EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 December 2009
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# Guide to the European Medicines Agency

This is a guide to the various Units, Sectors and Sections at the European Medicines Agency.

It gives the names of the Heads of Unit, Heads of Sector and Section Heads. It also gives a general description of what each Unit does within the Agency.

The information is correct as at 8 December 2009.

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## Executive Director and the Heads of Unit

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| Executive Director | Thomas LÖNNGREN |
| Head of Human Medicines Development and Evaluation | Patrick LE COURTOIS |
| Head of Patient Health Protection | Noël WATHION |
| Head of Veterinary Medicines and Product Data Management | David MACKAY |
| Head of Information and Communications Technology | Hans-Georg WAGNER |
| Head of Administration | Andreas POTT |

The European Medicines Agency is headed by the Executive Director, who is appointed by the Agency's Management Board.

The Agency is organised into five Units, each with between two and four Sectors. Most Sectors are further divided into a number of Sections; in addition there are some smaller services or functions that report directly to a Head of Unit or Head of Sector. Each Head of Unit, and in some cases also Heads of Sector, has a business and operational support group directly attached to them.

The Executive Director and Heads of Unit together make up the Agency's senior management team.

In addition to its staff, the Agency is composed of a Management Board and six scientific committees. The committees, composed of members of all EU and EEA-EFTA states, some including patients' and doctors' representatives, conduct the main scientific work of the Agency: the Committee for Medicinal Products for Human Use (CHMP), the Committee for Medicinal Products for Veterinary Use (CVMP), the Committee for Orphan Medicinal Products (COMP), the Committee on Herbal Medicinal Products (HMPC), the Paediatric Committee (PDCO) and the Committee for Advanced Therapies (CAT). The committees and working parties are supported by more than 4,500 European experts.

Information on the Management Board, the committees and working parties is available on the Agency's website at www.ema.europa.eu.

## Executive Director and Directorate Services

**Executive Director**

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The Directorate is composed of four services reporting directly to the Executive Director.

The services provide support and advice to the Executive Director on a range of operational and scientific issues.

The services also have a cross-Agency support function in areas such as planning and reporting, institutional and international relations, communications, legal advice, data protection, internal auditing and quality management.

**Office of the Executive Director**[1]

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[1] The Sector includes the following functions reporting directly to the Head of the Office of the Executive Director:

- Corporate Governance
- Institutional Liaison
- International Liaison
- Communications and Media

[2] The Sector includes the following functions reporting directly to the Head of Legal Service

- Legal Advisers
- Data Protection Office
- Procurement Office

## Human Medicines Development and Evaluation

**Head of Unit**

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The Human Medicines Development and Evaluation Unit is responsible for the delivery of all activities relating to medicines for human use from the development stage right through the scientific advice and product life-cycle including special requirements for paediatric, orphan and advanced therapy medicinal products.

It provides the secretariats of the COMP, PDCO and numerous working parties and scientific advisory groups of the CHMP. The Unit contributes to public health projects at European and international level; provides scientific support for activities related to emerging science; and includes the Agency's Small and medium-sized enterprises Office providing support services covering both human and veterinary medicinal products.

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[3] This Sector includes the 'Research Activities' group, reporting directly to the Head of Safety and Efficacy of Medicines.

## Patient Health Protection

**Head of Unit**

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The Unit contributes to patient health protection through a proactive approach to pharmacovigilance and risk management throughout the lifecycle of centrally authorised medicinal products for human use. It manages Community procedures aimed at reviewing the benefit and risk of centrally and nationally approved medicines. The Unit is also responsible for crisis management of centrally authorised products.

It provides regulatory and procedural support to staff, scientific committees, working parties and experts participating in activities related to medicines for human use. It provides the secretariats of the CHMP, HMPC, CAT and several working parties. It is also responsible for the quality review of product information, provision of information to patients and healthcare professionals, and for fostering relations with representatives of civil society.

The Unit coordinates the verification of compliance with good clinical, manufacturing and laboratory practices, and pharmacovigilance requirements. It manages suspected quality defects and counterfeit medicines through the Agency's coordinating role in the EU regulatory system network, and coordinates the sampling and testing of centrally authorised products. It facilitates the implementation and operation of the clinical trials legal framework in the EU and operates the schemes for certificates of medicinal products and parallel distribution notifications.

**Compliance and Inspection**

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[4] This Sector includes the 'Information Compliance and Consistency' group, reporting directly to the Head of Medical Information.

[5] This Sector includes the 'Business Coordination and Scientific Projects' group, reporting directly to the Head of Pharmacovigilance and Risk Management.

## Veterinary Medicines and Product Data Management

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| **Head of Unit** | David MACKAY<br>+44 (0)20 7418 8413<br>david.mckay@ema.europa.eu |

The Unit is responsible for the effective and efficient delivery of all activities of the Agency with respect to veterinary medicinal products.

The Unit also has responsibility for overseeing administrative activities related to the management of information, knowledge, data and documents in support of the scientific activities of the Agency relating to the authorisation and maintenance of centrally authorised medicinal products for human and veterinary use.

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| **Product Data Management** | Alexis NOLTE (Acting)<br>+44 (0)20 7523 7188<br>alexis.nolte@ema.europa.eu |
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| ▪ Document and Information Services | Beatrice FAYL<br>+44 (0)20 7418 8426<br>beatrice.fayl@ema.europa.eu |

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| **Veterinary Medicines** | Kornelia GREIN<br>+44 (0)20 7418 8432<br>kornelia.grein@ema.europa.eu |
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| ▪ Veterinary Regulatory and Organisational Support | Melanie LEIVERS<br>+44 (0)20 7418 8646<br>melanie.leivers@ema.europa.eu |
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## Information and Communications Technology

**Head of Unit**[6]

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The Unit enables the Agency, its staff, members of its committees, working parties and advisory groups, and other stakeholders, to make efficient and effective use of information and communications technology in order to achieve its organisational and policy objectives. The Unit provides high-quality and advanced ICT infrastructure solutions and e-services, support services, and unified telecommunications facilities including solutions for physical and virtual meetings. In addition to the information systems required to support EMEA corporate business processes. The Unit delivers the systems defined in the EU telematics strategy for use by the European regulatory network, pharmaceutical industry, healthcare professionals and the general public.

**ICT Development**

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**ICT User and Application Support**

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- User Registration, Training and Service Desk

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[6] The following functions report directly to the Head of Information and Communications Technology:

- Enterprise Architecture, Standards and Methodologies
- Budget and Financial Services

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# Administration

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The Unit is responsible for managing revenue, expenditure and accounts according to existing rules and regulations, for recruiting, managing and administering staff and seconded personnel, as well as for providing and running the necessary infrastructure services for an effective functioning of the Agency.

The Unit cooperates closely with the European Parliament and the Council (Budgetary Authority) as well as the Commission and the Court of Auditors on matters relating to administration, the budget, personnel and rules and regulations on finances, audit and accounting. For this reason the Unit maintains regular contacts with the above institutions and with the other European agencies.

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| **Human Resources** | Frances NUTTALL<br>+44 (0)20 7418 8475<br>frances.nuttall@ema.europa.eu |
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| **Finance and Budget** | To be appointed |
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