European Medicines Agency

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

The Committee for Medicinal Products for Human Use (CHMP) held its April plenary meeting from 18 – 21 April 2005.

The Committee noted a change with respect to the Maltese member and alternate. Dr. Borg is now the CHMP member and Dr. Bonnano is the CHMP alternate.

Centralised procedure

Opinions

The CHMP did not adopt any opinion on an initial marketing authorisation application at this meeting.

Extensions of indication and other recommendations

- The CHMP adopted a positive opinion for **Temodal** (temozolomide), from SP Europe, to extend its use to patients with newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and subsequently as monotherapy treatment. Temodal was first authorised in the European Union on 26 January 1999 for the treatment of malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy.

- The Committee also recommended changes in the way **Xigris** (drotrecogin alfa (activated)), from Ely Lilly Nederland B.V., is used by doctors. Xigris is currently approved in the European Union for the treatment of adult patients with severe sepsis with multiple organ failure, when added to best standard care. Having reviewed the latest available data, the Committee considers that Xigris should only be used in high-risk patients, mainly in situations when therapy can be started within 24 hours of the onset of organ failure. In addition, the CHMP is recommending that it should only be used by experienced doctors in institutions skilled in the care of patients with severe sepsis. Xigris should not be used in patients with single organ dysfunction, especially if they have had recent surgery (within 30 days).

A summary of opinion on Temodal and Xigris is 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.

Lists of Questions

The Committee also adopted six Lists of Questions on initial applications (3 Part A and 3 Part B) and one List of Questions on a "line extension application (Part B) (in accordance with Annex II of Commission Regulation (EC) No. 1085/2003).

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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 March 2005 is provided in **Annex 2.** The post-authorisation centralised procedures finalised during this meeting are summarised in **Annex 3.**

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 January 2005 CHMP are provided in **Annex 4**.

Referrals

- Further to the 7 April 2005 statement on the suspension of use of **Bextra** (valdecoxib), the Committee held a hearing with Pfizer and reviewed data on serious skin reactions occurring with valdecoxib and its parent compound parecoxib (**Dynastat**). The Committee discussed the preliminary information provided and agreed that this raised questions for all COX-2 inhibitors. The Committee agreed that it was important to analyse the occurrence of skin reactions in order to arrive at a conclusion on the benefit-risk balance of the COX-2 class of medicines.

  The European Commission has now formally asked the CHMP to include the assessment of serious skin reactions in the ongoing class review, in addition to the cardiovascular safety aspects. Further hearings will be held with the companies at the 23-26 May 2005 CHMP meeting, with the review expected to be concluded in June 2005. Pending the finalisation of the review, it was agreed that Bextra will not be reintroduced on the market in the European Union.

- The Committee concluded its review on the safety of **Hexavac**, from Sanofi Pasteur MSD, SNC, and confirmed its previous position that no regulatory action or changes to the product information are necessary. The review was initiated at the request of Germany in February 2005. The previous public statement of December 2003 is available on the EMEA website: http://www.emea.eu.int/pdfs/human/press/pus/588903en.pdf.

- The Committee concluded a referral procedure for **Crestor** (rosuvastatin) 5mg from AstraZeneca. The referral was initiated by the UK in November 2004 under Article 29 of the Community code on medicinal products for human use and related to differing views on recommendations for the Crestor starting dose (5 mg or 10 mg). The Committee concluded that the benefit-risk ratio is favourable for either Crestor 5mg or 10mg as alternative start doses. The choice in individual patients should take into account aspects of efficacy and safety, as detailed in the prescribing information. The recommended start dose for patients with predisposing factors for myopathy, patients of Chinese and Japanese ancestry, and elderly patients (>70 years) is 5 mg. Crestor is authorised in a number of EU Member States in dosages ranging from 5 to 40 mg.

- The Committee concluded a referral procedure for **Calcium Sandoz Effervescent tablets, 500/1000 mg** from Novartis Consumer Health SA. The referral was initiated by the marketing authorisation holder under Article 30 of Directive 2001/83/EC, as amended, in order to harmonise the SPCs and the formulations across all EU Member States. The Committee adopted a positive opinion recommending the harmonisation of the SPC as regards indications, posology, interactions, undesirable effects and recommendations for use.

- The CHMP began a referral for arbitration under Article 6(12) of Commission Regulation (EC) No 1084/2003 for **Coversyl** 2 and 4 mg (perindopril tert-butylamine salt) and associated trade names from Les Laboratoires Servier. The scope of the procedure is the extension of the therapeutic indication and the referral was initiated by The Netherlands. Coversyl is authorised in a number of EU Member States and is currently indicated for the treatment of hypertension and symptomatic heart failure.

- The CHMP began reviews on dermatological medicinal products containing **pimecrolimus**, from Novartis Healthcare, and **tacrolimus**, from Fujisawa GmbH, used in the treatment of atopic dermatitis. The reviews were initiated by the European Commission and by Denmark following concerns of potential cancer risks to patients. Tacrolimus is authorised throughout the European Union as **Protopic** and **Protopy**. Pimecrolimus is authorised in a number of Member States under different trade names. The reviews are initiated under Article 31 of the Community code on medicinal products for human use and under Article 18 of Regulation (EEC) No 2309/93.

- The CHMP began a referral under Article 30 of Directive 2001/83/EC, as amended, for **Prograf** and **Prograft** (tacrolimus) capsules and concentrate for infusion from Fujisawa GmbH. The marketing authorisation holder initiated the procedure in order to harmonise the prescribing information (summary of product characteristics, SPCs) across all EU Member States. The products are authorised in most EU Member States for the prevention and treatment of rejection after various types of organ transplantations.

CHMP Working Parties

The CHMP was informed of the outcome of the discussions of the Scientific Advice Working Group (SAWP) meeting, which was held on 4 - 5 April 2005. For further details, please see **Annex 5**.

The EMEA Executive Director T. Lönngren presented to the Committee a new framework for Scientific Advice and Protocol Assistance. The Committee agreed on the proposal, which will be presented to the Heads of Medicines Agencies, and will then be released for public consultation.

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

Invented Name Review Group (NRG)

The Group at its April 2005 meeting has adopted the "Guideline on acceptability of invented names for human Medicinal Products processed through the Centralised Procedure (rev.4)" (please see Procedural Announcement of this Monthly Report).

Upcoming meetings following the April 2005 CHMP plenary meeting:

- The 11th meeting of the CHMP will be held at the EMEA on 23 – 26 May 2005.
- The next Invented Name Review Group meeting will be held at the EMEA on 23 May 2005.
- The next Mutual Recognition Facilitation Group Meeting will be held at the EMEA on 23 May 2005.
- The Informal CHMP/COMP meeting will be held in Luxembourg on 3-4 May 2005
- PDA Viral and TSE Safety Conference: Updating the Strategy for the 21st Century will be held on 16-18 May 2005 in Bethesda, Maryland (in Co-Sponsorship with EMEA and FDA).

Organisational matters

The main topics addressed during the April 2005 CHMP related to:

- The adoption of the Composition of the following Working Parties: CHMP Pharmacogenetics Working Party (PgWP) and Blood Products Working Party (BPWP) (revised composition).

- The adoption by the Committee of a proposed policy on the time taken for companies to respond to questions arising during the assessment of new applications. The document is published on the EMEA webpage for public consultation.

- The adoption of the 2005-2006 Workplan for the EMEA/CHMP Working Group with Patients' Organisations (to be released at the EMEA Website in the near future).

- The adoption of the Composition of the Diagnostics and the HIV/Viral Diseases Scientific Advisory Groups.

EMEA Implementation of the New EU Pharmaceutical Legislation

The third CHMP/EMEA Implementation Task Force (CEITAF) meeting took place on Monday 18 April 2005.

Documents on the following review implementation topics were adopted by the CHMP and will be transmitted to the European Commission:

- Optional scope of the centralised procedure
- Conditional Marketing Authorisation
- Accelerated assessment
- Data protection 8 years/market protection 10 years and additional 1 year
- Compassionate Use
- Exceptional circumstances
- EPAR summary for the public

Initial discussions took place on the following review implementation topics:
Re-examination of opinions, Guideline on one-year additional data exclusivity based on a change of classification of medicinal product (from prescription product to non-prescription product) and Guideline on one-year additional data exclusivity based on a new therapeutic indication for a well-established substance.

In addition, the draft Guideline on "Monitoring and inspection of compliance with pharmacovigilance obligations" has been discussed. This draft Guideline will be transmitted to PhVWP, CVMP, GMP, GCP Inspection group for review prior to release for public consultation.

The Group also discussed the European Commission proposal for a Guideline of a potential serious risk to public health
(http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2005/02_05/guideline_risk_human_02-05.pdf).

PROCEDURAL ANNOUCEMENT

Guideline on acceptability of invented names for human Medicinal Products processed through the Centralised Procedure (rev.4).

Further to the 3-months external consultation period and the receipt of the comments from many Interested Parties, the CHMP has revised its Guideline on Acceptability of Invented Names for Human Medicinal Products processed through the Centralised Procedure, taking into account these comments, where appropriate. This revised Guideline will be published shortly at the EMEA website.

Revision 4 of the Guideline includes new and revised criteria Applicants/MAHs should take into consideration when proposing invented names for upcoming centralised applications and also further clarification with regard to the procedures of reviewing invented names. It also includes a new mailing box for reporting of medication errors related to invented names.

With regard to recommendations for invented names for "non-prescription" and "generics" medicinal products, these requirements will be developed towards the end of the year and made publicly available, as they will be developed.

Mutual Recognition procedure

The CHMP noted the report from the Mutual Recognition Facilitation Group (MRFG) meeting held on 18 April 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	33	466
Follow-up to Scientific Advice	71	1	72
Protocol Assistance	59	14	73
Follow-up to Protocol Assistance	12	2	14

	1995-2004			2005			
	Part A	Part B	Total	Part A	Part B	Total	
Applications submitted	153	303	456	3	6	9	465
Consultation for Medical Device[1]	0	1	1	0	1	1	2
Withdrawals	22	62	84	0	2	2	86
Positive opinions[2]	107	197	304	0	2	2	306[3]
Negative opinions[4]	2	5	7	0	0	0	7[5]
Marketing authorisations granted by the Commission	98	190	288	3	7	10	298[6]

	1995-2004			2005			Overall Total
	Part A	Part B	Total	Part A	Part B	Total	
Variations type I	863	1937	2800	31	89	120	2920
Positive opinions, variations type II	758	886	1644	73	60	133	1777
Negative opinions, variations type II	1	6	7	0	0	0	7
Extensions (Annex II applications)	53	63	116	1	2	3	119

[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] 19 positive opinion corresponding to 19 Orphan Medicinal Products
[3] 306 positive opinions corresponding to 237 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] 298 marketing authorisations corresponding to 229 substances

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

Invented Name	Aloxi
INN	palonosetron
Marketing Authorisation Holder	Helsinn Birex Pharmaceuticals Ltd
Proposed ATC code	pending
Indication	Aloxi is indicated for the prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy and the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy
CPMP Opinion date	15.12.2004
Marketing Authorisation Date	22.03.2005

Invented Name	Aclasta
INN	zoledronic acid
Marketing Authorisation Holder	Novartis Europharm Ltd
Proposed ATC code	M05 BA08
Indication	Treatment of Paget's disease of the bone.
CPMP Opinion date	20.01.2005
Marketing Authorisation Date	15.04.2005

OUTCOME OF THE APRIL 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
16 SPC changes	16 Positive opinions
19 Quality changes	19 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN) **MAH**	**Outcome**	**Comments**
Carbaglu (carglumic acid) Orphan Europe SARL	Positive Opinion	The Marketing Authorisation will remain under exceptional circumstances.
Neurobloc (botulinum toxin type B) Elan Pharma International Ltd	Positive Opinion	Since all specific obligations have now been fulfilled, it was agreed that there were no remaining grounds to keep the Marketing Authorisation under exceptional circumstances. Annex II was revised accordingly.
Renagel (sevelamer) Genzyme B.V.	Positive Opinion	The Marketing Authorisation will remain under exceptional circumstances.
Viread (tenofovir) Gilead Science International Limited	Positive Opinion	Since all specific obligations have now been fulfilled, it was agreed that there were no remaining grounds to keep the Marketing Authorisation under exceptional circumstances. Annex II was revised accordingly.
Zevalin (ibritumomab tiuxetan) Schering AG	Positive Opinion	The Marketing Authorisation will remain under exceptional circumstances.

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN) **MAH**	**Outcome**	**Comments**
Xigris (drotrecogin alfa (activated)) Eli Lilly Nederland B.V	Positive Opinion	The Marketing Authorisation will remain under exceptional circumstances.

Opinions for Renewal applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Avandia (rosiglitazone) GlaxoSmithKline	Positive Opinion	---
Keppra (levetiracetam) UCB S.A	Positive Opinion	---
Lantus (insulin glargine) Aventis Pharma Deutschland GmbH	Positive Opinion	---
Optisulin (insulin glargine) Aventis Pharma Deutschland GmbH	Positive Opinion	---
Visudyne (verteporfin) Novartis Europharm Ltd	Positive Opinion	---

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

Active substance	***Sponsor/applicant***	***EU Designation Number & Date of Orphan Designation***	***Designated Orphan Indication***
Recombinant human monoclonal antibody to hsp90 (Mycograb)	NeuTec Pharma plc	EU/3/01/073 05/12/2001	Treatment of invasive fungal infections
Rufinamide (Inovelon)	Eisai Limited	EU/3/04/240 20/10/2004	Treatment of Lennox-Gastaut syndrome

OUTCOME OF THE APRIL 2005 CHMP 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	Ankylosing Spondylitis	X						X	
Biological	Osteosarcoma		X			X	X	X	X
Chemical	Infantile colic	X				X	X	X	
Chemical	Unipolar depression	X						X	
Chemical	Invasive aspergillosis	X						X	
Chemical	Acute Myeloid Leukemia		X					X	X
Chemical	Familial Adematous Polyposis		X					X	X
Chemical	Chronic Myeloid Leukemia	X						X	
Biological	Growth failure due to inadequate secretion of normal endogenous growth hormone and short stature associated with Turner syndrome	X				X	X	X	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 6 Scientific Advice letters and 3 Protocol Assistance letters were adopted at the 18-21 April CHMP meeting.

The Committee accepted 13 Initial Scientific Advice Requests, 4 Initial Protocol Assistance Requests, 4 Follow Up Scientific Advice Requests and 3 Follow Up Protocol Assistance Requests.

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

BIOLOGICS WORKING PARTY

Reference number	Document	Status
CHMP/BWP/99/04	Guideline on potency labelling for insulin analogue containing products with particular reference to the use of "International Units" or "Units"	Released for 6 months consultation

EFFICACY WORKING PARTY

Reference number	Document	Status
CHMP/EWP/552/95 rev. 2	Recommendation on the need for revision of CHMP Note for Guidance on Post-menopausal osteoporosis in women	Adopted

Outcome on Ad-Hoc expert meeting on Metabolic Syndrome.

The CHMP convened a multidisciplinary expert meeting (with the participation of endocrinologists, cardiologists, specialists in internal medicine and regulators) on Metabolic Syndrome. Based on questions from CHMP, the group was expected to address whether with the available information Met Synd could be an acceptable therapeutic indication and, in such case, what key regulatory recommendations for the clinical development of drugs intended for its treatment should be considered.

There was an agreement among experts that at present there is not an adequately validated definition of Met Synd and that the existing definitions present important differences in terms of the population defined. The experts agreed that Met Synd cannot be considered today as a target for therapy in itself, but rather as an additional tool to identify patients at high cardiovascular risk. The concept is useful in making people aware of their increased cardiovascular risk, but additional tools are needed to quantify that risk for individual patients/patient groups. Different subsets are included, for which the risk levels may be very different. The experts also stressed the importance of life-style modification in the management of this group of patients.

Further work is needed to define Met Synd, and to validate the definition.

Companies developing medicinal products in this area are recommended to apply for Scientific Advice.

SAFETY WORKING PARTY

Reference number	Document	Status
CHMP/SWP/94227/04	Guideline on the Non-clinical investigation of the Dependence Potential of Medicinal Products	Released for 6 months consultation

WORKING PARTY WITH PATIENTS' ORGANISATIONS

Reference number	Document	Status
EMEA/136459/2005	2005-2006 Workplan for the EMEA/CHMP Working Group with Patients' Organisations	Adopted

Report from the meeting held on 18 April 2005

General Issues

MRFG Sub-group on Article 17 and 18 procedures

The MRFG sub-group on Article 17 and 18 procedures held its fourth meeting in the morning following the MRFG plenary session to continue the discussions on the national pending applications in the new Member States for which a Mutual Recognition Procedure will have to be triggered and, in the case of nationally authorised medicinal products, a Reference Member State appointed.

Applicants are reminded that a proposed different legal basis for the same medicinal product in different Member States cannot be considered a reason to continue an application as a purely national one.

Joint MRFG/QRD Working Group on Patient information

The Joint MRFG/QRD Working Group on Patient information held its third meeting in the morning following the MRFG plenary session to continue the discussions on the new legal requirements for package leaflets and the need for guidance on user testing.

Implementation of Commission Decisions following an arbitration procedure

The European Commission confirmed that the implementation of Commission Decisions following an arbitration procedure is done nationally by the MSs addressed in the Decision and that it is a decision of the National Competent Authority how to implement it, i.e., if a national variation application is necessary or not to implement the Commission Decision. Nevertheless, the implementation of a Commission Decision cannot be done via a variation application submitted through the Mutual Recognition Procedure.

Informal MRFG

An informal MRFG meeting will be held in Luxembourg on 3-4 May 2005. The meeting will be focused on the new legal requirements for package leaflets, labelling and the need for guidance on user testing. The transparency requirements of the new legislation, the role of the MRI-Product Index, a proposal for the templates for the public assessment reports, the Decentralised procedure and the 1 year experience of a new Member State in the MRP, following the enlargement of the EU on 1 May 2004, will also be on the Agenda.

Meeting schedule

The next MRFG meeting will be held on 23 May 2005.

Mutual Recognition Monitoring

The MRFG noted that **89** new mutual recognition procedures were finalised during the month of March 2005, as well as **355** type IA variations, **164** type IB variations and **95** type II variations. **1** arbitration according to Article 6(12) (of Commission Regulation (EC) No 1084/2003 has been referred to CHMP

The status as of 31st March of procedures and for the whole year 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	202	225	842	394	240	1 Var.

100 new procedures (regarding **192** products) started in March 2005. The categories of these procedures are as follows:

5 new active substances, including **1** multiple application and **3** repeat use.

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

71 abridged applications including **21** multiple applications and **6** repeat use.

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

The new procedures started related to **16** full dossiers, **64** generics, **10** bibliographic applications, **1** informed consent and **9** for different use, route or dose.

The procedures consisted of **100** chemical substances[1].

100 of these procedures were prescription-only medicinal products in the reference Member State [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 March 2005

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (1)	5
DE (1)	5
DE (1)	3
DE (1)	12
DE (2)	4
DE (1)	8
DE (1)	2
DE (3)	2
DE (4)	15
DE (2)	15
DK (3)	7
DK (2)	7
DK (2)	1
DK (1)	2
DK (3)	4

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DK (3)	15
DK (3)	4
DK (3)	3
DK (2)	1
DK (2)	1
DK (2)	2
DK (1)	4
DK (2)	1
DK (1)	7
DK (3)	2
DK (4)	1
DK (4)	1
ES (2)	3
FI (1)	8
FI (1)	9
FI (1)	1
FI (1)	1
FI (3)	8
FI (3)	1
FI (3)	11
FI (3)	3
FI (3)	8
FI (3)	2
FI (1)	20
FI (1)	2
FR (1)	2
FR (2)	4
FR (1)	12
FR (1)	5
IT (1)	10
IT (1)	10
NL (1)	1
NL (1)	1
NL (2)	17
NL (3)	1
NL (3)	1
NL (3)	1
NL (1)	23
NL (1)	1
NL (1)	1
NO (3)	1
NO (2)	1
NO (3)	1
NO (2)	1
SE (1)	1
SE (3)	9
SE (1)	5
SE (1)	1
SE (1)	1
SE (1)	1
SE (1)	1
SE (1)	1
SE (1)	6
SE (1)	1
SE (4)	4
SE (4)	1
SE (2)	15
SE (2)	2
SE (1)	2
SE (1)	1
SE (2)	4
SE (2)	1
SE (2)	5

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
SE (2)	17
SE (2)	1
SE (2)	14
SE (2)	2
SE (2)	4
SE (1)	1
SE (1)	1
SE (1)	10
SE (4)	2
SE (1)	1
UK (1)	10
UK (1)	6
UK (3)	7
UK (1)	4
UK (1)	2
UK (1)	3
UK (4)	1
UK (3)	10
UK (3)	4
UK (3)	1
UK (2)	3
UK (1)	1

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 chair of the MRFG on behalf of the Luxembourg Presidency:

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