

Departmental Functions

Office of the CEO

The office of the Chief Executive Officer vests the legal and judicial representation of the Medicines Authority. The Chief Executive Officer has the overall responsibility of the leadership, management and performance of the Authority including the management of the day-to-day operations of the Authority and overall achievement of planned targets.

Licensing Directorate

The Licensing directorate processes all applications for product pre-authorisation and post-authorisation activities through established national and European procedures. This includes the granting, withdrawal, variation, revocation or suspension for all product related licences and authorisations. The directorate also processes applications for work-sharing of European procedures.

Post-Licensing Directorate

The Post-Licensing Department is responsible for the constant monitoring of the safety of medicines after authorisation ('pharmacovigilance' and 'advertising'). The Medicines Authority receives safety reports from within the EU and outside concerning authorised medicinal products and acts upon the information relating to the safety and quality of medicinal products.

Inspectorate and Enforcement Directorate

The two main activities of the IED are inspections of wholesalers, manufacturers/importers and pharmacies and the issue of their licences, their renewals and variations plus the remit to carry out enforcement activities in line with the Medicines Act 2003 and its subsidiary legislation.

Finance and Administration

The Finance and Administration Unit plans, organises, directs and controls finance related matters including the issue of management accounts, budgets and liaison with external auditors. It is responsible for all procurement, travel arrangements and the drafting and maintenance of Medicines Authority contracts. It is also responsible for the recruitment process and for the overall administration of the Medicines Authority.

Quality Management

The Quality Manager is responsible for the overall quality system of the Authority and to ensure that quality management is implemented in all areas. The Quality manager is responsible to plan and execute the internal audit programme of the Authority and to ensure that there is a system of continual improvement through the follow up of corrective and preventive action and Management Review. The Quality Manager coordinates the Benchmarking of the European Medicines Agency exercise of the Authority and ensures that follow up action is done.

Information Systems

The role of the Information Systems Unit is to deploy and maintain a robust and secure ICT infrastructure and application functionality to support the operations of the national competent authority and legislation regulating the local pharmaceutical sector. Moreover new developments within the EU Telematics Programme are monitored to ensure that information systems comply with EU Directives.

Operations and Regulatory Affairs

The Operations and Regulatory Affairs Unit is responsible for relevant corporate operations and the overall planning, monitoring and support of the operations and regulatory affairs at the Medicines Authority. The Unit is responsible for EU and local regulatory affairs, Customer Satisfaction, Corporate Communications, Corporate Risk Management, Corporate Human Resources Management, Training, Development, Occupational Health and Safety of employees at the Medicines Authority. The Unit is also responsible for certain horizontal operations, other government and authority specific initiatives such as Better Regulation and Green Initiatives and other tasks/ projects as delegated by the CEO.