EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Eligibility issues and meeting opportunities

How can we help?

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Overview

Eligibility

- Right to place an application for the centralised procedure

Letter of intention to submit an application

Pre-submission support and support during development

- Regulatory Advice
  - Pre-submission meetings
- Scientific support
  - Scientific Advice
  - Innovation Task Force

Contacts and references

Eligibility

- governed by Regulation (EC) No 726/2004

Mandatory scope - *Article 3(1) and Annex of Regulation*

- These product applications must make use of the centralised procedure
- Veterinary medicinal products developed by means of a biotechnological process
  - Recombinant DNA technology
  - Controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells
  - Hybridoma and monoclonal antibody methods
- Veterinary medicinal products including those not derived from biotechnology, intended primarily for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals

Eligibility

- governed by Regulation (EC) No 726/2004

Optional scope - *Article 3(2)*

a) New active substance which, on 20 November 2005, was not authorised in the Community for use in a medicinal product intended for use in animals

- Examples: new fixed combinations of known substances, substances authorised first time after 20 Nov 2005

b) Product constitutes a significant therapeutic, scientific or technical innovation or that the granting of the MA is in the interests of animal health at Community level

Immunological products for treatment of diseases that are subject to Community prophylactic measures

Eligibility

- governed by Regulation (EC) No 726/2004

Automatic access - *Article 3(3)*

- Generic medicinal products to centrally authorised products

Eligibility

- key items needed for a successful request

A complete pre-submission request form

A draft Summary of Product Characteristics (SPC)

A justification of the product's eligibility for evaluation under the Centralised Procedure

- In case of a product falling under the scope of Article 3 of the Regulation (EC) No 726/2004, a concise summary document of preferably maximum 2 pages stating why the product should qualify for the granting of a marketing authorisation through the Centralised Procedure

Eligibility

- how to apply

When - well in advance of submission (months-years)

How

- Pre-submission request form and Q&A available on EMA website
- Send by email to vet.applications@ema.europa.eu

Decision

- The Committee for Medicinal Product for Veterinary Use (CVMP) will consider application and justification at their next plenary meeting
  - Application to be received 15 days in advance of CVMP meeting
- Eligibility is rejected/confirmed, however circumstances may change
  - Sometimes additional information is requested prior to decision
  - The applicant will be informed of the outcome in writing, including information on project manager contact details if close to submission

Letter of intention to submit

- after or at same time as eligibility

Letter of intention to submit an application

- 7 months in advance of intended submission date and 15 days prior to a CVMP meeting
  - Pre-submission request form and attachments
  - N.B. Recommended dates for intended submission of marketing authorisation applications are published on EMA website
- Consideration by CVMP at next plenary meeting
  - Appointment of rapporteur and co-rapporteur
  - Applicant to be informed in writing of outcome

Pre-submission support and support during development

Possibilities for interaction

- brief overview

Regulatory advice

- Queries vet.applications@ema.europa.eu
- EMA website
  - Notice to Applicants; Scientific and regulatory guidelines, SME guidance
  - A pre-submission Q&A for innovative products (*update in process*)
- Pre-submission meetings
  - Before submissions – scientific advice, applications for MA

Support during development

- Innovation Task Force
- Scientific advice
  - Upon request for all veterinary medicinal products irrespective of eligibility for the centralised procedure or not

Pre-submission meetings

- scope

The Agency emphasises the importance of pre-submission meetings with applicants

- Each application is unique

Opportunity to obtain procedural and regulatory advice

To enable applicants to submit applications which are in conformity with the legal and regulatory requirements and which can be validated speedily.

To enable applicants to establish contact with the Agency staff closely involved with the application as it proceeds.

Pre-submission meetings

- organisation

Meeting at least 4 to 6 months prior to the anticipated date of submission of the application

- Earlier pre-submission meetings can also be arranged

Teleconference or face-to-face meeting

- Organised at the Agency
- Agency staff attendance on basis of items to discuss
- Exceptionally CVMP members (rapporteurs) attendance if scientific elements
    - If (co)rapporteurs have been appointed (this requires prior submission of letter of intention to submit an application)
    - Exceptionally may be organised by (co)rapporteur's home organisation

Pre-submission meetings

- documents

Pre-submission meeting request form

A (draft) SPC

A (draft) application form

A draft meeting agenda

- Any other topics not included on pre-submission form

Relevant background information, if appropriate

- Presentation of product, packaging, studies etc to serve as basis for discussion on the question

Copy of any scientific advice given related to the application

Send to vet.applications@ema.europa.eu

Innovation Task Force (ITF) - now open to VMPs

Multidisciplinary platform

for **preparatory dialogue and orientation on**

innovative medicines, technologies and methods

News Item foreseen on EMA website 8 November 2013

Innovation Task Force (ITF)

Purpose

- Provide a forum (soft landing zone) for innovation
- Complementary and preparatory to existing other formal procedures

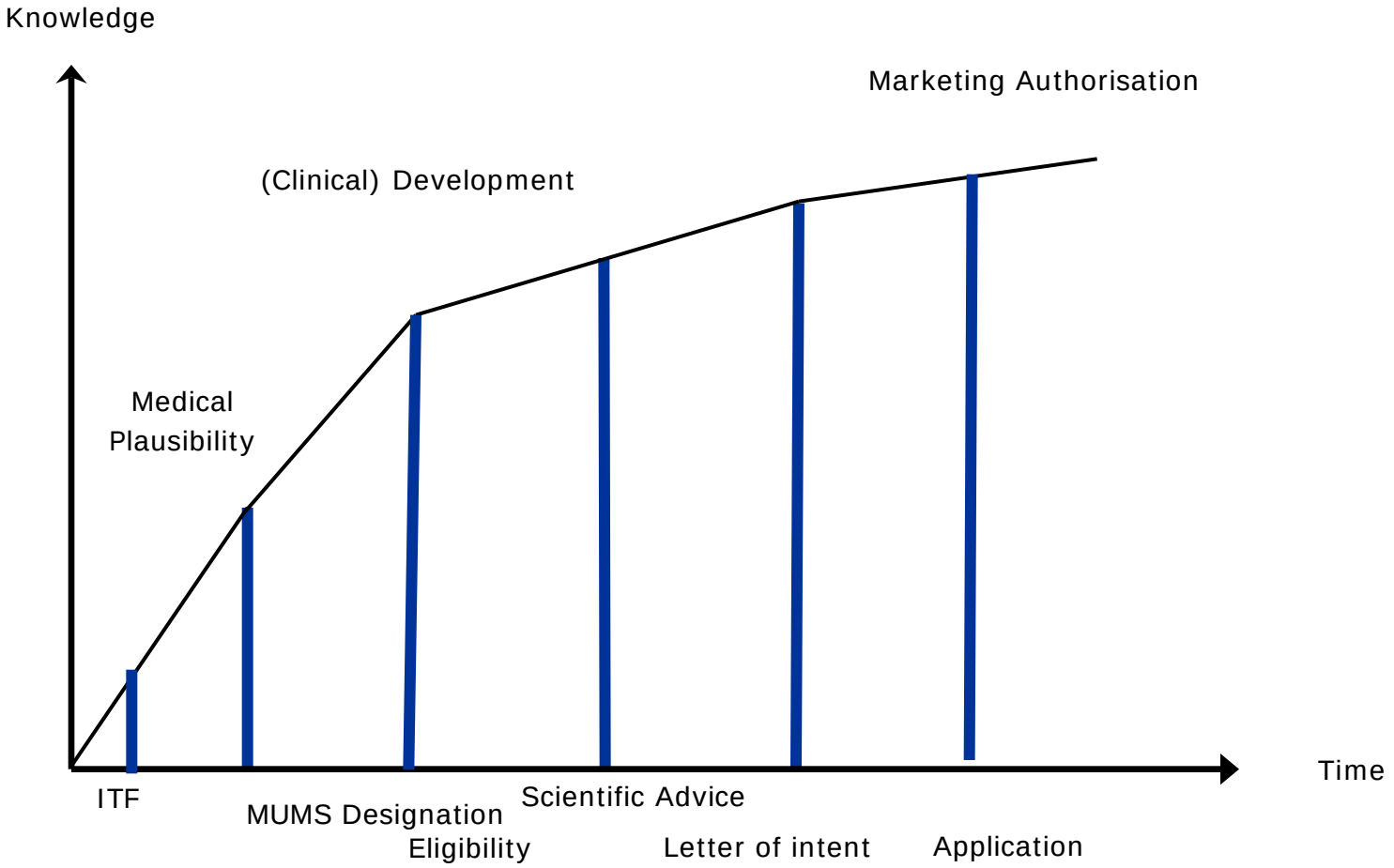
Tools

- Briefing meetings with applicant and regulators
- Scientific recommendations on classification (medicine or not)
- Workshops (e.g. nanomedicines, stem cells)

Veterinary pre-step

- Initial review of ITF request
  - useful to allow better consultation prior to official submission
- Allows the veterinary division to customise the process
- How to contact initially: vet.applications@ema.europa.eu

Interactions – some schematic points in time



Contacts and references

EMA website www.ema.europa.eu

Email: vet.applications@ema.europa.eu