



**Study on the experience acquired
as a result of the operation of
centralised and decentralised
marketing authorisation
procedures**

"Study on MA procedures"

Background:

Legal basis: Obligation to publish at least every 10 years a general report on the experience acquired as a result of the operation of CP, MRP and DCP.

Art. 86 of Reg. 726/2004 and **Art. 38(2) of Dir. 2001/83**



Article 86

At least every ten years, the Commission shall publish a general report on the experience acquired as a result of the operation of the procedures laid down in this Regulation, in Chapter 4 of Title III of Directive 2001/83/EC and in Chapter 4 of Title III of Directive 2001/82/EC.



Article 38

1. The Agency shall publish an annual report on the operation of the procedures laid down in this Chapter and shall forward that report to the European Parliament and the Council for information.
2. At least every ten years the Commission shall publish a report on the experience acquired on the basis of the procedures described in this Chapter and shall propose any amendments which may be necessary to improve those procedures. The Commission shall submit this report to the European Parliament and to the Council.

**** Last report published by the Commission in 2010.**

Study on MA procedures

Indicative timetable:



Timeframe: 2009-2017

Scope:

CP

MRP AND DCP
within the scope
(**except for**
aspects or
subjects of
exclusive
competence of
MS)

Purely
national
authorisation
procedures
are out of
the scope

Veterinary
products are
excluded

Overarching objectives:

Gather available data and evidence on the operation of centralised, DC and MR procedures in the period 2009-2017

Analyse those data and evidence in order to assess the achievement of the objectives set by the regulatory framework for marketing authorisations in the EU/EEA and to assess the relationship between resources used and output generated by the existing system

Compare the situation today with the findings of the 2010 report

Report on the follow up and implementation of the recommendations of 2010

Specific objectives:

The European Medicines Regulatory Network

- Assess the overall structure, evolution across the last 10 years, its effectiveness and efficiency and the adequacy of the scientific expertise.

Procedures Preceding Submission of Marketing Authorisation Applications

- Critical analysis of the impact of EMA's and NCA's pre-submission activities, opportunities vs barriers for various stakeholders.

Initial Marketing Authorisation Procedures

- Assess effectiveness and efficiency of the various types of initial Marketing Authorisations Procedures: CP, MRP and DCP. Attention also to specific categories of applications, such as biosimilars and generics, and how to facilitate access to these categories of products.

Post-Marketing Authorisation Procedures

- Assessment of the current approach to post-marketing assessment; identify opportunities for reduction of regulatory/administrative burden for all stakeholders, summarise the experience with the current framework for handling of variations; harmonisation of authorisation decisions through referral procedures etc.

Support activities

- Telematics, digitalisation and communication activities.

Data Collection: What to expect?





Thank you!