HISTORY & MILESTONES

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 (ERMS)

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

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 the second HMA strategy (2011-2015)

2016
Joint HMA/EMA strategy to 2020 and adoption of a Multi Annual Work Plan at HMA level

2018
First revision of the Multi Annual Work Plan

HMA
Heads of Medicines Agencies

www.hma.eu

HEADS OF MEDICINES AGENCIES
Permanent Secretariat
c/o Paul Ehrlich Institute,
Paul-Ehrlich-Straße 51-59
63225 Langen, Germany
hma-ps@pei.de

Edited by:
HMA Working Group of Communication Professionals

Designed by:
Press & Communication Office
Italian Medicines Agency - AIFA

March 2019

PROTECTING AND PROMOTING PUBLIC & ANIMAL HEALTH IN EUROPE

HMA
Heads of Medicines Agencies

The Heads of Medicines Agencies (HMA) is a network of the heads of all the National Competent Authorities responsible for the regulation of medicines for human and veterinary use in the European Economic Area.

The HMA provides for a unique model of cooperation and work-sharing across statutory as well as voluntary regulatory activities. It works in close collaboration with the European Medicines Agency (EMA) and the European Commission to foster an effective and efficient European medicines regulatory system.

Experts and representatives from the agencies of 31 European countries support the network by providing high-quality professional and scientific resources to all areas of medicines regulation. One of the key activities of the HMA is to oversee the mutual recognition (MRP) and decentralised procedures (DCP) in the EU thorough the work of the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) and the Coordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv).

www.hma.eu/cmdh.html
www.hma.eu/cmdv.html

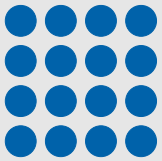
The exchange of information and sharing of best practice are among the primary objectives of the HMA. Since it was formally established, the network has also increased its coordination mandate to include clinical trials authorisation, safety monitoring, availability of medicines, interpretation of legal provisions and product testing. The HMA has also commenced a number of shared initiatives across the network which has resulted in the establishment of European-wide projects relating to IT infrastructure, benchmarking, training programs and communication policy.

The HMA is coordinated by a Management Group. Its work is supported by a Permanent Secretariat and several Working Groups covering specific areas of responsibility.

Following the finalisation of a joint HMA/EMA strategy to 2020, the HMA adopted a Multi Annual Work Plan in February 2016 to ensure delivery of the overarching strategy at a HMA level with the support and involvement of all National Competent Authorities and the EMA.

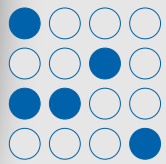
www.hma.eu

THE EUROPEAN APPROVAL SYSTEM



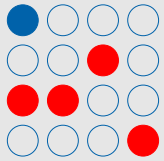
CENTRALISED PROCEDURE

Companies can obtain a marketing authorisation valid throughout the EU. The application is submitted directly to the European Medicines Agency for assessment, that is carried out through the scientific expertise of the Member States. The centralised procedure is compulsory for particular categories of medicines and optional for others.
See www.ema.europa.eu



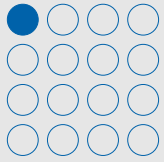
DECENTRALISED PROCEDURE

Companies can apply for the simultaneous authorisation of a medicine in more than one National Competent Authority once it has not yet been authorised in any EU Member State 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 as the Concerned Member States (CMS).



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 National Competent Authorities concerned agree to accept the validity of the original national marketing authorisation.



NATIONAL PROCEDURE

Companies can apply for a marketing authorisation from a National Competent Authority where the product falls outside the scope of the centralised procedure. The application is submitted for assessment directly to the National Competent Authority in that country.