



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Innovation Task Force and ITF briefing meetings: What can be gained

EMA Veterinary Medicines Innovation Day 19 April 2018

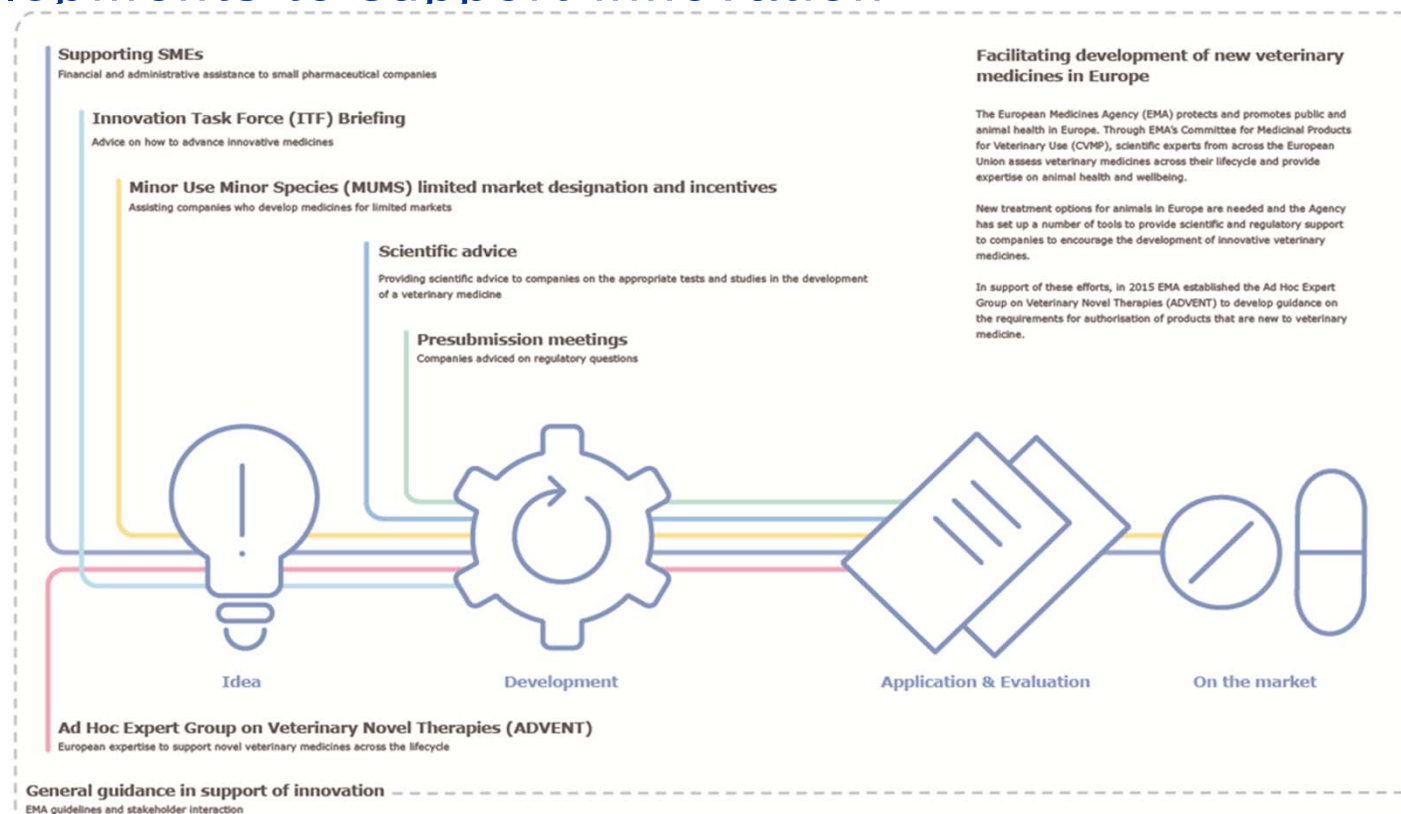
Presented by Minna Leppänen on 19 April 2018
Head of Veterinary Biologicals and Emerging Therapies

An agency of the European Union





EMA developments to support innovation



- 1 Innovation Task Force and ITF briefing meetings: What can be gained



Innovation Task Force (ITF) (1)

A multidisciplinary group that includes scientific, regulatory and legal competences:

- To establish a discussion platform for **early dialogue** with applicants to proactively identify scientific, legal and regulatory issues of emerging therapies and technologies.
- To address the **impact of emerging therapies and technologies** on current scientific, legal and regulatory requirements with the Agency's committees and their working parties.
- To identify the **need for specialised expertise** at an early stage.
- To **provide advice** on the eligibility to Agency procedures relating to research and development, in conjunction with relevant EMA committees and other authorities.



Innovation Task Force (ITF) (2)

A multidisciplinary group that includes scientific, regulatory and legal competences:

- To review the **regulatory and scientific implications** of emerging therapies and technologies, in conjunction with the Agency's committees and their working parties.
- To **increase awareness and learning** in emerging therapies and technologies at the Agency.



ITF briefing meetings

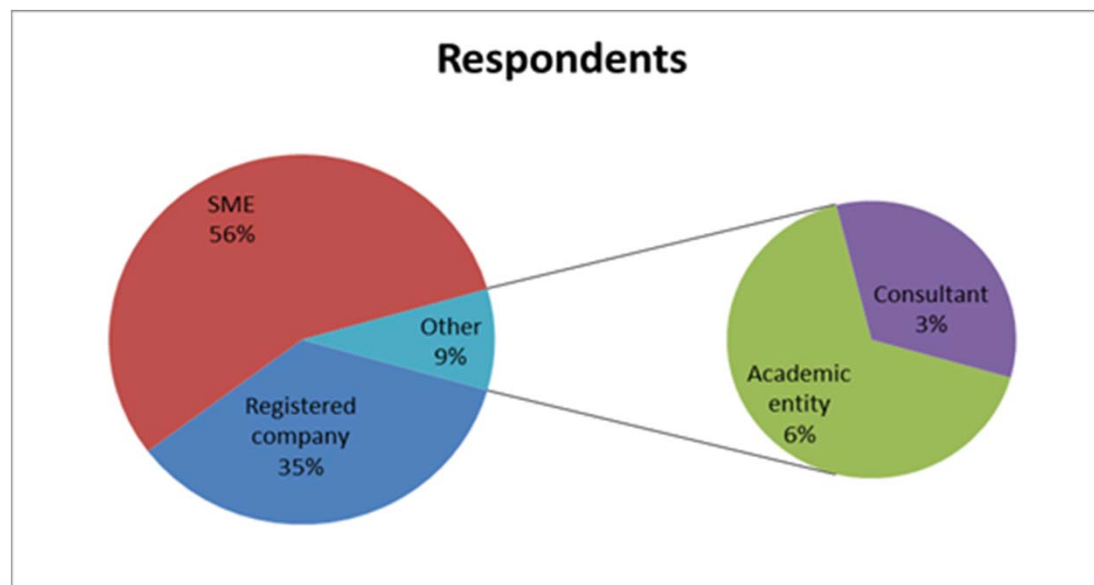
The ITF holds briefing meetings with applicants covering regulatory, technical and scientific issues arising from the development of innovative medicines, new technologies and borderline products.

- Intended to facilitate the **informal exchange of information** and the provision of guidance **early** in the development process.
- Experts from the Agency's network, working parties and committees, with the **best available scientific expertise** being represented.
- Are intended **to complement** and reinforce existing **formal** regulatory **procedures**.
- Within 60 days of receipt of a valid request from an applicant.
- **Free of charge**.
- ITF briefing meetings in veterinary medicines were initiated 2014, so far 13 meetings held.



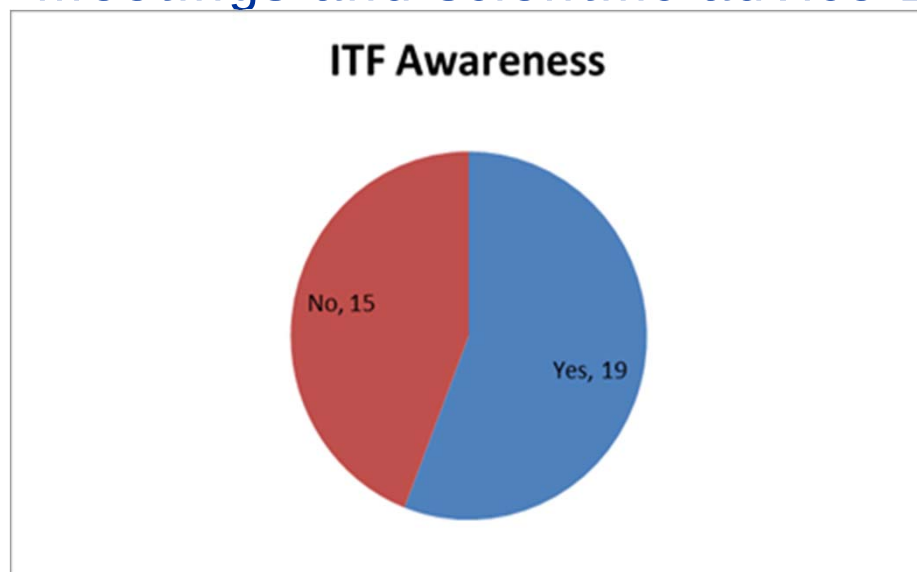
A survey on impact of Innovation Task Force briefing meetings and scientific advice 2018: initial results

Total 34 responses





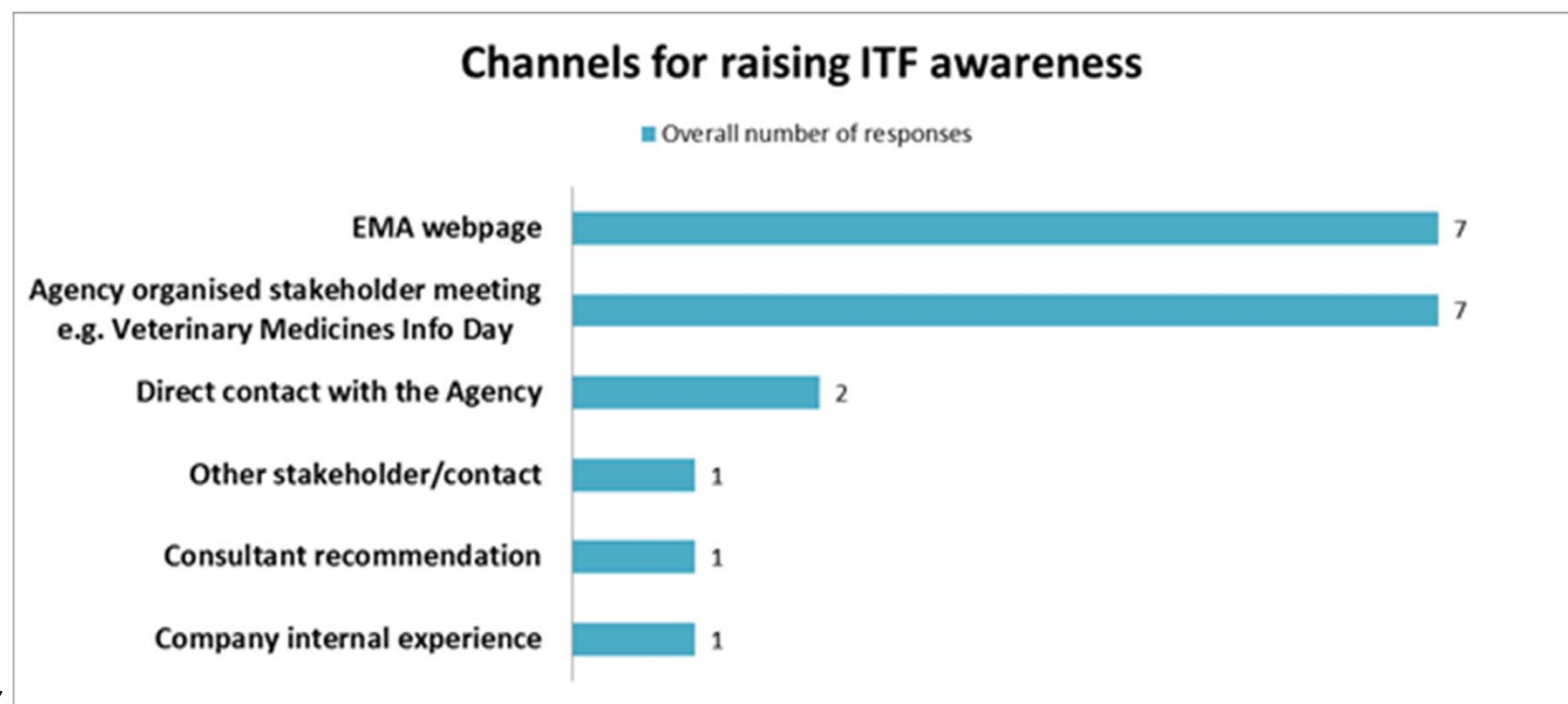
A survey on impact of Innovation Task Force briefing meetings and scientific advice 2018: ITF awareness



- 9 SMEs were aware of the possibility to request ITF briefing meetings during early development
- 12 out of the 19 (63%) respondents have submitted an ITF request

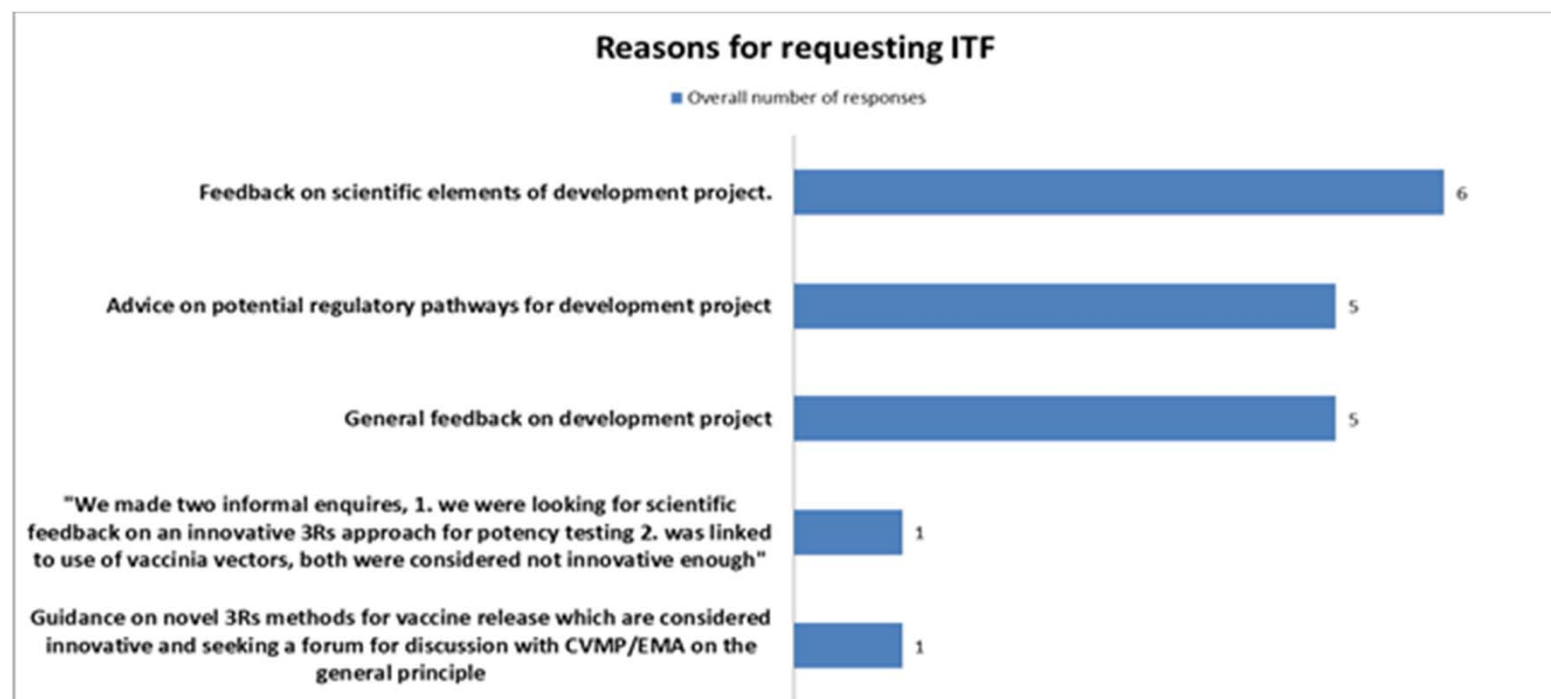


A survey on impact of Innovation Task Force briefing meetings and scientific advice 2018: ITF awareness





A survey on impact of Innovation Task Force briefing meetings and scientific advice 2018: Reasons for requesting an ITF BN





Value of ITF briefing meetings

7 out of 9 participants considered an ITF briefing meeting beneficial.

Comments received:

- Honest, instructive, refining process, supportive, helpful, detailed
- Useful opportunity for open discussion, relevant, credible, engaging
- Too generic
- Expectations are often rather to get specific advice
- ITF appear to be rather informing CVMP on plans and backgrounds in order to help CVMP to prepare its later position.

BUT there is still room for development and improvement



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Any questions?

Further information

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