The European Agency for the Evaluation of Medicinal Products
Directorate

London, 15 January 2001
Doc. Ref: EMEA/D/817/01

Press release

New EMEA human medicines units announced

Thomas Lönngren, EMEA Executive Director, has announced the following with effect from 15 January 2001.

The former Unit for the Evaluation of Medicinal Products for Human Use has been re-organised into two operational units, dealing with pre- and post-authorisation aspects of medicinal products for human use.

The appointment of Noël Wathion as head of unit for post-authorisation matters was announced on 25 July 2000 (see EMEA/D/20840/00). The head of unit for pre-authorisation evaluation will be announced once the recruitment procedure has been finalised. A recruitment competition will be published shortly in the Official Journal for the post of head of sector for pharmacovigilance and post-authorisation safety and efficacy of medicines.

Product teams will replace the system of individual project managers. The team members will be drawn from both the pre- and post-authorisation units, allowing the team to follow the product during its entire life cycle. The role of members will vary according to the different phases and aspects of procedures, from orphan drug designation, scientific advice and authorisation through to post-authorisation maintenance.

Specialised groups have been created within the safety and efficacy sectors of both the pre- and post-authorisation units. This should allow a more integrated scientific and operational peer review system within specific therapeutic areas and classes of products.

The structure of the new units is attached.

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New structure of the units for the evaluation of medicines for human use:

Unit for the Pre-authorisation evaluation of medicines for human use

[To be announced]
Head of Unit

Sector for scientific advice and orphan drugs
Patrick LE COURTOIS
Head of Sector
- Dealing with scientific advice, protocol assistance and orphan medicinal product designation

Sector for quality of medicines
John PURVES
Head of Sector
- Biotechnology section (biotechnology and biological products)
- New chemical entities section

Sector for safety and efficacy of medicines
Isabelle MOULON
Head of Sector
Marisa PAPALUCA AMATI
Deputy Head of Sector
- Anti-infective/immunology specialised group (anti-infective, immunology, gastroenterology, musculoskeletal)
- Oncology/CVS specialised group (cancer, haematology, blood, diagnostics, CVS)
- CNS/Endocrinology specialised group (CNS, endocrinology, metabolic, urology, respiratory, diabetes, dermatology, ophthalmology)

Unit for the Post-authorisation evaluation of medicines for human use

Noël WATHION
Head of Unit

Sector for regulatory affairs and organisational support
Anthony HUMPHREYS
Head of Sector
- Regulatory affairs/CPMP/MRFG section
- Legal affairs section
- Central information group

Sector for pharmacovigilance and post-authorisation safety and efficacy of medicines
[Post vacant]
Head of Sector
Sabine BROSCH
Deputy Head of Sector
- EU pharmacovigilance coordination section
- Anti-infective/immunology specialised group (anti-infective, immunology, gastroenterology, musculoskeletal)
- Oncology/CVS specialised group (cancer, haematology, blood, diagnostics, CVS)
- CNS/Endocrinology specialised group (CNS, endocrinology, metabolic, urology, respiratory, diabetes, dermatology, ophthalmology)