1
DK (2)	1
DK (2)	1
DK (2)	1
DK (2)	1
DK (2)	1
DK (2)	1
DK (2)	1
DK (4)	11
DK (3)	1
DK (4)	1
DK (4)	1
DK (4)	1
DK (4)	1
DK (4)	1
DK (3)	1
DK (4)	1
DK (4)	1
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DK (4)	1
DK (4)	1
DK (4)	1
DK (4)	1
DK (4)	1
DK (3)	1
DK (3)	1
ES (1)	9
FI (2)	2
FI (2)	2
FI (2)	8
FI (5)	3
FI (5)	2
FI (3)	1

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
FI (4)	5
FI (5)	1
FI (5)	1
FI (3)	15
FI (3)	8
FI (3)	3
FI (4)	2
FI (4)	1
FI (4)	2
FI (4)	6
FI (4)	6
FI (4)	1
FR (2)	8
FR (1)	1
FR (1)	9
FR (1)	8
NL (1)	12
NL (1)	1
NL (1)	1
NL (1)	3
NL (1)	4
NL (2)	10
NL(2)	1
NL (2)	1
NL (2)	11
NL (3)	11
NL (3)	10
NL (4)	4
NL (2)	1
NL (2)	1
NL (2)	1
NL (1)	6
NL (2)	8
NL (2)	5
NL (2)	1
NL (2)	1
NL (2)	1
NL (2)	3
NL (2)	2
NL (2)	8
NL (1)	14
NL (4)	7
SE (1)	4
SE (1)	1
SE (1)	16
SE (2)	2
SE (4)	3
SE (1)	1
SE (2)	2
SE (1)	2
SE (1)	3
SE (1)	7
SE (2)	1
SE (2)	1
SE (2)	1
SE (2)	1
SE (2)	1
SE (2)	1
SE (4)	3
SE (4)	2
SE (4)	1
SE (4)	1
SE (4)	4

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
SE (1)	13
UK (2)	5
UK (3)	1
UK (3)	5
UK (1)	3
UK (1)	6
UK (1)	7
UK (5)	5

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

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

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