EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Workshop on harmonising the approach to VeDDRA coding: Overview of process for VeDDRA revision

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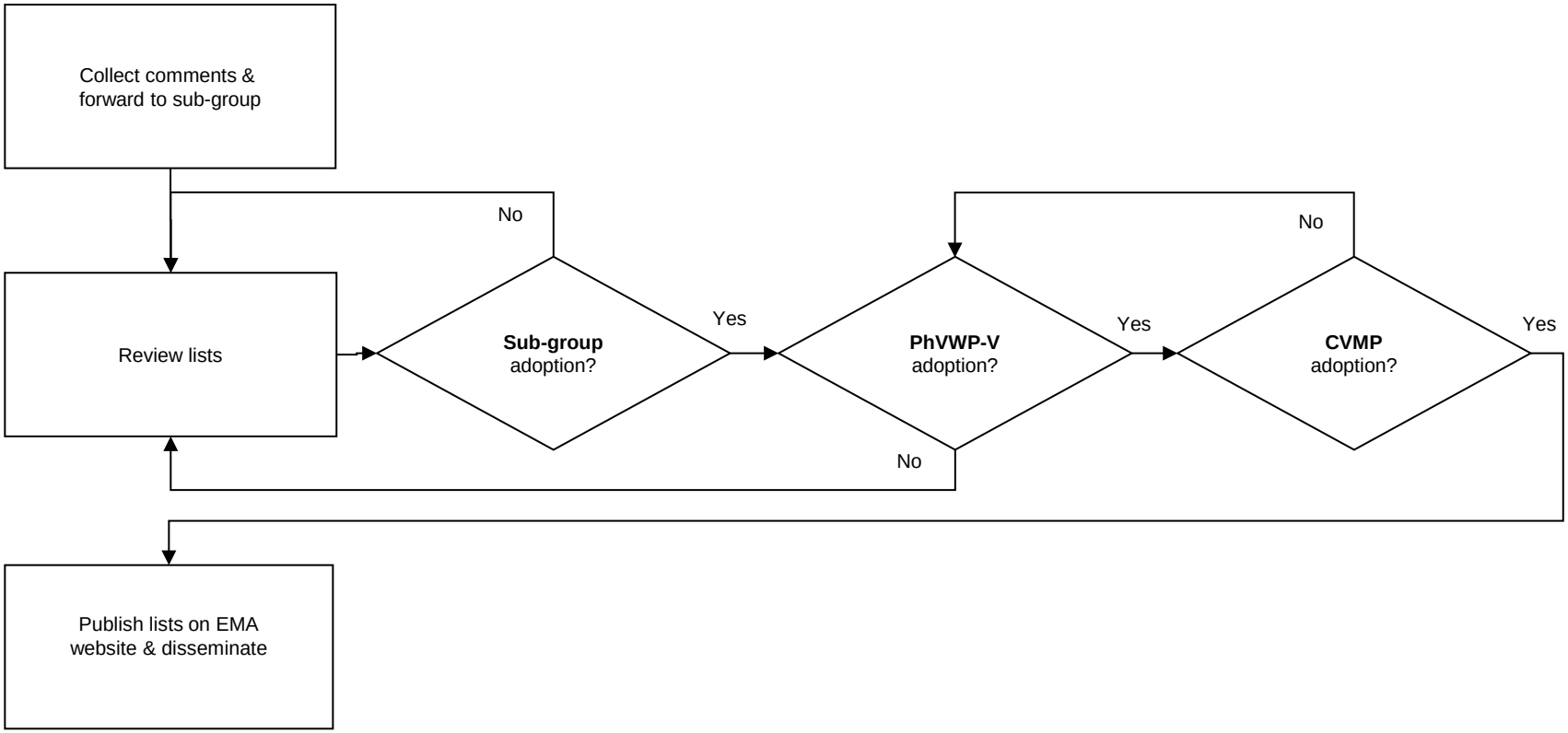
Introduction

- CVMP PhVWP-V VeDDRA sub-group
  - PhVWP-V members, industry representatives, VICH observers
- Standard lists reviewed annually
  - Combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (EMA/CVMP/10418/2009);
  - List of species and breeds for electronic reporting of adverse reactions in veterinary pharmacovigilance (EMA/CVMP/553/2003)

VeDDRA review process



Submitting comments for VeDDRA review

- Permanent call for comments
  - New deadline: **1 March** each year

- Template for submission of comments
  - ✓ Refer to current version (on EMA website)

Line no.	Current term	Current key	*Proposed* term	*Proposed* key	Action	Comments
	(SOC/HLT/PT/LLT/Term type (A,H,C))					

References and hyperlinks

- **Call for comments** on standard lists for EudraVigilance Veterinary
- **Guidance notes** on the use of Veterinary Dictionary for Drug Related Affairs terminology for reporting suspected adverse reactions in animals and humans
- **Combined Veterinary Dictionary for Drug Related Affairs** list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products
- **List of changes** to combined Veterinary Dictionary for Drug Related Affairs list of clinical terms for reporting suspected adverse reactions in animal and humans to veterinary medicinal products for 2013
- **Non-current** Veterinary Dictionary for Drug Related Affairs (VeDDRA) low-level terms (LLT) and codes
- **List of species and breeds** for electronic reporting of suspected adverse reactions in veterinary pharmacovigilance

  http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000173.jsp&mid=WC0b01ac058002dea6#section3

- **Standard operating procedure:** Annual review of standard lists to be used in EudraVigilance Veterinary (SOP/V/4019)
  http://www.ema.europa.eu/docs/en_GB/document_library/Standard_Operating_Procedure_-_SOP/2009/09/WC500003094.pdf

Thank you for your attention!

Questions?