1995 The Mutual recognition Facilitation Group is established.

1996 First meeting of the Head of Agencies (HoA) responsible for medicinal products for human use.

1997 First meeting of Head of Agencies responsible for medicinal products for veterinary use (HEVRA).

2000 Joint meeting of HoA and HEVRA.

2002 HoA and EMA developed a European Risk Management Strategy (ERM S).

2004 HoA and HEVRA decided to unify the two groups: the HMA is formally established and Management Group and Permanent Secretariat approved.

2005 The Benchmarking of European Medicines Agencies (BEMA) Working Group is established.

2006 Start-up of the human and veterinary Coordination Groups for Mutual Recognition and Decentralised Procedures. HMA formally adopted the HMA Strategy Paper on European Medicines Regulator Network.

2010 Adoption of a second HMA strategy document for the period 2011-2015.
THE HEADS OF MEDICINES AGENCIES (HMA) IS A NETWORK OF THE HEADS OF THE NATIONAL COMPETENT AUTHORITIES WHOSE ORGANISATIONS ARE RESPONSIBLE FOR THE REGULATION OF MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE IN THE EUROPEAN ECONOMIC AREA.

MISSION AND ORGANISATION
The HMA works to foster an effective and efficient European medicines regulatory system.

The HMA is coordinated and supervised by a Management Group.

It is also supported by several Working Groups, covering specific areas of responsibility, and by a Permanent Secretariat.

The HMA co-operates with the EMA (European Medicines Agency) and the European Commission in the operation of the European medicines regulatory network.

MAIN ACTIVITIES
The HMA:

• Addresses key strategic issues for the network, such as the exchange of information, IT developments and sharing of best practice.

• Focuses on the development, co-ordination and consistency of the European medicines regulatory system.

• Ensures the most effective and efficient use of resources across the network. This includes developing and overseeing arrangements for work-sharing.

• Co-ordinates the mutual recognition (MRP) and decentralised procedures (DCP).

• Member agencies support the network by providing high-quality professional and scientific resources to all areas of medicines regulation including centralised, MRP, DCP and national procedures.

THE HMA STRATEGY FOR 2011-2015 PERIOD
The HMA’s second strategy paper focuses on three main themes. For each of these themes, specific work areas have been identified:

SAFEGUARDING PUBLIC AND ANIMAL HEALTH
- Strengthening surveillance of the benefits and risks of medicines in the European population
- Good communication including the HMA website www.hma.eu
- Strengthened monitoring of the quality of medicines

SUPPORTING INNOVATION
- Efficient and proportionate regulation of new medicines and clinical trials
- Provision of excellent scientific and regulatory advice

FURTHER IMPROVING THE OPERATIONAL EFFICIENCY OF MEDICINES AUTHORISATION BY DCP AND MRP
- Identifying with stakeholders areas to address and more targeted communication
- Risk-based proportionate regulation
- Harmonisation of assessment
- Work-sharing
- Harmonised training
- Best use of information technology
- Continued dialogue with industry on operational matters

THE EUROPEAN APPROVAL SYSTEM
CENTRALISED PROCEDURE
Companies can obtain a marketing authorisation valid throughout the EU. The application is submitted directly to the European Medicines Agency for assessment. This procedure is compulsory for particular categories of medicines and optional for others. See www.ema.europa.eu

DECENTRALISED PROCEDURE
Companies can apply for the simultaneous authorisation of a medicine in more than one EU country once it has not yet been authorised in any EU country and it does not fall within the mandatory scope of the centralised procedure. In this procedure, one country is requested to be the Reference Member State (RMS) while the other countries involved are known at the Concerned Member States (CMS).

NATIONAL PROCEDURE
Companies can apply for a marketing authorisation in any one EU country where the product falls outside the scope of the centralised procedure. The application is submitted for assessment directly to the competent authority in that country.

MUTUAL-RECOGNITION PROCEDURE
Companies that have a medicine authorised in one EU Member State can apply for this authorisation to be recognised in other EU countries. The countries concerned agree to accept the validity of the original, national marketing authorisation.

FOR FURTHER INFORMATION:
www.hma.eu/cm dh.html www.hma.eu/cm dv.html