EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

How Scientific Advice Procedures can Support Innovation

EMA Veterinary Medicines Innovation Day

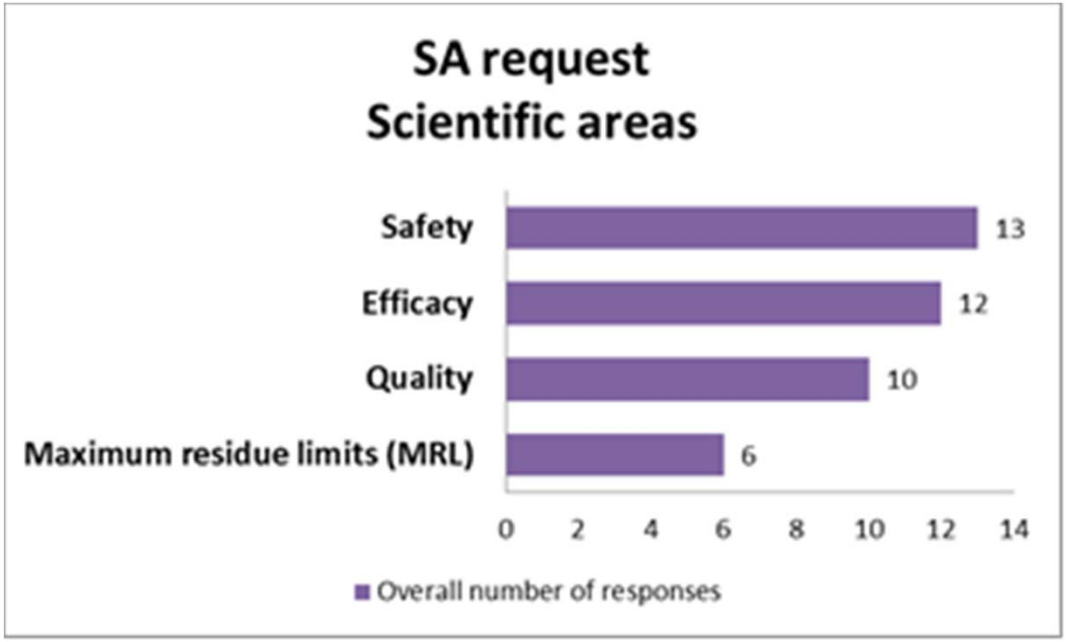
Presented by Rory Breathnach 19 April 2018

An agency of the European Union

Who SAWP-V are and what we do

- Comprised of 15-17 members of CVMP
- Deal with all aspects of SA (Q, S, E and MRLs) – Regulatory issues are for EMA
- What are we? A confidential insurance policy, a “get inside our head” policy
- What we are not:
  - Regulatory creep/trying to control you
  - Data snooping
  - Trying to catch you out or make you feel silly

Breakdown according to topic

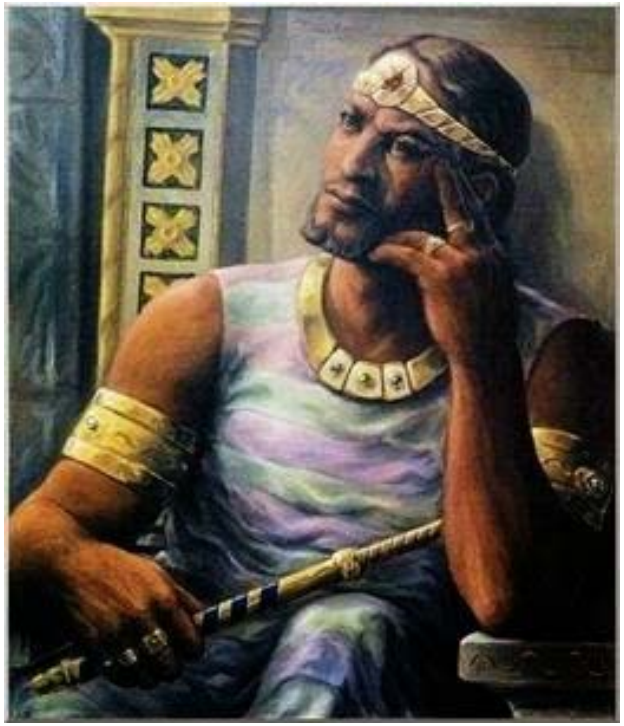


Let's be clear, our ultimate goal

- Precisely same as YOU!!
- Assist industry in getting top quality products on market by successfully negotiating regulatory hurdles
  - we know that funds and time can be very limited, especially for SMEs
- Society wants innovative products available for a whole range of conditions
  - everyone in EU wins

How does SAWP-V add value?

Well, we don't have the wisdom of Solomon!!



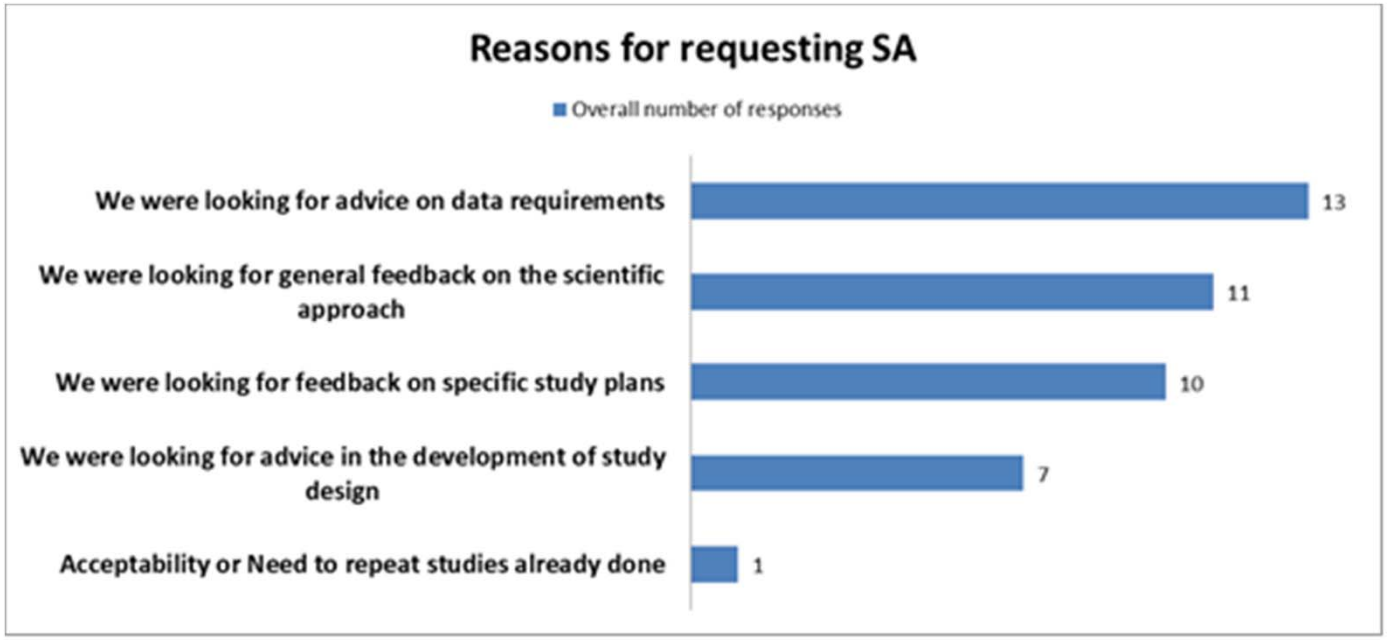
Equally ..

We're not
Mystic Meg!

But we add value, because

- (Although applications becoming increasingly complex), we have access to:
  - EU Regulatory network
  - Additional experts in niche areas (MAbs, bacteriophages etc.)
  - FDA if joint SA
- We often know what works, when you may be able to combine studies (*N.B.* 3Rs)
- Sometimes, more importantly, we know what doesn't work!!

What requests drive innovation



Ok, to enhance innovation, let's address recent survey and lessons we've learned/need to learn

What's good:

- companies love SA when it agrees with their position/reduces data requirements
- the opposite is also true
- CVMP accepts bone fides when SA followed

Positives:

- 99% of companies know about SA procedure
- clarification advice is free and often used
- SA often allows significant study modification before commencement
- 65% felt it enhanced predictability of MA application

What more would enhance innovation?

- Cost considerations – are fees fair? MUMS and SME reductions clearly exist
  - Should follow-up SA be free?
- Communication is key issue
  - Face-to-face meetings (before and during procedure). Web meetings?
  - Can coordinator liaise more after meeting to clarify answer?
  - Open debate rather than company “feeling on trial”

OFIs (cont.)

- Minimize TT – 60 days most common at present

- Be less neutral – many (SAWP-V) members fully agree!!
  - But, if you want clear advice, need very clear questions/proposals
  - We take 3Rs and MUMs criteria extremely seriously, but …
  - Sometimes, you're the pioneers of your science, and it's your results that dictate future policy
  - However, ……..

If we’re both looking in the same direction, what can possibly go wrong?


Thank
You!

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Any questions?

Further information

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