CMDv

Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

CMDv work on the implementation of the VMP Regulation

Laetitia Le Letty
Chair of CMDv

Veterinary Medicines Info Day – 25 March 2021

Article 144 - **Tasks of the coordination group**

- examine questions concerning MRP/DCP
- examine advice from the pharmacovigilance WP concerning risk management measures in pharmacovigilance related VMPs and issue recommendations to the MS and to the MAHs as necessary.
- examine questions concerning variations to the terms of marketing authorisations granted by MS.
- provide recommendations to Member States whether a specific product or a group of products is to be considered a VMP within the scope of this Regulation.
- coordinate the selection of the lead authority responsible for the assessment of the results of the signal management process referred to in Article 81(3).
- draw up and publish an annual list of reference veterinary medicinal products which shall be subject to harmonisation of SPC.

- And consequently :
  - Update BPG/SOP according to new rules of the NVR
  - Deletion of existing BPG (sunset cause, renewals)
  - Establish new guides for new procedures (as SPC harmonisation, re-examination of the AR - DCP)
  - Links with existing WG to be defined : EMA, CVMP, pharmacovigilance, QRD, QWP, CMDh, …

→ CMDv Legislation WG revival

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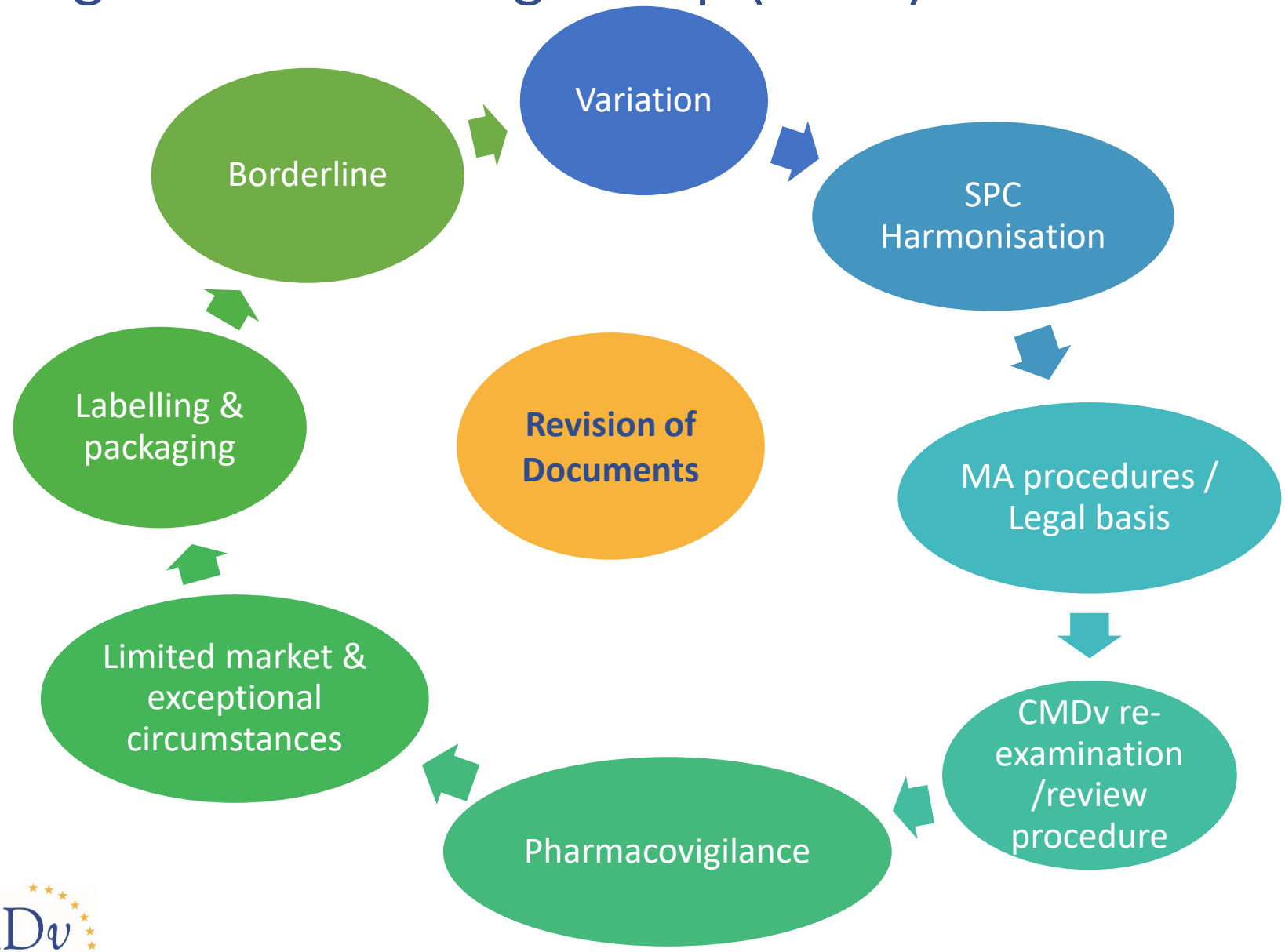
Legislation Working Group (LWG)



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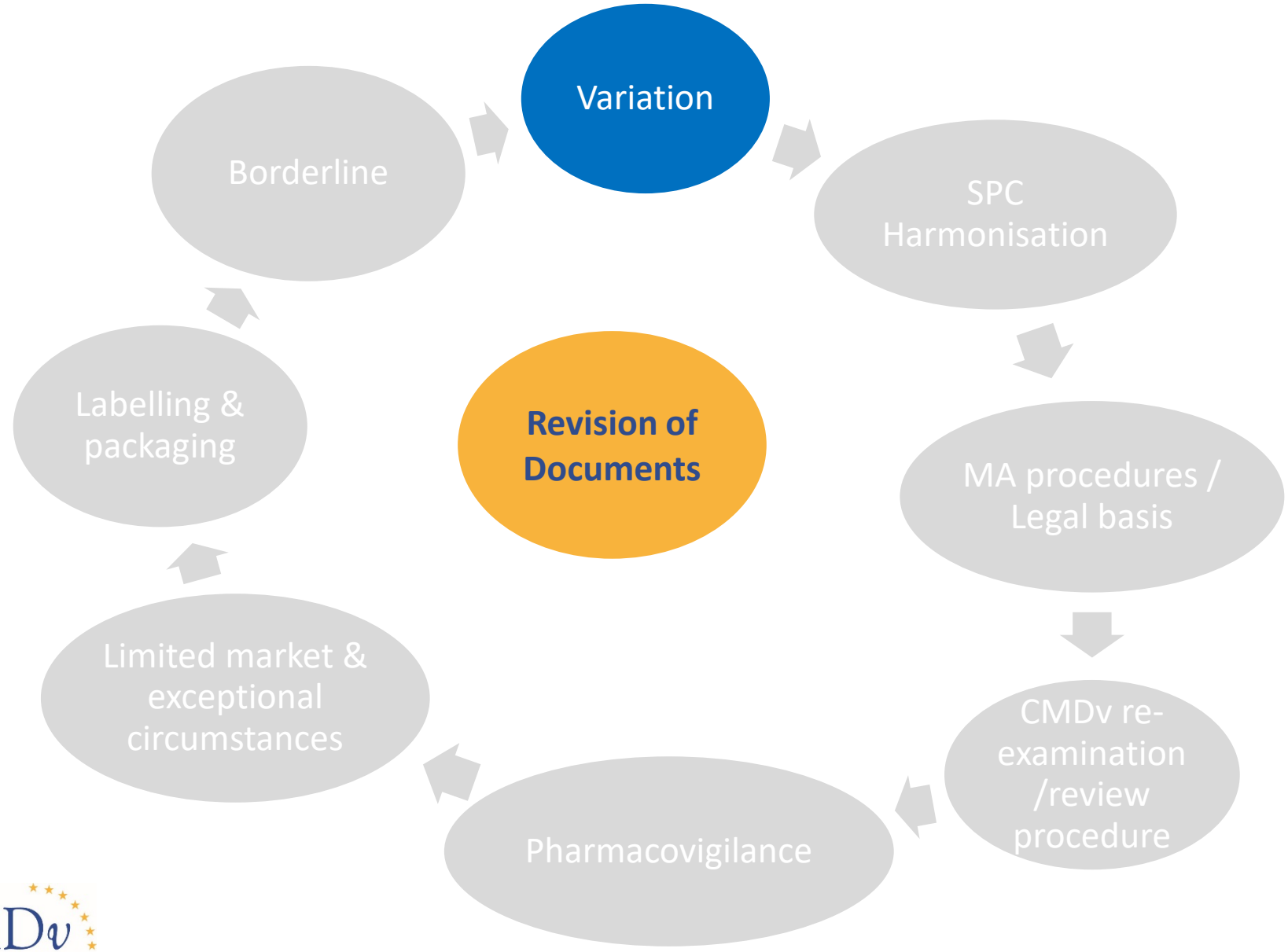

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Variations

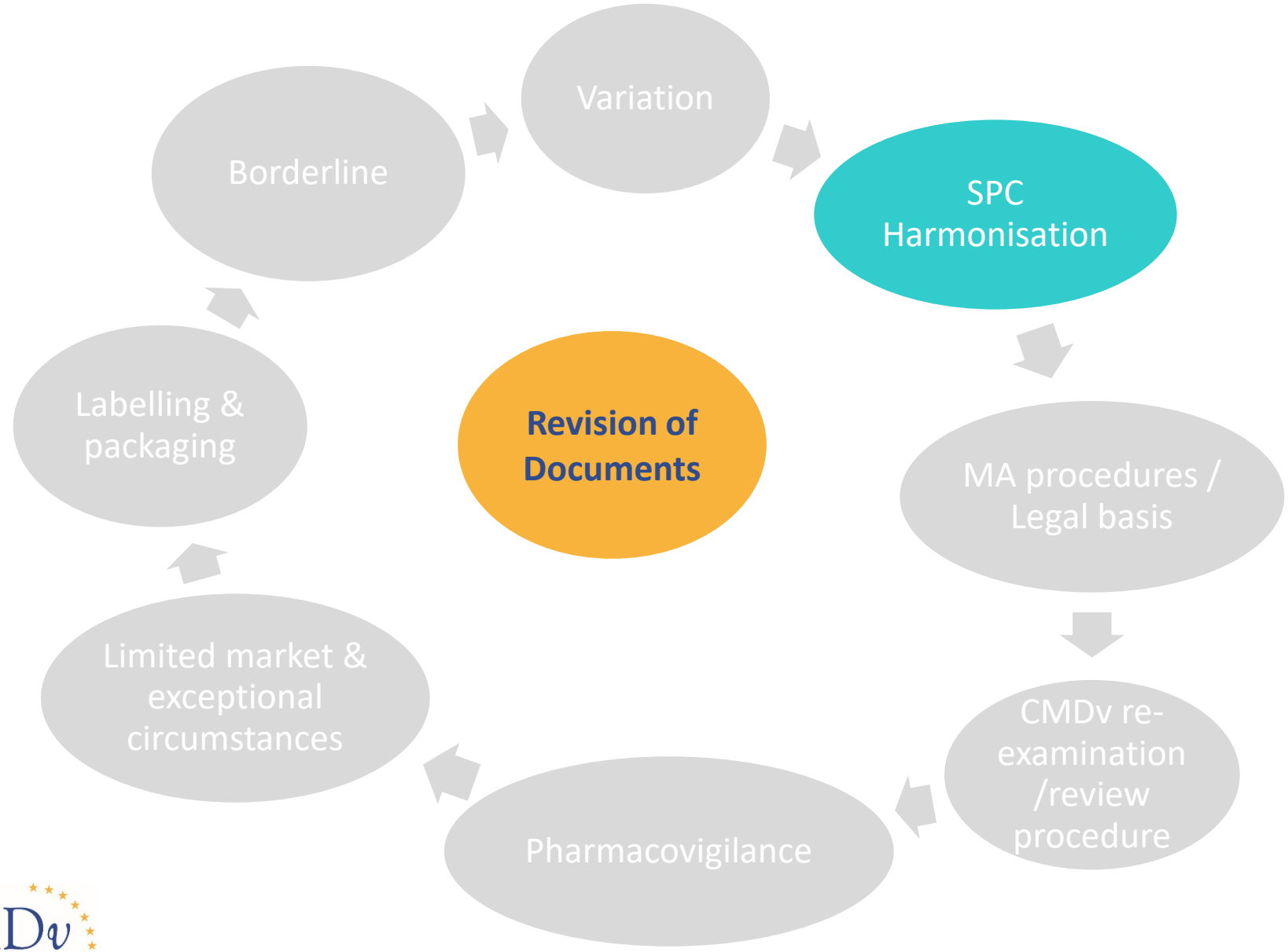
- Commission Implementing Regulation (EU) 2021/17 of 8 January 2021 establishing a **list of variations not requiring assessment** in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council **and**
- Commission Implementing Regulation (EU) 2021/16 of 8 January 2021 laying down the necessary measures and practical arrangements for the Union database on veterinary medicinal products (**Union product database**)

→ Adopted 08.01.2021, published in OJ on 11.01.2021

- Decision to have **two documents** for daily work:
  - The Annex of Commission Implementing Regulation (EU) 2021/17 for the VNRA
  - A CMDv/EMA guidance document for classification of VRA which will apply to CAP, MRP/DCP and NAP

Variations

- Classification Guidance for VRA
  - Starting point = classification guideline with an annex = list of VRA with recoding starting from “E” (A-> D = VNRA).
  - Reference to human side-issues removed
  - Documentation requirements kept where given for IBs and II and renumbered if necessary
- Best Practice Guides under development at CMDv :
  - VNRA : Still need to know more about IT environment,
  - VRA : Final reply from EC on some questions necessary,
  - “Unforeseen” variations : Adaptation, mutual information between CMDv and CMDh mentioned
  - Allocation of procedure number: Adaptation required (naming of VRA)
- Application form for VRA will have to be adapted.
- Adaptation of the CTS database.
- VNRA will be submitted only to the UPD including required SPC/PIL and documentation, not via CESP anymore.



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SPC Harmonisation - Global overview of the process

Reference VMPs

Selection phase
- Selection of reference VMPs
- Selection of RMS

Part II harmonisation
- Pharmaceuticals : before or simultaneously with the SPC harmonisation
- Immunologicals: before SPC harmonisation

Examination phase
- max 180 days to agree upon a harmonised SPC

Union interest referral
- In case of disagreement

National phase & MRP tansfer
- MAH: 7 days to submit the translations
- NCA: 30 days to amend the MA
- MRP transfer MANDATORY

generics/hybrids

Examinatio n phase
- 60 days to harmonise the SPC of the generic/hybrid with the SPC of the reference VMP

Coordination group referral
- Optional: in case of disagreement

Union interest referral
- Optional: in case of no agreement at the end of the coördination group referral

national phase
- MAH: 7 days to submit the translations
- NCA: 30 days to amend the MA

Part II harmonisation & MRP transfer
- Optional: MAH to submit a part II harmonisation
- MRP transfer

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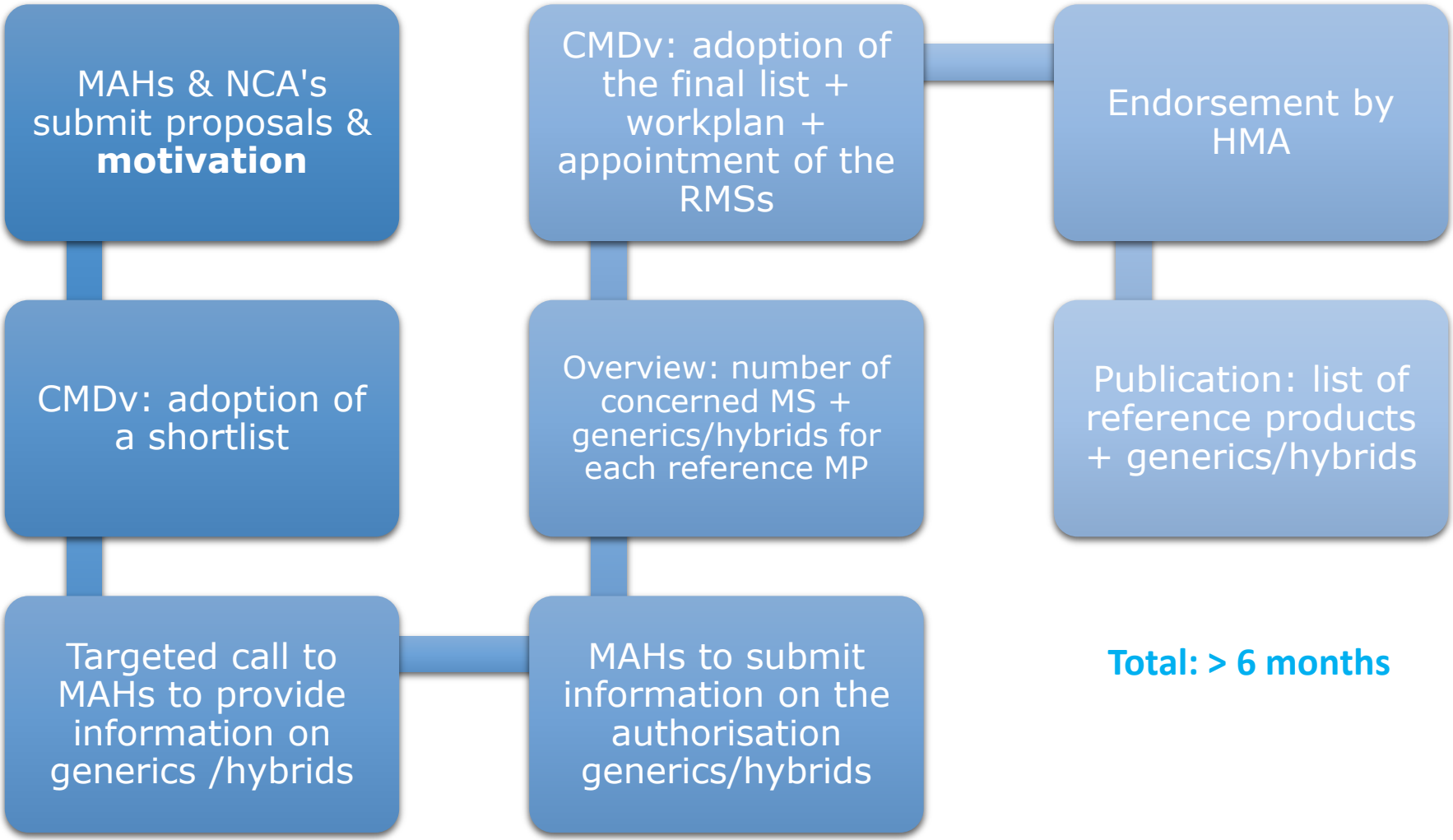
SPC Harmonisation – Phase 1 - Selection of the products to be harmonised



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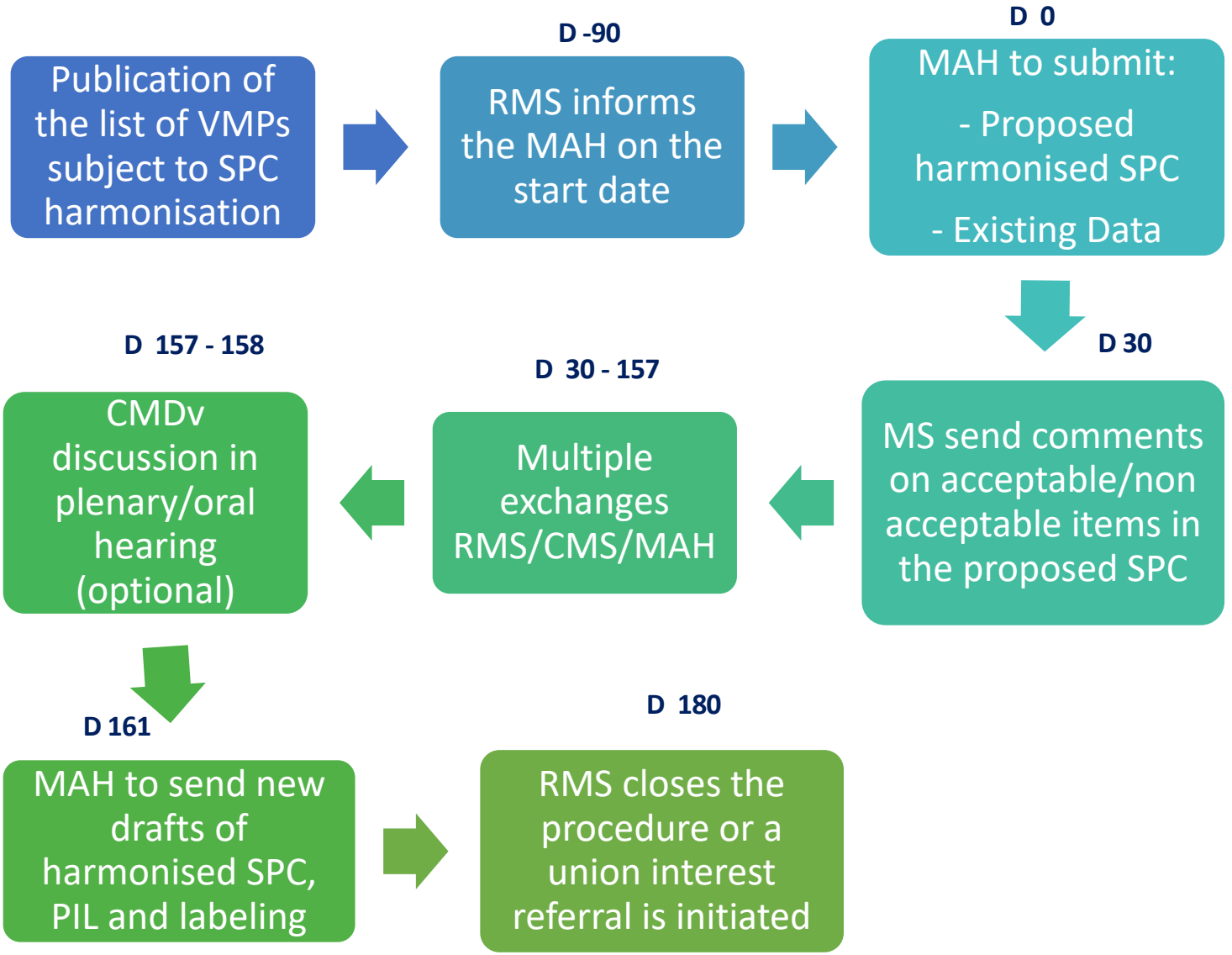
SPC Harmonisation – Phase 2 - Procedure for the harmonisation of reference VMPs



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SPC Harmonisation – Part II harmonisation + Transfer to MRP

For reference VMPs the transfer to MRP is mandatory => need to harmonise part II by means of a variation requiring assessment.

- Timing : before or simultaneously to SPC harmonisation for Pharmaceuticals and BEFORE for immunologicals.
- Content of dossier : 10 CPCs for pharmaceutcials, complete part II for immunologicals.
- No new data can be submitted within the variation for the part II harmonisation

RMS will create a procedure in CTS before the start of the procedure. Proposed format procedure number: IT/V/xxxx/SPC/001

At the end : transferred to MRP

=> receives a product number : e.g. IT/V/0369/001

(if 0369 is the next sequential number)

This number will be stored in the UPD

SPC Harmonisation – Phase 3 – Examination phase for generics/hybrids

Generic/hybrid authorised in 1 MS	Generic/hybrid authorised by means of DCP	Generic/hybrid authorised by means of a national procedure in multiple MS
• the subsequent harmonisation is a purely national procedure in the NCA	• subsequent harmonisation should be done by means of a MRP variation under coordination of the RMS of the generic/hybrid	• Harmonisation by WS • As for current WS: RMS proposal by the MAH

Within 60 days after end of procedure for ref. product
Duration-Procedure = VRA (60 days)

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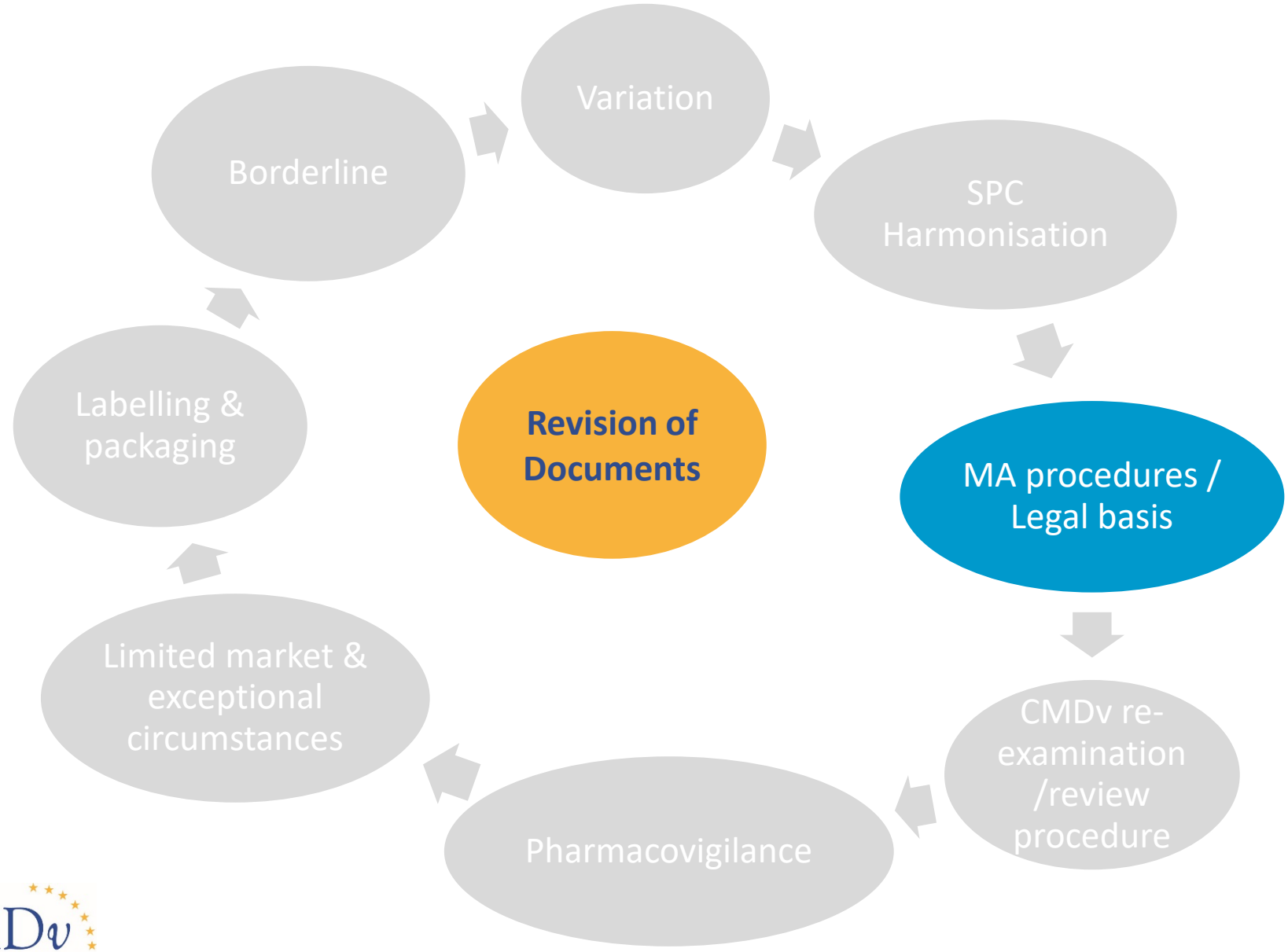

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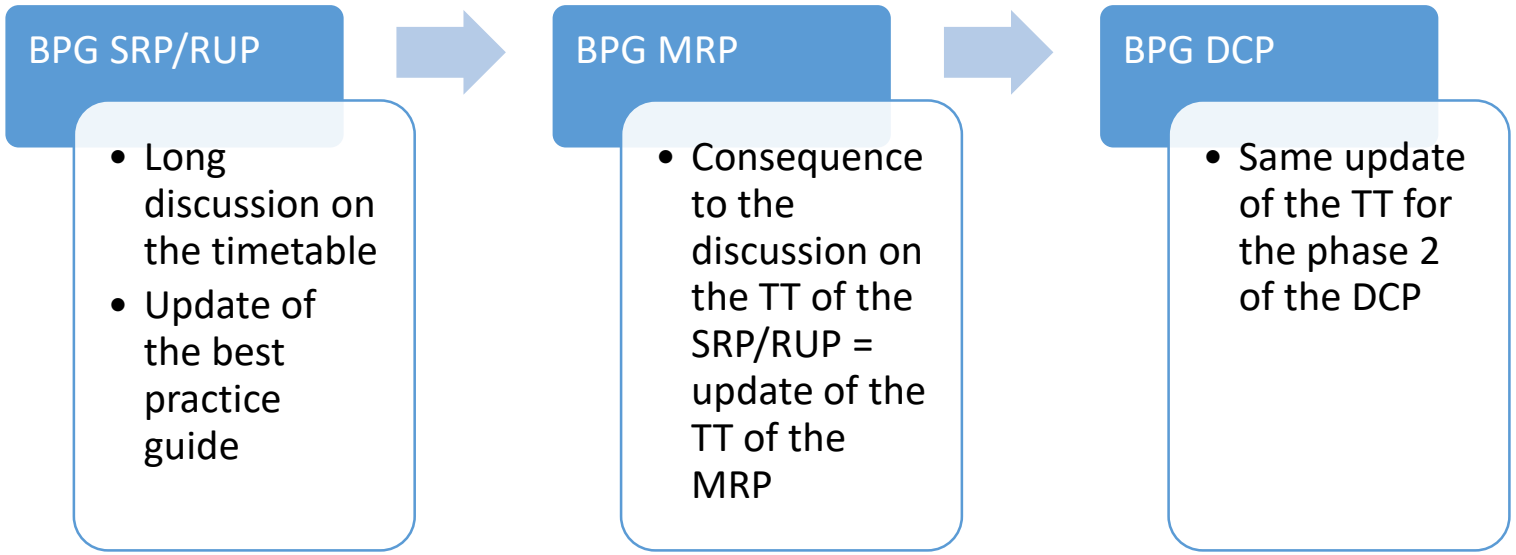
Marketing Autorisation Procedures



- And also : update of all related templates.
- Next steps : legal basis, data protection, parallel trade products.
- Adaptation of the CTS database.

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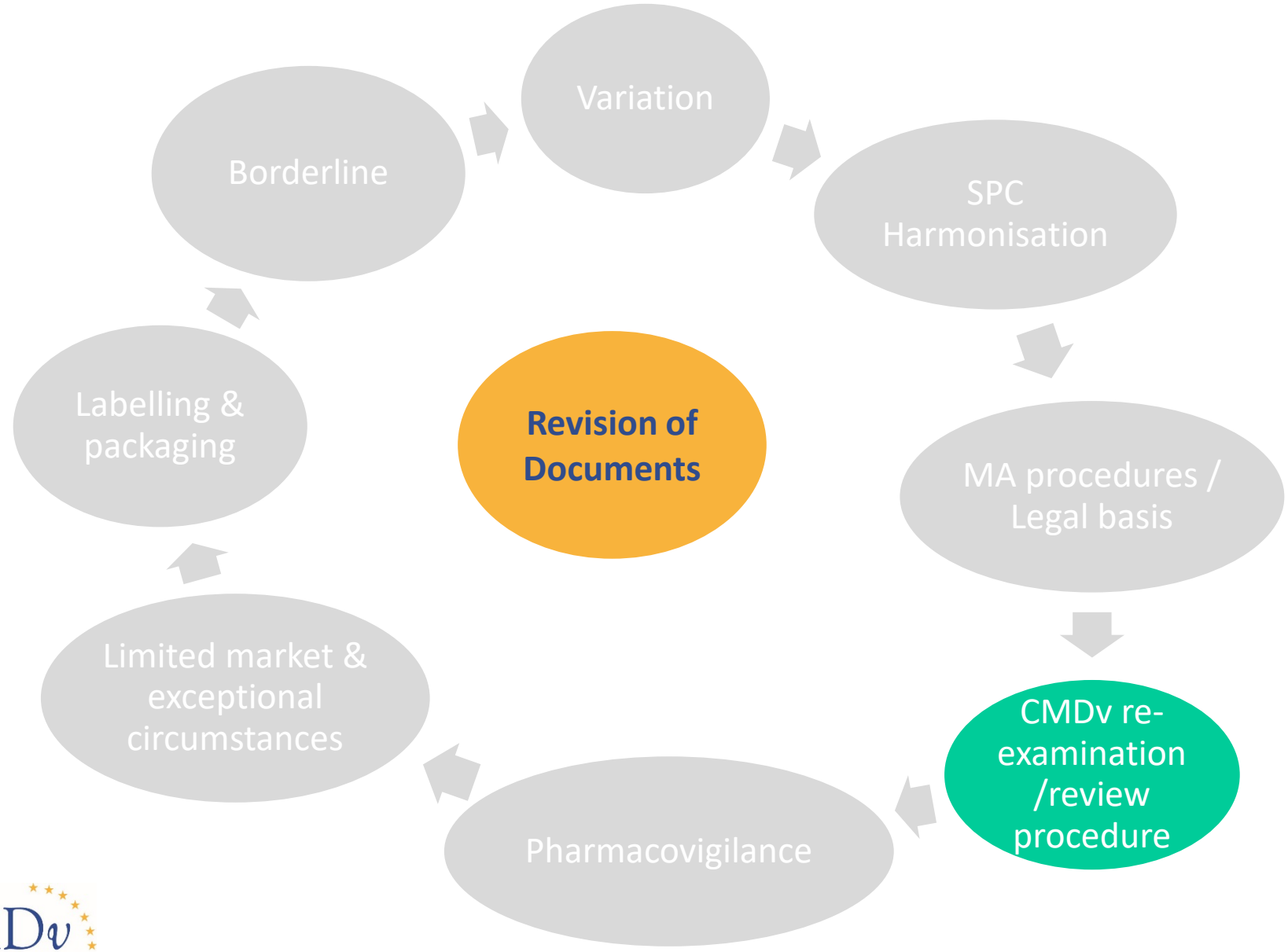

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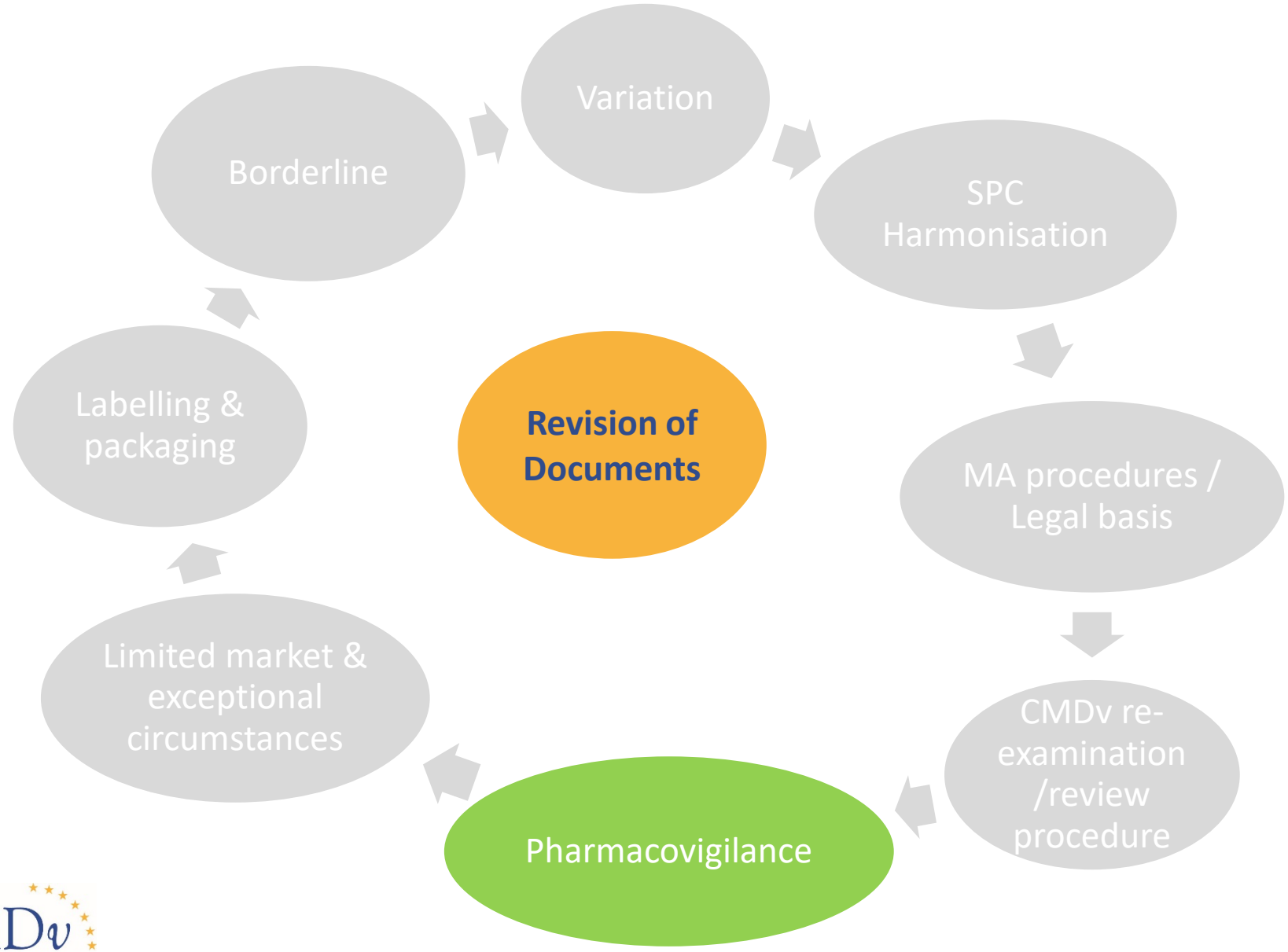
Re-examination Procedure - Review

- Art 50 : Request by the applicant for re-examination of the assessment report
  - At the end of a DCP or a VRA/Worksharing procedure.
  - BPG under preparation with a proposed timetable and a template for applicant to request a re-examination.
- Next step = Review procedure according to article 54



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Pharmacovigilance

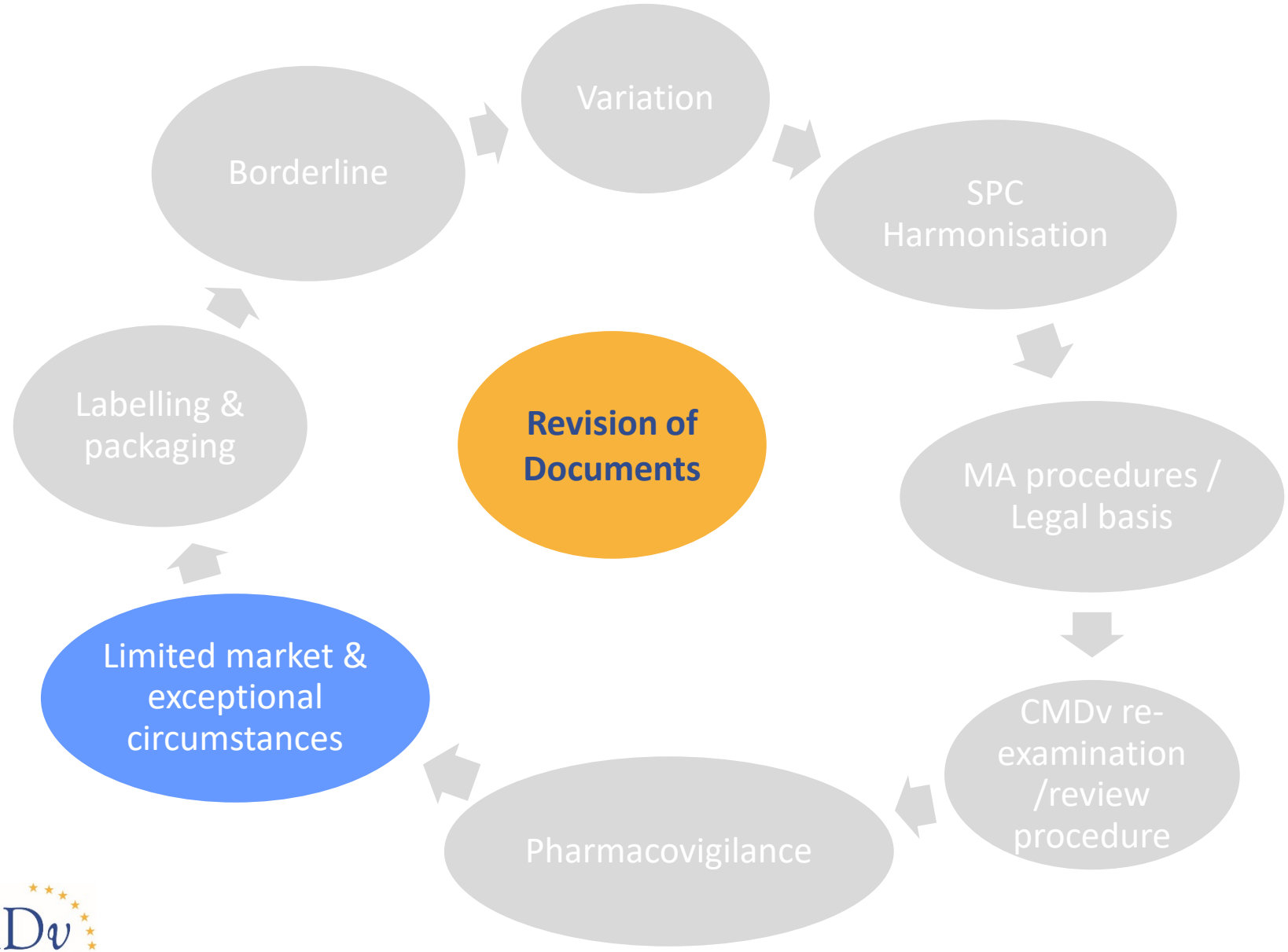
New tasks for the CMDv :

- examine advice from the pharmacovigilance WP concerning risk management measures in pharmacovigilance related VMPs and issue recommendations to the MS and to the MAHs as necessary.
- coordinate the selection of the lead authority responsible for the assessment of the results of the signal management process referred to in Article 81(3).

⇒ As a result of this regulation, CMDv will be much more involved in Pharmacovigilance actions, particularly in the Signal Management Process

LWG :

- first discussion between CMDv and Pharmacovigilance WP.
- Questionnaire to have overview of NCAs views on several proposals for fulfilment of regulatory missions.
- Next step : Preparation of a BPG.



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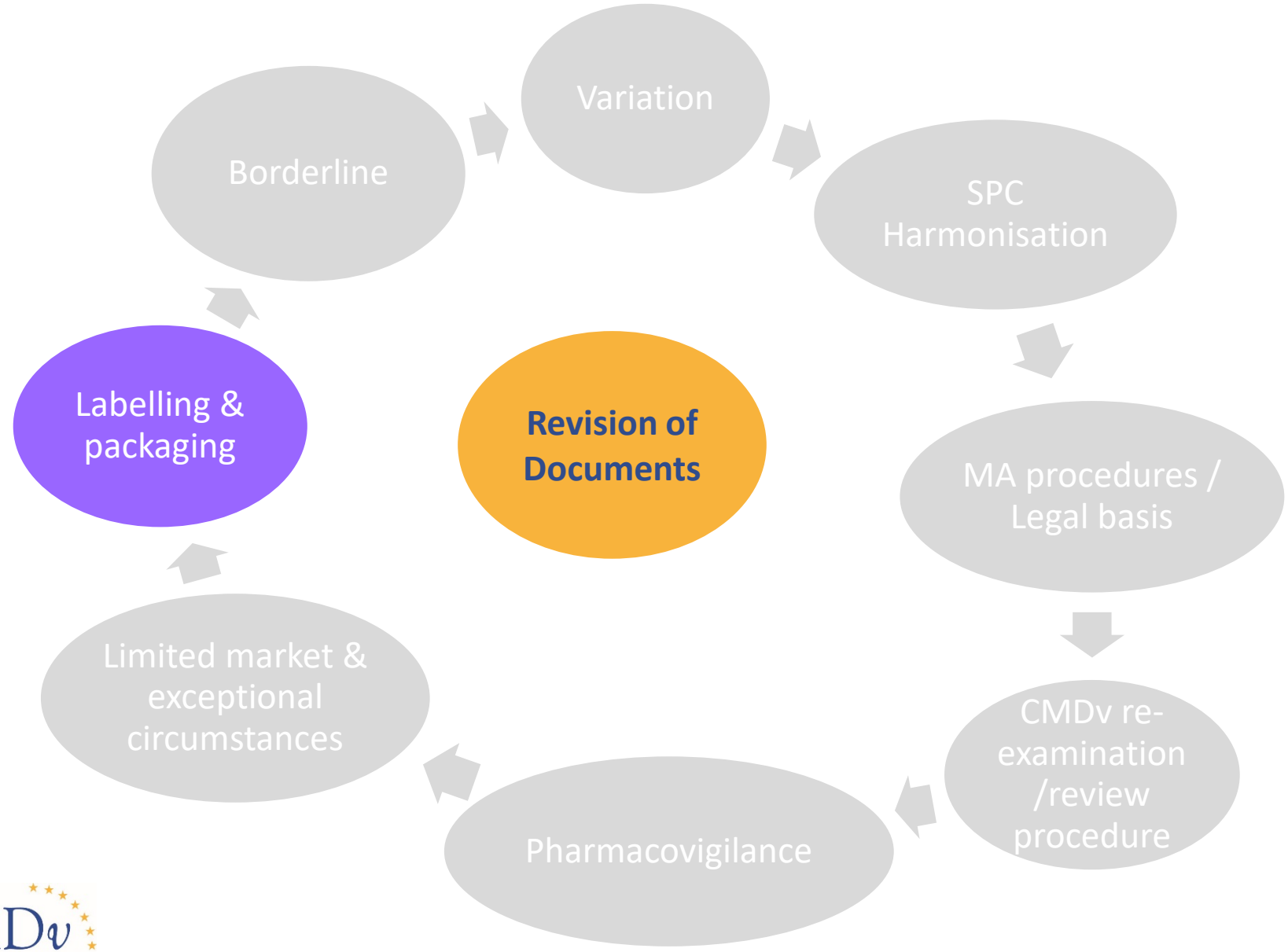
Limited market & exceptional circumstances

- EMA/CVMP : reflection paper under consultation phase (https://www.ema.europa.eu/en/veterinary-regulatory/research-development/minor-uses-minor-species-limited-markets/guidance/classification-product-intended-limited-market-eligibility-authorisation-under-article-23-regulation)
- Next step for CMDv :
  - Handling of limited market applications for MRP/DCP/NAP after classification/eligibility.
  - Handling of exceptional circumstances



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Labelling - Packaging

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- first discussion on the differences between current QRD templates and Regulation 2019/6
- NCAs comments.

QRD

- First proposals for update of QRD templates
- Several meetings with QRD members
- Finalisation of the EN templates expected in March then public consulation phase

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- Still questions on the transition phase : process to upate SPC/PIL.
- And also to be discussed : abbreviations and pictograms (art 10.2).

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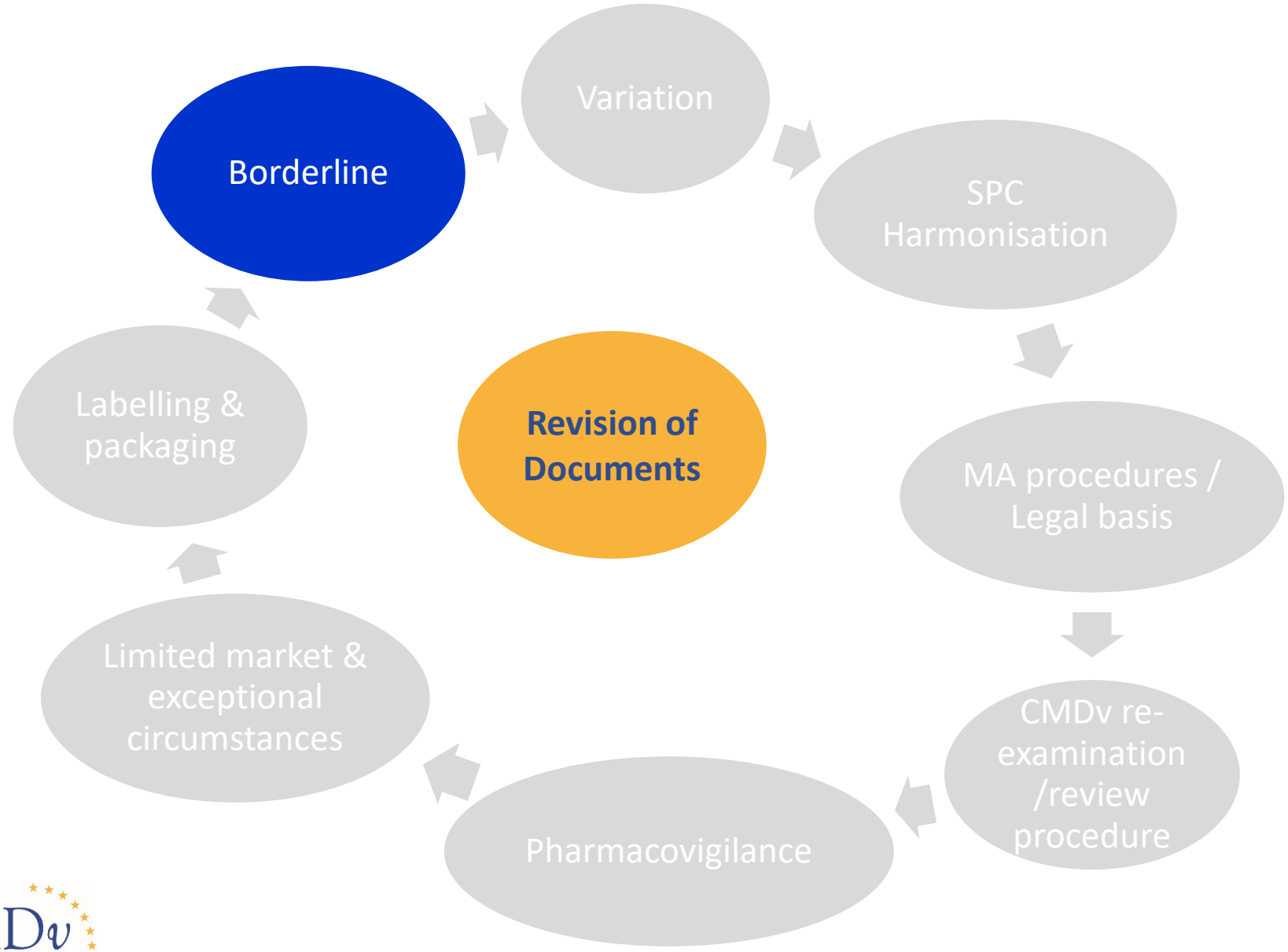

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Borderline Products

New task for the CMDv :

- provide recommendations to Member States whether a specific product or a group of products is to be considered a VMP within the scope of this Regulation.

LWG :

- CMDv has already a WG and guidance document to handle such request for classification. Update required but not yet started.

European Commission

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

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