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Challenges for Candidate Countries: implementing the Veterinary Medicines Legislation

PHARMACOVIGILANCE

TAIEX, AGR 26438
Zagreb, 18 March 2008

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“not an option
but an **obligation**”

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Pharmacovigilance

- **What** is monitored?
- **How** is it monitored?
- **Reports**
- **Vets** and pharmacovigilance

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What is monitored?

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What is monitored?

- Adverse reactions
- Serious adverse reactions
- Human adverse reactions

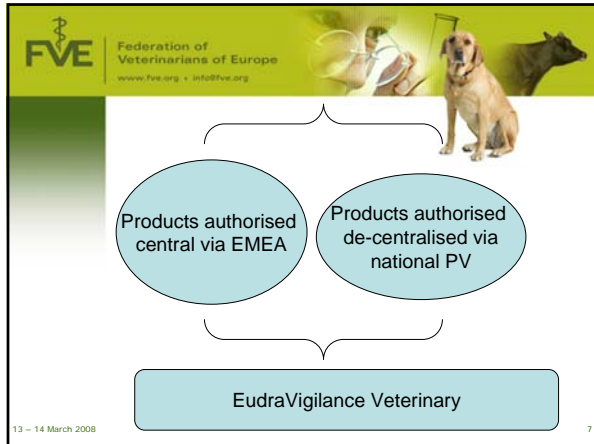
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How is it monitored?

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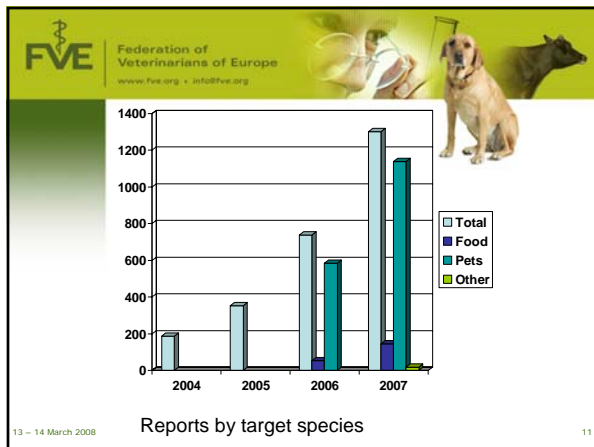
This is a screenshot of the EudraVigilance Veterinary website. The page title is 'EudraVigilance Veterinary'. It contains several sections:

- What is EudraVigilance Veterinary:** A brief description of the system as a European data-processing network and database management system for the exchange, processing and evaluation of Suspected Adverse Reaction Reports (SARs) related to veterinary medicinal products.
- How to register with EudraVigilance Veterinary:** A section detailing the registration process, including the need to identify the jurisdiction of the EMEA in the EEA and the provision of advice on the measures to ensure the safe and effective use of these products.
- Documents required for registration:** A list of documents that must be submitted to the EMEA.

 The URL <http://eudravigilance.emea.europa.eu/veterinary/index.asp> is provided at the bottom. The date '13 - 14 March 2008' is at the bottom left.

This slide features the FVE logo and name at the top left. The main text in the center reads 'CVMP Pharmacovigilance Working Party'. Below the text is an illustration of a group of people sitting around a table, representing a working party. The date '13 - 14 March 2008' is at the bottom left.

This slide features the FVE logo and name at the top left. The main text in the center reads 'Reports?'. The date '13 - 14 March 2008' is at the bottom left.



This slide features the FVE logo and name at the top left. It defines two types of reports:

- SAR = suspected serious adverse reaction report**
- PSUR = periodic safety update report**

 The date '13 - 14 March 2008' is at the bottom left.

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Vets and pharmacovigilance?

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Veterinarians are more motivated to report adverse effects, when they see an added value:

- when they encounter something new
- when it is considered a serious case
- when it does not cause too much extra work
 - preferably on-line reporting
- when they get feedback on the report
- when the owner of the animal complains

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