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

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CPMP/2522/00

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 63rd plenary meeting from 19 to 21 September 2000.

An Ad Hoc CPMP/EMEA/Interested Parties meeting was held in the afternoon of the 21 September 2000 in order to prepare contributions for the upcoming EMEA Workshop on Transparency which is planned to be held prior to the end of this year.

Membership of the CPMP and its Working Parties

Dr Hans van Bronswijk has been elected as Vice-Chair of the CPMP, in replacement of Dr Mary Teeling.

The CPMP welcomed Prof Rolf Bass from Germany and Dr Patrick Salmon from Ireland as new members, succeeding respectively Prof Alfred Hildebrandt and Dr Mary Teeling.

The CPMP appointed Dr van Zwieten-Boot, currently Vice-Chair of the EWP, to act as Chairperson for the remaining two EWP meetings.

The CPMP warmly thanked Prof Giuseppe Vicari (Italy), who resigned as chairman of the Biotechnology Working Party, for his excellent achievements and collaboration.

The CPMP appointed Prof Jean-Hugues Trouvin (France) as chairman of the Biotechnology Working Party.

Furthermore, at the July 2000 CPMP meeting, the following CPMP Members were appointed by CPMP, to take over Dr Mary Teeling's other duties:

- Dr Markku Toivonen (Finland) as new Chairman of the Scientific Advice Review Group
- Dr Patrick Salmon (Ireland) as new chair of the Ad Hoc Expert Group on update of Guidance on Summary of Product Characteristics
- Dr Eric Abadie (France) as new ICH Steering Committee CPMP representative

These appointments are for the remaining term of the present CPMP mandate (December 2000).

Centralised Procedures[1]

In August 2000, the CPMP adopted by written procedure 8 positive opinions for centralised type I variations following a type II procedure and 6 positive opinions for centralised type II variations.

During its September 2000 CPMP plenary meeting, the Committee adopted:

- Six positive opinions on initial centralised marketing authorisation applications by consensus relating to two active substances (Part B).
- Two positive opinions on "line extension" applications (in accordance with Annex II of the Commission Regulation (EC) No 542/95 as amended) by consensus relating to two applications (one Part A application for a new multidose presentation and one Part B application for new strengths concerning two already centrally authorised medicinal products).

[1] Note for Editors:
Applicants may appeal any CPMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

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- Three positive opinions by consensus for centralised type I variations following a type II procedure.
- Fourteen positive opinions by consensus for centralised type II variations.
- Three positive opinions by consensus following the annual re-assessment of:
  - Avonex (interferon beta-1a) (Part A) indicated for the treatment of multiple sclerosis
  - Cystagon (mercaptamine bitartrate) (Part B) indicated for the treatment of nephropathic cystinosis
  - Vitravene (fomivirsen sodium) (Part B) indicated for local treatment of CMV retinitis in patients with AIDS

  The CPMP recommended that the three above mentioned marketing authorisations should remain "under exceptional circumstances".
- Two positive opinions by consensus on the renewal of the marketing authorisation relating to two active substances (one Part A and one Part B).
- The Committee adopted three lists of questions (two Part B and one Part A) and heard four oral presentations from applicants concerning ongoing procedures.

An overview of centralised applications is given in Annex I.

For marketing authorisations granted by the European Commission since the last CPMP in July 2000, see Annex II.

Scientific Advice

The Committee adopted the following scientific advice letters:

Product	**Indication(s)**	**Topic**
Chemical Substance	Metastatic bone disease of breast cancer	Scientific Advice sought on clinical development programme.
Chemical Substance	Parkinson's disease	Scientific Advice sought on clinical development programme.
Chemical Substance	Generalised anxiety disorder	Scientific Advice sought on the quality, pre-clinical and clinical development programmes.
Chemical Substance	Schizophrenia	Scientific Advice sought on the pre-clinical and clinical development programmes.
Chemical Substance	Stress urinary incontinence	Scientific Advice sought on clinical development programme.
Chemical Substance	Colorectal adenomas and colorectal cancer	Scientific Advice sought on clinical development programme.
Biological Substance	Chronic hepatitis B,C, chronic myelogenous leukaemia and renal cell carcinoma	Scientific Advice sought on quality development programme.

In August 2000, there two following final scientific advice letters were also adopted by written procedure:

Product	**Indication(s)**	**Topic**
Chemical Substance	Modular and superficial basal cell carcinoma	Scientific Advice sought on clinical development programme.
Chemical Substance	Actinic keratosis	Scientific Advice sought on clinical development programme.

Six new and one follow-up request for scientific advice were accepted and Co-ordinators were appointed.

Referrals

The Committee heard one oral presentation from the marketing authorisation holder concerning ongoing referral procedures.

Working Parties, Ad Hoc Expert Groups and Organisational Matters

The CPMP heard reports from its Quality, Biotechnology, Safety, Efficacy and Pharmacovigilance Working Parties and from the Ad Hoc Working Group on Blood Products.

Safety Working Party

Reference number	Document	Status
CPMP/SWP/2145/00 draft 4	Note for guidance on Non-clinical local tolerance testing of medicinal products	Release in September 2000 for 3-month consultation.

Ad Hoc Expert Group for the revision of the anticancer guideline

Reference number	Document	Status
CPMP/EWP/205/95 rev. 1	Note for guidance on Evaluation of anticancer medicinal products in man	Release in July 2000 for 4 months and consultation period and extended in September 2000 for 2 extra months.

Mutual Recognition

The CPMP noted the report from the Mutual Recognition Facilitation Group (MRFG) of 18 September 2000, which is circulated together with this Press Release (Annex III).

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This Press Release and other documents are available on the Internet at the following address: http://www.eudra.org/emea.html

EMEA CENTRALISED PROCEDURES

	1995-1999			2000			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Scientific Advice	61	77	138	5	26	31	169
Follow-up to scientific advice	11	6	17	1	4	5	22

	1995-1999			2000			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Applications submitted	80	144	224	16	27	43	267
Withdrawals	12	26	38	0	5	5	43
Positive CPMP opinions	44	82	126	13	20	33	159[1]
Negative CPMP opinions[2]	1	3	4	0	1	1	5[3]
Marketing authorisations granted by the Commission	40	78	118	12	11	23	141[4]

	1995-1999			2000			Overall Total
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**	
Variations type I	159	346	505	54	165	219	724
Positive opinions, variations type II	89	131	220	33	66	99	319
Negative opinions, variations type II	0	2	2	0	0	0	2
Extensions	32	15	47	2	2	4	51

[1] 159 positive opinions corresponding to 121 substances
[2] In case of appeal the opinion will not be counted twice
[3] 5 negative opinions corresponding to 4 substances
[4] 141 Marketing Authorisations corresponding to 108 substances

Medicinal products granted a Community Marketing Authorisation under the Centralised Procedure since the July 2000 Press Release

Brand name	Visudyne
INN	verteporfin
Marketing Authorisation Holder	Ciba Vision Europe Ltd.
ATC code	L01XX
Indication	Treatment of age-related macular degeneration in patients with predominantly classic subfoveal choroidal neovascularisation
Opinion receipt date	15/05/00
Date of Commission Decision	27/07/00

Brand name	Datscan
INN	ioflupane
Marketing Authorisation Holder	Nycomed Amersham plc.
ATC code	V09AB03
Indication	Diagnosis of Parkinson's disease
Opinion receipt date	05/05/00
Date of Commission Decision	27/07/00

Brand name	NovoMix 30
INN	insulin aspart
Marketing Authorisation Holder	Novo Nordisk A/S
ATC code	A10A
Indication	Diabetes mellitus
Opinion receipt date	17/05/00
Date of Commission Decision	01/08/00

Brand name	Kogenate Bayer
INN	octocog alfa
Marketing Authorisation Holder	Bayer AG
ATC code	B02BD02
Indication	Congenital factor VIII deficiency
Opinion receipt date	05/06/00
Date of Commission Decision	04/08/00

Brand name	Helixate Nexgen
INN	octocog alfa
Marketing Authorisation Holder	Bayer AG
ATC code	B02BD02
Indication	Congenital factor VIII deficiency
Opinion receipt date	05/06/00
Date of Commission Decision	04/08/00

Brand name	Hepacare
INN	triple antigen hepatitis B vaccine
Marketing Authorisation Holder	Medeva Pharma Ltd
ATC code	J07BC
Indication	Immunisation against infections caused by hepatitis B virus
Opinion receipt date	16/05/00
Date of Commission Decision	04/08/00

Brand name	Herceptin
INN	trastuzumab
Marketing Authorisation Holder	Roche Registration Ltd
ATC code	L01XC03
Indication	Treatment of patients with metastatic breast cancer
Opinion receipt date	03/07/00
Date of Commission Decision	28/08/00

Report from the meeting held on 18 September 2000

The MRFG noted that 69 new mutual recognition procedures were finalised during the months of July and August 2000, as well as 119 type I and 69 type II variations.

The status as of 31 August 2000 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
2000	168	119	650	45	204	140	2 N.A. and 2 variations

104 new procedures (regarding 183 products) started in July and August 2000. The categories of these procedures are as follows:

12 new active substances (first authorisation in the European Community after RMS approval), including **1** multiple application and **4** repeat use.

19 known active substances (already authorised in at least one member state), including **1** multiple application and **3** repeat use.

69 abridged applications including **19** multiple applications and **5** repeat use.

5 line extension applications.

The new procedures started this month relate to 25 full dossiers, 1 informed consent application, 6 bibliographic applications, 56 generics, 2 fixed combinations, and 15 for different use, route or dose.

The procedures consisted of 102 chemical substances and 3 biological products[1].

87 of these procedures were prescription-only medicinal products in the reference Member State and 17 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 2000:

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (1)	6
DE (4)	3
DE (2)	14
DE (1)	13
DE (2)	8
DE (1)	8
DE (1)	9
DE (1)	1
DE (1)	1
DE (4)	5

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (1)	16
DK(4)	4
DK(3)	11
DK(1)	10
DK(1)	1
DK(1)	5
DK(4)	4
DK(4)	11
DK(4)	1
DK(4)	1
DK(1)	1
DK(1)	1
DK(1)	1
DK(1)	1
DK(1)	1
DK(1)	1
DK(1)	1
ES (1)	16
FI (1)	7
FI (1)	14
FI (4)	3
FI (2)	6
FI (1)	5
FR (1)	4
FR (1)	13
FR (1)	2
FR (2)	15
FR (2)	5
FR (1)	1
FR (1)	13
FR (1)	10
FR (1)	16
FR (1)	10
IR (3)	5
IR (3)	4
IR (1)	8
NL (1)	6
NL (2)	2
NL (3)	4
NL (2)	6
NL (13)	5
NL (1)	1
NL (1)	7
NL (2)	8
NL (2)	7
NL (3)	3
NL (2)	13
NL (3)	2
NL (2)	6
NL (4)	4
NL (2)	4

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

General issues

Simplified handling of variations in MRP after a merger

The MRFG discussed a simplified handling of variations in specific cases and agreed the following: if the MAH in case of a merger wants to change the name of manufacturers and/or the name and address of the MAH in different CMSs for a number of products in different strengths and pharmaceutical forms, it is possible to submit one variation per product including the above mentioned changes due to

the merger.

Status of authorisations for MR New applications started within the timeframe of the Joint MRFG – Industry Survey on MRP

The MRFG has been internally monitoring the procedures started within the timeframe of the Survey. Information in the Eudratrack database for those MR-procedures is almost complete and the few missing data will be inserted within the next ten days by the Member States.

MRFG Best Practice Guide for the Reference Member State in the Mutual recognition Procedure

The MRFG adopted this best practice guide which will be published on the Heads of Agencies' Website.

Contact information for the CADREAC Observers in the MRFG
Detailed addresses of the CADREAC observers are indicated below. These addresses can be used by industry in order to send documents to CADREAC observers.

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Meeting schedule

The next MRFG meeting will be held on 16 October 2000.

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 by the presiding chair of the MRFG:

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*Alternatively, you could visit the **MRFG website** at the EUROPEAN NATIONAL MEDICINES AUTHORITIES WINDOW:*

http://heads.medagencies.org/