Symposium on the New European Legislation on VMPs

SPC Harmonisation procedure

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1. Drivers for SPC harmonisation

Impact assessment on the New Veterinary legislation

(GHK report July 2011)

Policy option	Sub-option	Impact ++: significant positive 0: neutrl --: significant negative			Impact on admin burden	Implementation challenges	Possible mitigation
		Free movement	Medicines availability	Health protection			
7. Enabling the free circulation of authorised products	Authorised products with a record of safe use would be allowed to freely circulate throughout the EU/EEA following an administrative assessment	++	++	0	-14.2M euro p.a.	Definition of safe use Lack of trust in historical authorisations	Restrict to authorisations since 2001/2004, (or 1981) Restrict to low-risk products
	Systematically harmonise SPCs for authorised products	++	++	0	Decrease for companies. Increase for authorities	Cost of harmonisation. Choice of SPC against which to harmonise Danger of loss of indications	Focus on priority Medicines. Companies free to select SPC for authorisations since 2001/2004

1. Drivers for SPC harmonisation

Recital (51)

The *majority* of VMPs on the market have been authorised under national procedures. The lack of harmonisation of SPCs for VMPs authorised nationally in more than one member state creates additional and unnecessary barriers for the circulation of VMPs within the European Union. It is necessary to harmonise those SPCs at least in regard to dosage, uses and warnings of the VMPs.

1. Drivers for SPC harmonisation

Points for attention

- Increase in workload for NCAs
- Risk of losing indications/availability of VMPs
- Potential number of products is high <-> network capacity

2. Scope of the harmonisation procedure (art.69)

Reference Medicinal Products

- MA in multiple MS, granted following the national procedure (art.47)
- Same pharmaceutical form
- Same quantitative & qualitative composition of active substances

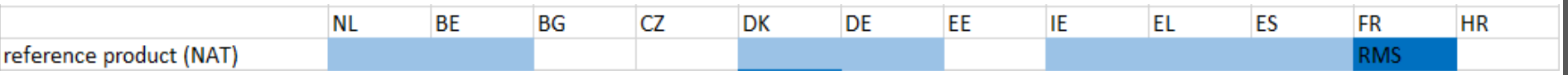
⇒ Harmonised SPC, PL and labelling

Pa[redacted]II?

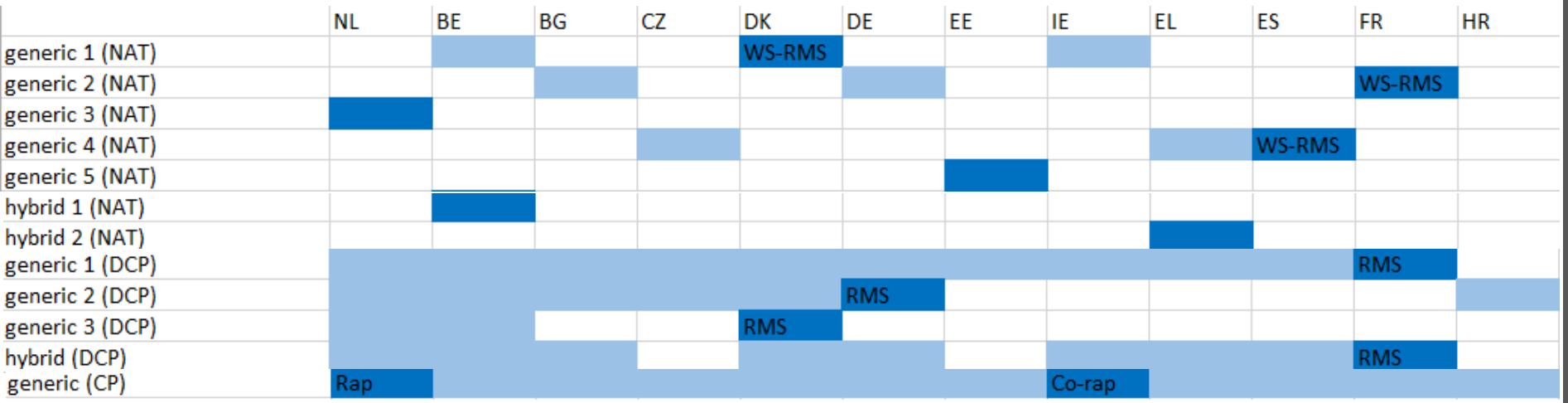
Generics and hybrids of the Reference Medicinal Products

2. Scope of the SPC harmonisation - Example

Phase I: Reference product (180 days)



Phase II: Generics/Hybrids (60 days)



Phase III: Similar products and their generics?

2. Scope of the harmonisation procedure

Legal limitations of the SPC harmonisation (art.72)

Products excluded from SPC harmonisation:

- reference products authorised before 1/10/2005 **and**
- identified as potentially harmful to the environment **and**
- not been subject to an environmental risk assessment.

For these products, excluded from harmonisation, the NCA must request the MAH to update the environmental safety documentation.

➔ Definition of 'potentially harmful'?
➔ How to identify these products?
➔ Impact on the number of potential candidates for harmonisation?

2. Scope of the harmonisation procedure

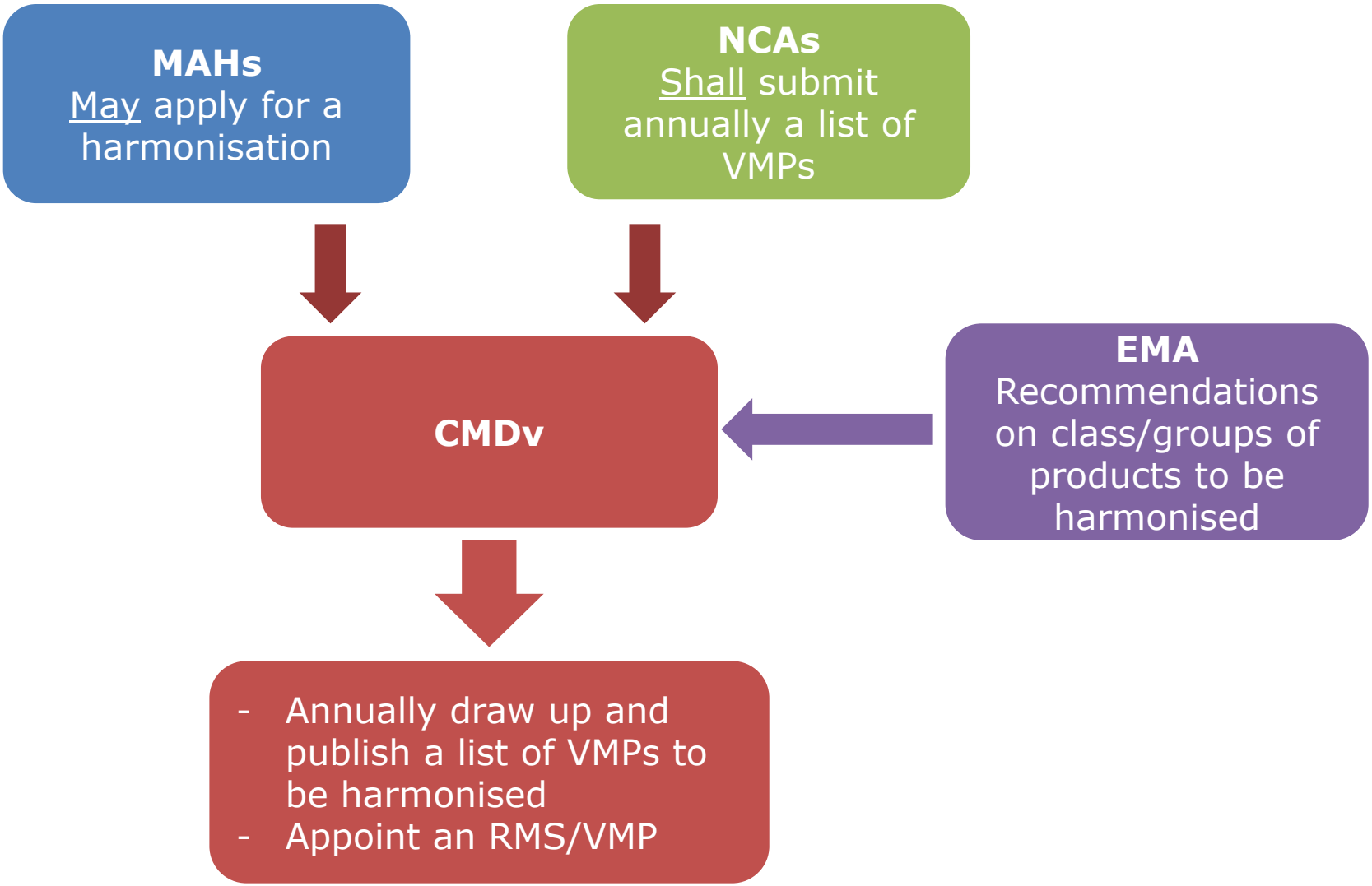
Points for attention

- SPC harmonisation does not include part II harmonisation and transfer to MRP

  ⇒ CMDv proposal to industry for a 'package' SPC harmonisation + Part II harmonisation + MRP transfer

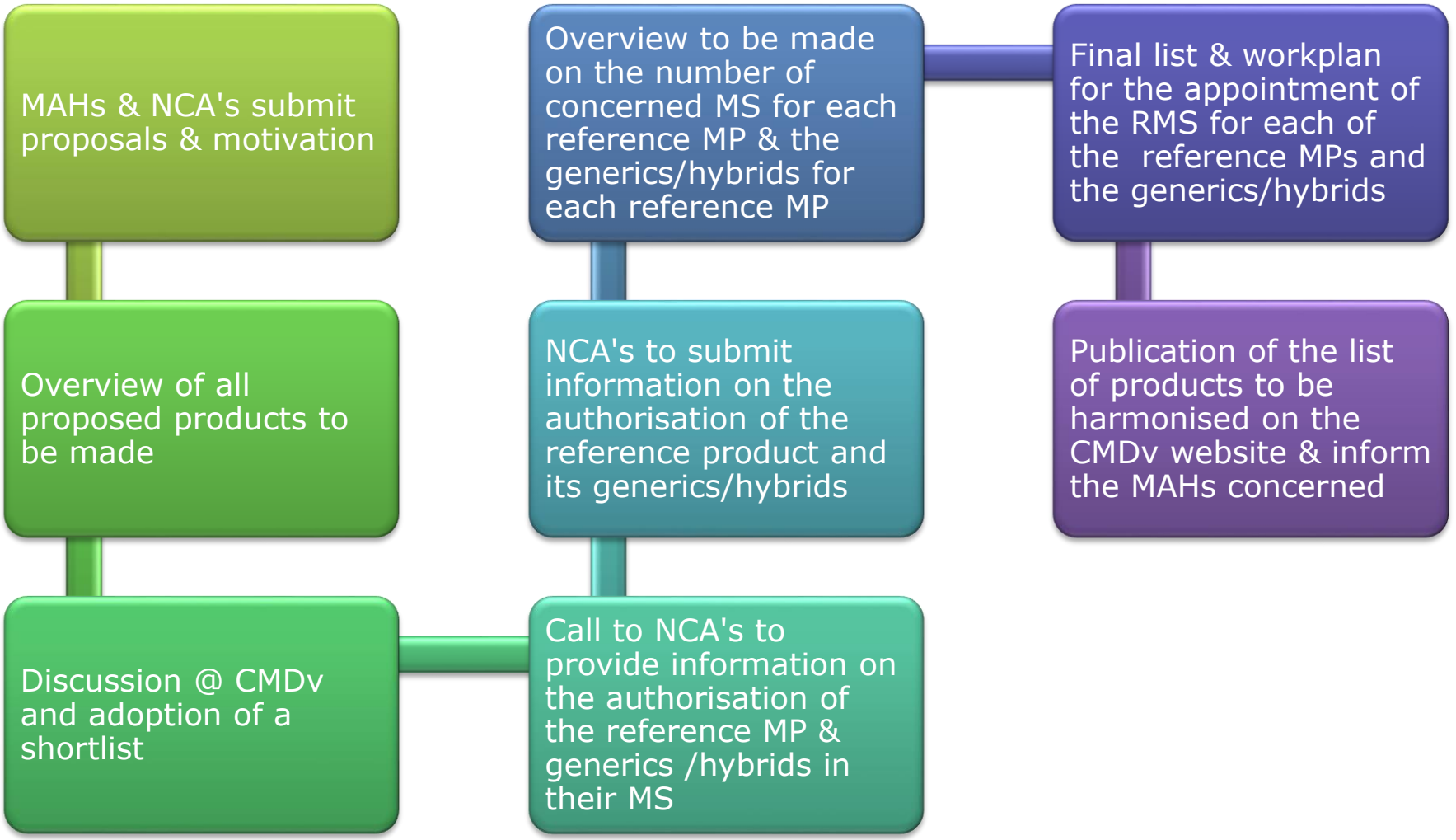
- Cascade of workload due to subsequent harmonisation of generics/hybrids
- Harmonised approach on the identification of products excluded due to article 72 is required and should take into account the risk of a cascade of referrals

3. Procedure for the selection of a reference VMP (art.70)



3. Procedure for the selection of a reference VMP

Potential flow



3. Procedure for the selection of a reference VMP

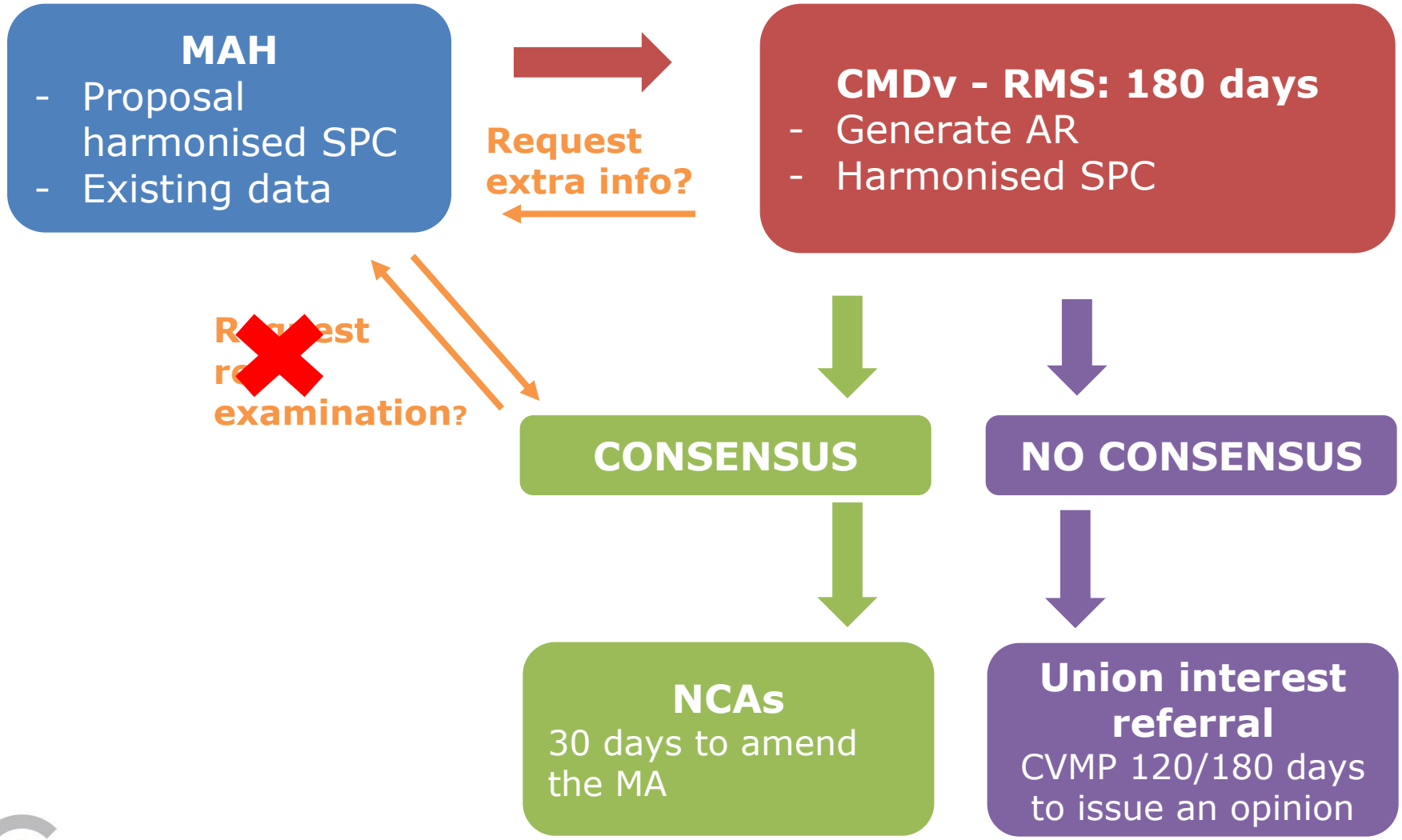
Points for attention

- Number of requests >> capacity
- Selection criteria for prioritisation of reference VMPs need to be elaborated

⇒ Types of products that are prior/have priority or are of major importance for industry/vets to be harmonized?

- Criteria for selection of the RMS for the harmonisation procedure

4. Procedure for the harmonisation of reference products (art. 70)

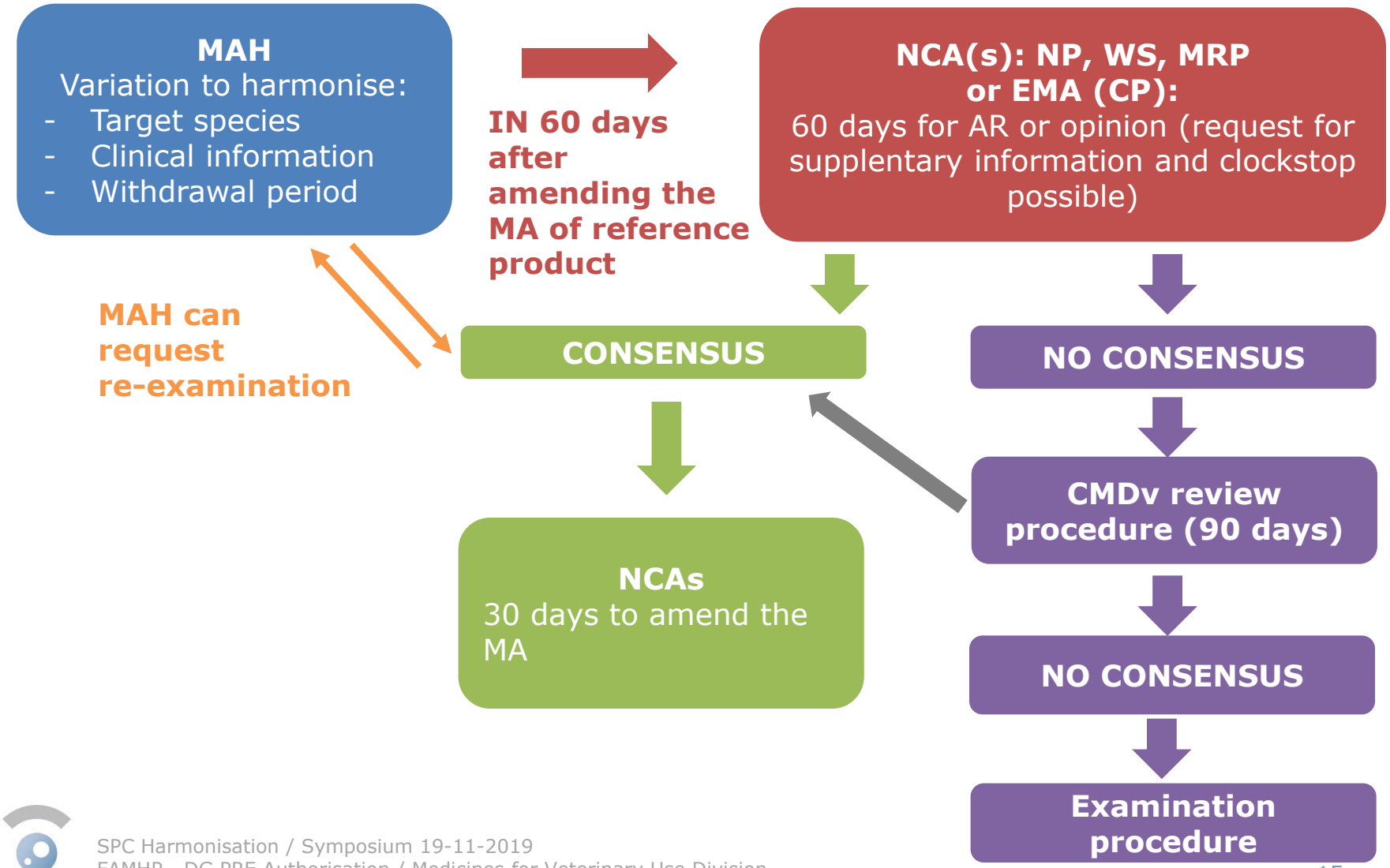


4. Procedure for harmonisation of reference products

Points for attention

- No possibility for the MAH of the reference VMP to request a re-examination
- Absence of a CMDv referral procedure => increase of European Union interest referrals?
- Coordination of the national phase is required in order to facilitate subsequent harmonisation of generics & hybrids
- Time needed for MAHs to prepare a harmonized SPC & submit appropriate existing data?

5. Procedure for the harmonisation of generics/ hybrids (art.71 & 62)



5. Procedure for the harmonisation of generics/hybrids

Points of attention

- What about generics for which bio-equivalence was demonstrated for a subset of the target species?
- What if the variation to harmonise with the reference product is not submitted within the timeframe?
- Differences in excipients ➔ differences in clinical information

6. Next steps for the SPC harmonisation

CMDv Legislation Working group will work on:

- List of questions for clarification has been send to the EC
- Elaboration of a BPG for MAHs of reference products + application form
- Elaboration of a BPG for MAHs of generics/hybrids
- Elaboration of a procedure (tasks & timelines for RMSs & CMSs)
- Elaborate criteria for the selection of reference VMPs
- Elaborate criteria for the selection of RMSs

➔ timing: end 2020

Thank you for your attention!

Read todays presentations and NVR text again?

- www.fagg.be/nl/presentaties
  www.afmps.be/fr/presentations