NVR changes to Veterinay Pharmacovigilance

hvordan håndteres ikke-alvorlige indberetninger, som ikke er overført til jer/EVVET og som ej heller bliver listet i PSURer, som jo udgår.

– 1. All MAHs will be invited to <u>upload</u> non-serious reports for all products to EVVET dating from the last PSUR DLP until the entry into application of Regulation (EU) 2019/6 or

– 2. For products for which the electronic upload cannot be made by the date of the first yearly signal detection review on EVVET in 2022, MAHs will be invited for the first yearly signal management update to upload a line listing to EVVET of all non-serious reports since the last PSUR DLP up to 28 January 2022.

– Info can be found at HMA webpage: https://www.hma.eu/fileadmin/dateien/Veterinary_medicines/CMDv_Website/Implementation_of_the_VMP_Regulation/CMDv_QA_on_transitional_arrangements_July_2021.pdf
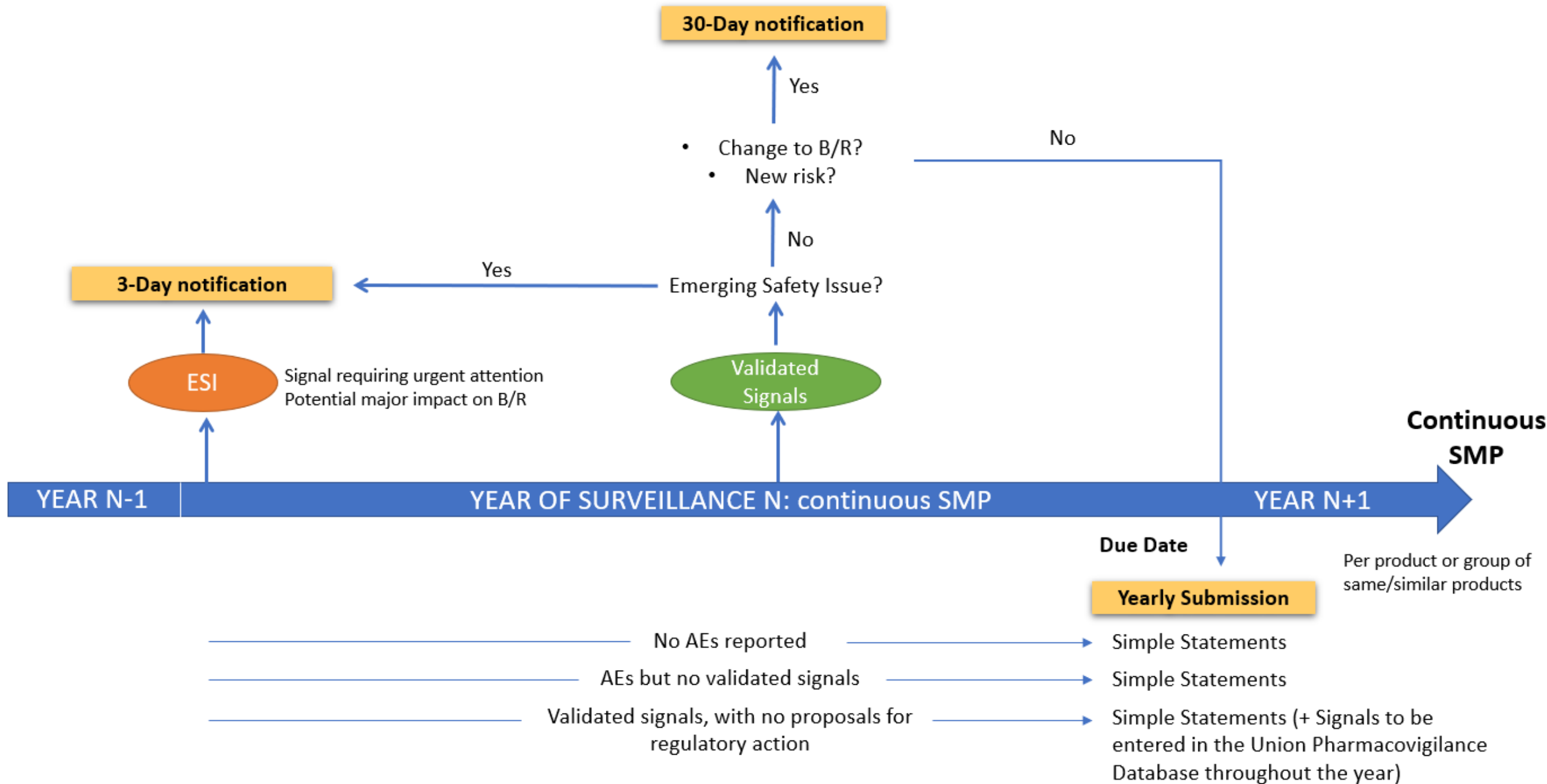
Guidance

– VGVP modules

   – **Collection and recording of SAR**

   – **Signal management**

   – PhV communication

   – PhV systems, QMS and PSMF (substitute DDPS)

   – Controls and PhV inspections

   – Annex: Glossary

– Implementing regulation (EU) 2021/1281

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Collection and recording of suspected SAR

– EVVET3

– All AEs in EVVET – connected with UPD and DWH

– any unfavourable and unintended reaction in an animal to a medicinal product for human use

– Reported in EVVET within 30 days – no "serious" classification

– Reports from internet – screening of internet

– Definition of minimum criteria for reports

– No causality assessment

– Training 13th of January 2022 (material available from previous training) https://www.ema.europa.eu/en

Signal management

– No more PSURs. Continuous signal management by MAH using a risk-based approach

– Annual submission of signal surveillance statement. Annual duedates per ATC-code (to be published)

– Incidence/sales data – to be developed and agreed (legal deadline 2024)

– Medically impotant VeDDRA terms list (MI) terms identify serious medical concepts. Tool for prioritisation

– Emerging safety issue (ESI) (3 days) – impact b/r

– Training 18th and 19th of January 2022 (material available from previous training)

– Upcoming detailed manual

30-Day notification

Yes

- Change to B/R?
  - New risk?

No

No

Yes

3-Day notification

Emerging Safety Issue?

ESI

Signal requiring urgent attention
Potential major impact on B/R

Validated
Signals

Continuous SMP

YEAR N-1 | YEAR OF SURVEILLANCE N: continuous SMP | YEAR N+1

Due Date

Per product or group of
same/similar products

Yearly Submission

No AEs reported → Simple Statements

AEs but no validated signals → Simple Statements

Validated signals, with no proposals for regulatory action → Simple Statements (+ Signals to be entered in the Union Pharmacovigilance Database throughout the year)

Følg os

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