EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pre-submission phase & guidance for novel products

EMA/IFAH-Europe Info Day
14 March 2014

Presented by:
Fia Westerholm (Head of Development and Evaluation of Veterinary Medicines);
Nikolaus Križ (Development and Evaluation of Veterinary Medicines)


Summit (29,028 ft)
Lhotse
(27,923 ft)
North Face
Camp IV
(26,000 ft)
Geneva Spur
Camp III
(24,500 ft)
South Face
Nuptse
(25,850 ft)
Camp II
(21,300 ft)
Lho La
Camp I
(19,900 ft)
Khumbu Icefall
Base Camp
(17,700 ft)
Khumbu Glacier

Guidance in pre-submission phase

- EMA is committed to provide guidance and support to applicants during pre-submission phase
- Aim is to enable the applicant to submit dossier, which is in conformity with the regulatory requirements and which can be evaluated in a smooth and efficient manner
- Purpose of this presentation:
  - Overview of guidance and support available
  - Info on streamlining of processes
  - Info on what is new
  - Info on what is in development

Pre-submission phase – What guidance is available and how

Guidance for product development and dossier submission

- European Medicines Agency website
  - Veterinary pre-submission Q&A *recently updated*
  - General and specific regulatory guidance
  - Scientific recommendations (“guidelines”)
  - Application and request forms *please use latest versions*
- Pre-submission meetings – upon request
- Scientific advice – upon request
- Innovation Task Force – for novelties upon request
- Responses to queries (vet.applications@ema.europa.eu)

Pre-submission phase – Veterinary pre-submission Q&A

- Responds to questions related to pre-submission guidance for new veterinary medicines
  - such that applicants or marketing authorisation holders (MAHs) typically may encounter
- Provides an overview of the European Medicines Agency's position
  - issues that are typically addressed in discussions or meetings with applicants/MAHs
- Emphasizes the importance of pre-submission meetings
  - enable applicants to establish contact with the Agency staff who will be involved with the application

Pre-submission phase – Recent changes

- Eligibility request – timing
- Notification of intention to submit – timing
- Appointment of rapporteurs – timing
- Agency involvement in pre-submission meetings
- ASMF – registration in advance

Recent changes - eligibility

- What? Confirmation that the centralised procedure can be used for a product
  - *Note*: No change in scope, Article 3 of Regulation (EC) No 726/2004 applies
- When? No later than 7 months in advance of intended submission
- How? Designated electronic form to be used
  - Justification and draft SPC
  - Send to central point vet.applications@ema.europa.eu
- Outcome: Response letter on whether product is eligible or not

Recent changes - intention to submit

- What? A notification of intention when the submission date is known ("letter of intent")
  - Triggers the appointment of rapporteur and co-rapporteur
  - Note: realistic submission date
- When? At 7 months prior to the intended submission date
  - Eligibility request can be combined, if not submitted before
- How? Designated electronic form to be used
  - Send to central point vet.applications@ema.europa.eu
- Outcome: Response letter including information on rapporteurs and project manager

Recent changes – active substance master file (ASMF)

New requirements for Centralised procedure (September 2013):

- ASMF reference number: EMEA/ASMF/XXXXX or EU/ASMF/XXXXX
- Submission only once and to be used for all applicable MAAs

ASMF assessment worksharing pilot phase (December 2013):

- Purpose: harmonised assessment throughout Europe, minimise the workload of ASMF holders, applicants and competent authorities
  - Not mandatory
- Eligibility: new ASMF submitted via centralised procedure (CP) or decentralised procedure (DCP) only
  - *new ASMF*: an ASMF that has not been previously assessed by a competent authority as part of a CP, DCP or mutual recognition procedure (MRP)
  - Other ASMFs intended to be eligible at a later stage

Pre-submission meetings

- Scope and Objectives:
  - open for all types of products - tailored approach
    - ➢ differences in products, needs, MAHs, experiences
  - present dossier / development plan
  - receive guidance on dossier and direction on necessary steps
  - meet Agency staff
- When? Throughout development
- How? Designated electronic form to be used
  - Send to central point vet.applications@ema.europa.eu

Recent changes – pre-submission meetings

Possibilities

- Guidance and advice for direction can be provided
  - Preparatory work needed by applicant
  - Based on available regulatory and scientific guidance

Limitations

- No specific scientific discussion
  - CVMP experts/ rapporteurs not involved
  - Not to overlap with scientific advice

Innovation Task Force (ITF) - now open to VMPs

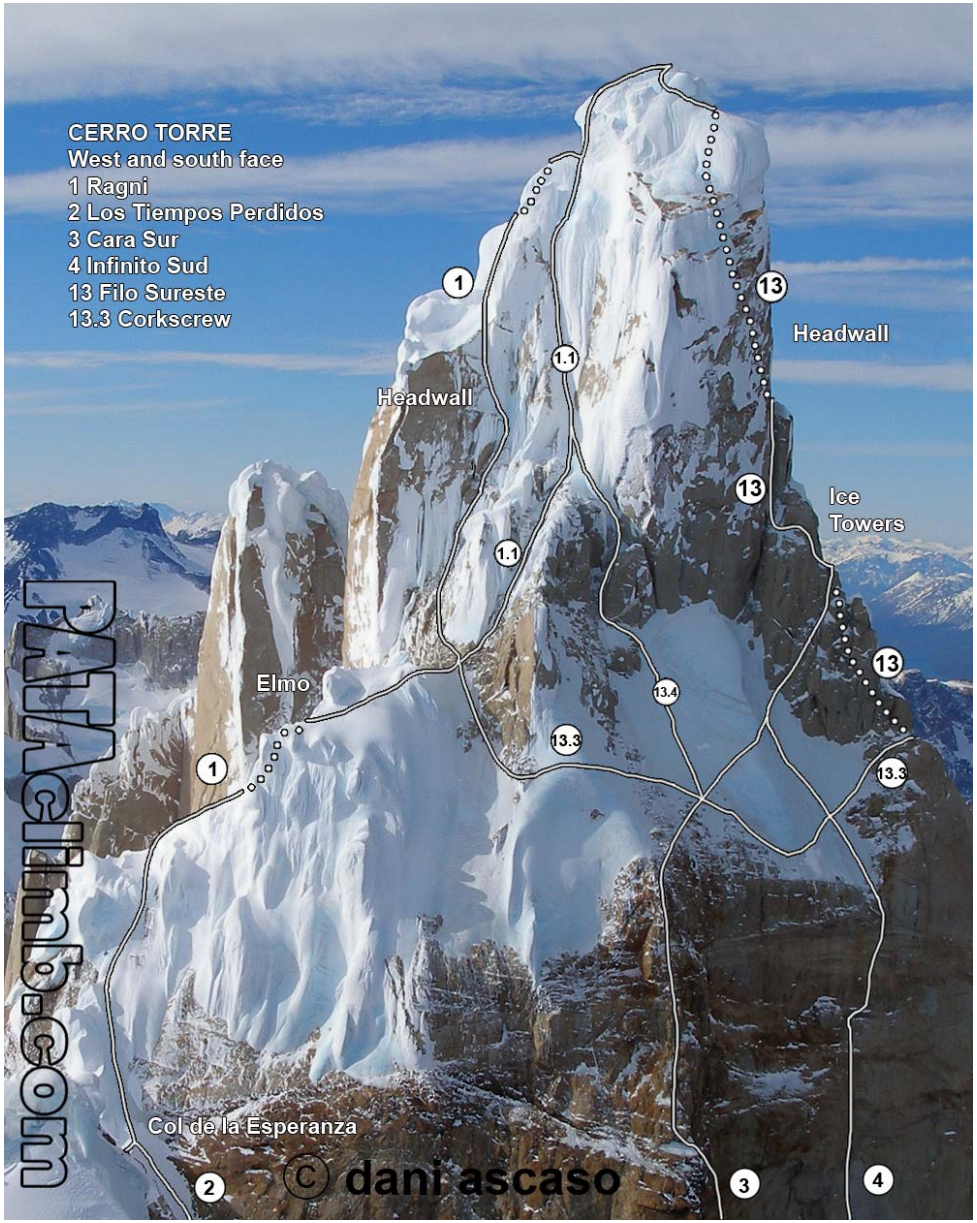
Multidisciplinary platform

for **preparatory dialogue and orientation on**

innovative medicines, technologies and methods

Innovation Task Force

- Provide a forum (soft landing zone) for innovation
- Identify scientific, legal and regulatory issues of emerging therapies and technologies
- Address the impact of emerging therapies and technologies on current scientific, legal and regulatory requirements with the Agency's committees and their working parties
- Review the regulatory and scientific implications of emerging therapies and technologies, in conjunction with the Agency's committees and their working parties
- Increase awareness and learning in emerging therapies and technologies at the Agency


CERRO TORRE
West and south face
1 Ragni
2 Los Tiempos Perdidos
3 Cara Sur
4 Infinito Sud
13 Filo Sureste
13.3 Corkscrew
Headwall
Headwall
Ice
Towers
Elmo
Col de la Esperanza
© dani ascaso
PATAGONIA.com

Innovation Task Force

- Provide advice on eligibility to Agency procedures relating to research and development, in conjunction with the CVMP and the European Commission as appropriate, for example:
  - where there are uncertainties on whether the concerned therapy contains a medicinal substance;
  - for borderline products, having characteristics belonging to diverse legal frameworks, e.g. medicines and medical devices;
  - for (medicinal) substances incorporated in medical devices for which the medicinal and ancillary functions are borderline;
- Areas of ITF engagement have included nanomedicines, pharmacogenomics, synthetic biology, biomaterials, modelling and simulation…

Innovation Task Force

- **Briefing** meetings with applicant and regulators
- ITF arranges these meetings within 60 days of receipt of a valid request from an applicant
- Discussions are led by experts from the Agency's network, working parties and committees, with the best available scientific expertise being represented
- Briefing meetings are intended to complement, reinforce and prepare existing formal procedures (e. g. scientific advice) and to identify the need for specialised expertise at an early stage
- **Veterinary pre-step**
- Initial review of ITF request
- Allows the veterinary division to customise the process
- How to contact initially: vet.applications@ema.europa.eu

Summary

- Guidance and support provided to applicants during pre-submission phase
  - Guidance on website
    - Latest versions of necessary forms
  - Queries
  - Innovation task force
  - Scientific advice
  - Pre-submission meetings
- Central correspondence point vet.applications@ema.europa.eu

THANK YOU