

Focus group on promotion of PhV for food producing animals – MAH view

IFAH-Europe
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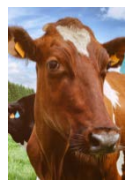
SCOPE



- Veterinary Medicinal Products Regulated by EMA or EU Member State (MS) Regulatory Agencies
- Does not include (though in practice, companies do generally follow similar internal processes to ensure product integrity and animal safety):
 - x Products regulated by EFSA (e.g. poultry anticoccidials)
 - x Nutritionals
 - x Diagnostics
 - x etc.
- Does not include Product Defects (missing label etc.) as this covered under Good Manufacturing Practice (GMP) legislation (although much of this information is usually captured in a similar way by the MAH)



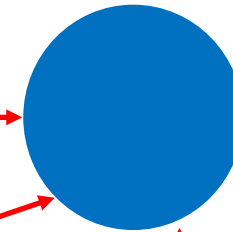
PhV Information flow



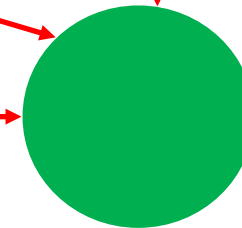
Animal
Owner



Veterinarians



Regulatory
Agency



MAH

Data anonymised: initials
and part post code ONLY

Drivers for Animal Owners / Veterinarians:

Is an AE recognised?

Know how to report an AE?

What are the benefits of reporting an AE?

Any obligation to report an AE?

Are there any downsides/costs of acting?

Are there any consequences of not acting?

Is there a significant financial cost?

Other driver:

In the absence of a professional obligations,
reporting is probably related to any gap between
customer 'expectation' and 'reality'

Barriers and Solutions to effective PhV information flow



Issue	Animal Owners	Ideas to overcome	Vets	Ideas to overcome
Recognition of AE?				
Know how to report an AE?				
Is there any value to reporting AE?				
Is there any obligation to report AE?				
Takes too much time to report?				
Is too costly?				
Others?				

*CPD: Continuing Professional Development

**NCA: National Competent Authority

Barriers and Solutions to effective PhV information flow



Issue	Animal Owners	Ideas to overcome	Vets	Ideas to overcome
Recognition of AE?	Probably	Vet communication, Trainings, Agric .College curriculums	Probably	CPD*, NCA** on Vet school curriculum
Know how to report an AE?	Probably – vet first point of call	Vet communication	+ / -	CPD NCA on Vet school curriculums
Is there any value to reporting AE?	Sometimes – need help	Vet communication	Yes (may lose client – unlikely?)	CPD, NCA on Vet school curriculums Reinforce professional ethics
Is there any obligation to report AE?	? Probably not	?	Yes / unknown	CPD, Reinforce professional ethics
Takes too much time to report?	?	Reporting needs to be easy, quick and simple. Vet communication	?	Reporting needs to be easy, quick and simple. Familiarity with reporting contact points / mechanisms.
Is too costly?	Investigation will cost esp. for LOE	?	Investigation – no. Reporting ?	(See ease of reporting above)
Others?	Cultural?	Vet communication	Cultural?	CPD, NCA on Vet school curriculums

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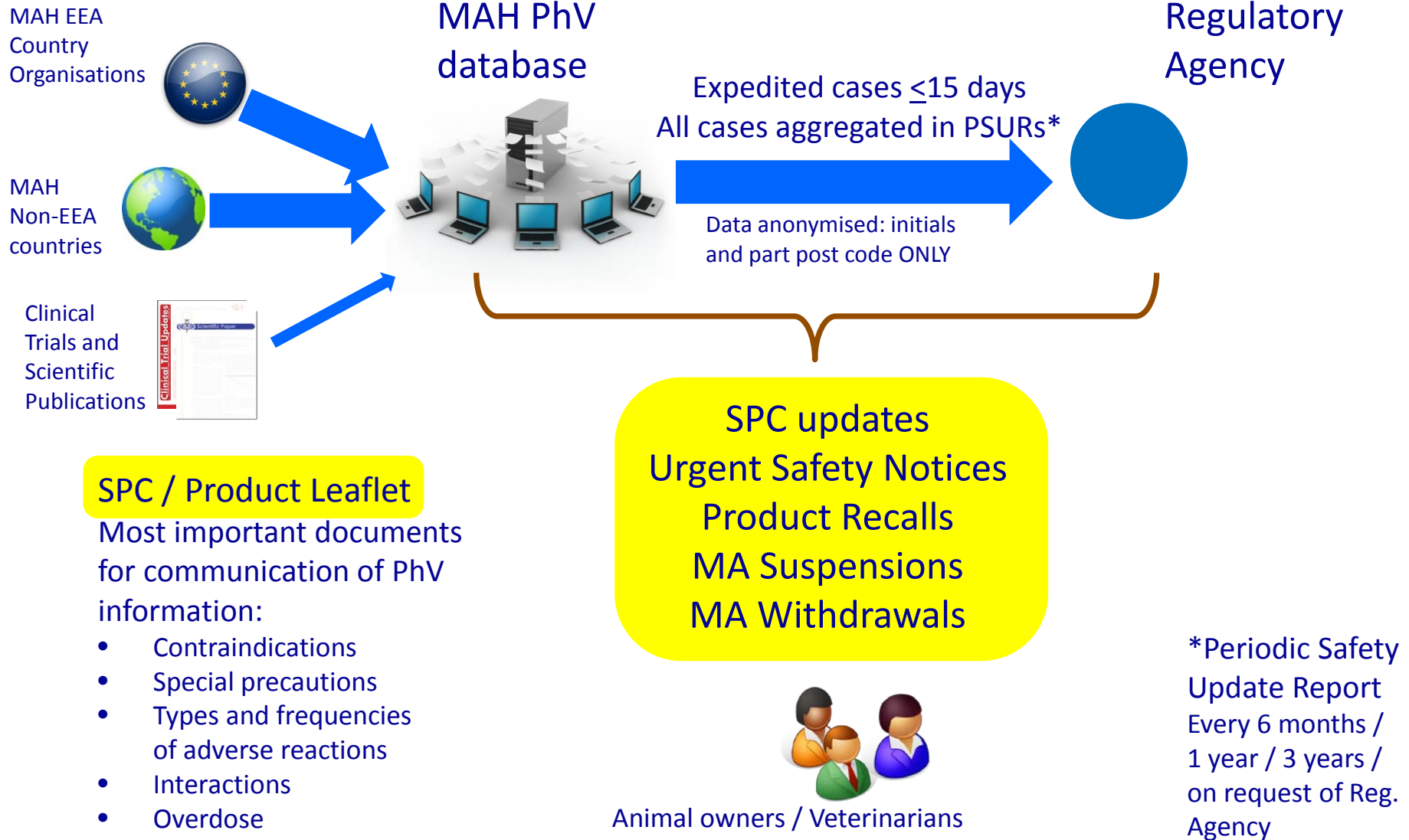
Barriers and Solutions to effective PhV information flow



Issue	Ideas for MAHs	Ideas for NCA*s
Recognition of AE?	N/A (driven by legislation)	Outreach to Vet Schools, Outreach to Veterinary Professional Societies
Know how to report an AE?		
Is there any value to reporting AE?		
Is there any obligation to report AE?		
Takes too much time to report?	N/A (driven by legislation) MAH contact information: phone / email / internet are easily accessed and simple	NCA contact information: phone / email / internet are easily accessed and simple
Is too costly?	N/A (driven by legislation)	N/A
Others? 'Culture'?	Assist in outreach to Vet Schools and Veterinary Professional Societies	Outreach to Vet Schools, Outreach to Veterinary Professional Societies
Comments:	MAH PhV systems and processes are routinely inspected by EMA / NCAs	

*NCA: National Competent Authority

MAH: Where does PhV information go?



MAH: Contribution to Food Producing Animal PhV



- What do MAHs do to help Food Producing Animal Pharmacovigilance?
 - Keep SPCs / Product leaflets up to date
 - Training of sales personnel, clinical research staff etc
 - Effective communication of benefits and risks through advertising and sales teams
 - Respond to veterinarian / animal owner questions or concerns promptly (eg MAH have to report 'serious' cases to NCA within 15 calendar days)
 - Signal detection: human / statistical basis
- Important to note:
Livestock Pharmacovigilance has had some notable successes in identifying previously unidentified risks which has led to Company/Regulatory Action
- Are there significant unrecognised issues?
 - Is Evolution (improvement) or Revolution (crisis) in Food Animal PhV needed?

THANK YOU!

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