MARKETING AUTHORIZATION APPLICATION (MAA) FOR EUROPE MARKET

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REVIEW ARTICLE

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ABSTRACT

This article states requirement of Marketing Authorization Application to get registration of Drug Product to EEA. The procedures for application of marketing authorization are: Centralised procedure, National procedure, Mutual recognition procedure, Decentralised procedure.

Keywords: MAA, EU, Rapporteur, Co-Rapporteur, EMA.

INTRODUCTION

Marketing Authorization Application is an application to the relevant authority to market a drug or medicine in Europe market. (Typically, the UK's MHRA or the EMA's Committee for Medicinal Products for Human Use (CHMP). Manufacturers can enter in EU market by using following authorized ways for application of MAA. The EEA unites the 28 EU member states & EEA European Free Trade Association (EFTA) states (Iceland, Liechtenstein, Switzerland & Norway).

Italy	Estonia	Portugal
France	Finland	Romania
Germany	Greece	Spain
Netherlands	Hungary	Sweden
Belgium	Czech	Slovak
Luxemburg	Ireland	Croatia
Austria	Denmark	**EFTA countries**
Bulgaria	Lithuania	Liechtenstein
Cyprus	Latvia	Norway
UK	Malta	Iceland
Slovenia	Poland	Switzerland

Marketing Authorisation Application [MAA] to EU countries

- **Marketing Authorization Application Modules**

Module	Contents	Details
1	EU administrative & prescribing information	▪ Application form ▪ Summary of Product characteristics ▪ Labelling text and mock-ups ▪ Information about the experts ▪ Environmental risk assessments ▪ Information relating to orphan market exclusivity ▪ Description of the pharmacovigillance system ▪ Risk management plan

2	High level summaries	▪ Quality ▪ Non-clinical overview ▪ Non-clinical summary (Pharmacology, Pharmacokinetic, Toxicology) ▪ Clinical overview ▪ Clinical summary (Biopharmaceutics, clinical pharmacology, efficacy, safety, study synopsis)
3	Quality documentation	▪ Body of data ▪ References
4	Non-clinical documentation	▪ Study report ▪ References
5	Clinical Documentation	▪ Tabular listing of studies ▪ References

➢ **Marketing Authorization Application (1)**

- At least seven months before submission applicant should notify the European Medicine Agency (EMA) of their intention to submit an application and give a realistic estimate of month of submission.
- MAA can be filled in four ways. (2)
  - Centralised procedure
  - National procedure
  - Mutual recognition procedure
  - Decentralised procedure.

Centralised Procedure

- A marketing authorisation granted under the centralised procedure is valid for the entire Community market, which means the medicinal product may be put on the market in all Member States.
- The Regulation (EC) 726/2004 lays down a centralised Community procedure for the authorisation of medicinal products, for which there is a single application, a single evaluation and a single authorisation allowing direct access to the single market of the Community.

National authorisation procedures

- In order to obtain a national marketing authorisation, an application must be submitted to the competent authority of the Member State.
- Each EU Member State has its own procedures for the authorisation, within their own territory
- The competent authorities of the Member States are responsible for granting marketing authorisations for medicinal products which are placed on their markets, except for medicinal products which are authorised under Regulation (EC) No 726/2004 (Community Authorisations).
- MA applications should be completed within 210 Days.
- If any organisation wishes to market their product only in one EU country then this is preferred procedure. No need to book the slot, only need to inform relevant authority prior filing
- In recent years, a national application is made in very limited number of cases.eg. Inability to get a slot with any RMS to run a DCP or complex product which any RMS does not wish to assess as part of DCP. In such cases, the company is left with the option of getting it approved in a single country first and then take support of this approval to extend authorisation in other countries by Mutual Recognition Procedure.

Mutual-recognition procedure

- Companies that have a medicine authorised in one EU Member State (which would be

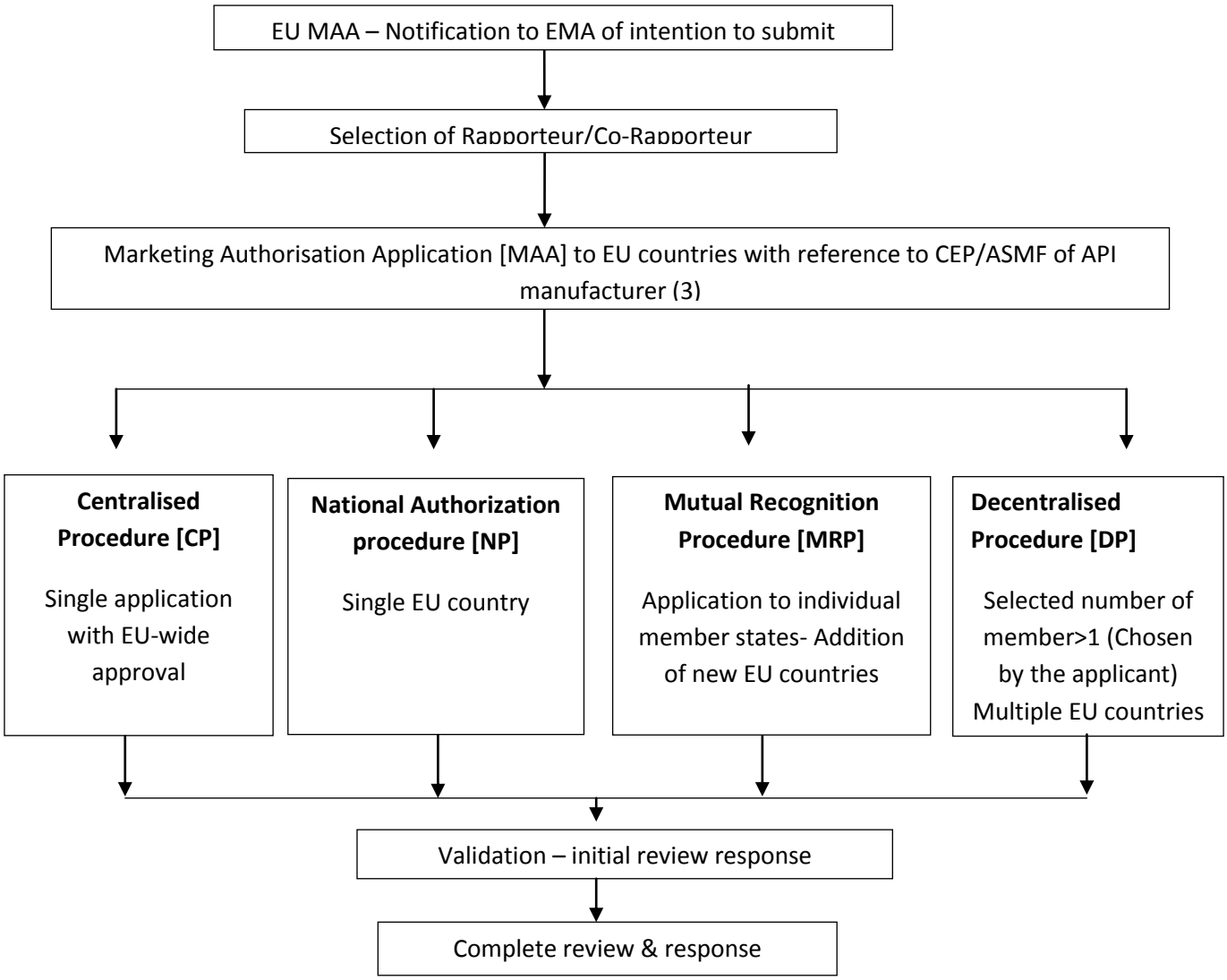
through a National Procedure) can apply for this authorisation to be recognised in other EU countries.

- Authorisation of the medicines in several countries simultaneously
- Quicker to first market
- Can withdraw application from critical CMS
- Second wave possible
- Different trade names possible
- 6/10 years data protection from first date

Decentralised Procedure (DCP)

- For products that fall outside the scope of the European Medicines Agency (EMA [www.ema.europa.eu]) with regard to centralized procedures, a sponsor can submit under the decentralized procedure. (1)
- Using this process, a sponsor can apply for simultaneous authorization in more than one EU country for products that have not yet been authorized in any EU country.
- Need to book slot with choice of RMS via slot booking procedure
- Once slot granted, application needs to be submitted to RMS & all CMS.[after payment of relevant fees]

EU: MAA Regulatory submissions – General Process Flow



CONCLUSION

Thus, various application procedures of EEA are discussed in this article. The procedures for application of marketing authorization are: Centralised procedure, National procedure, Mutual recognition procedure, Decentralised procedure.

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CONFLICT OF INTEREST

Author declares that there are no conflicts of interest.

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