



Role of OMCLs for control of emergency vaccines

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Focus Group Meeting on availability of Lumpy
Skin Disease vaccines authorised to
EU standards
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OMCL for IVMPs

= Official Medicines Control Laboratory for Immunological Medicinal Veterinary Products

o Goal of **Competent Authorities** (CA):

Ensure that the marketed products comply with the specification laid down in the application file and in any other relevant compendial requirements, which these same authorities approved

o Goal of an **OMCL**:

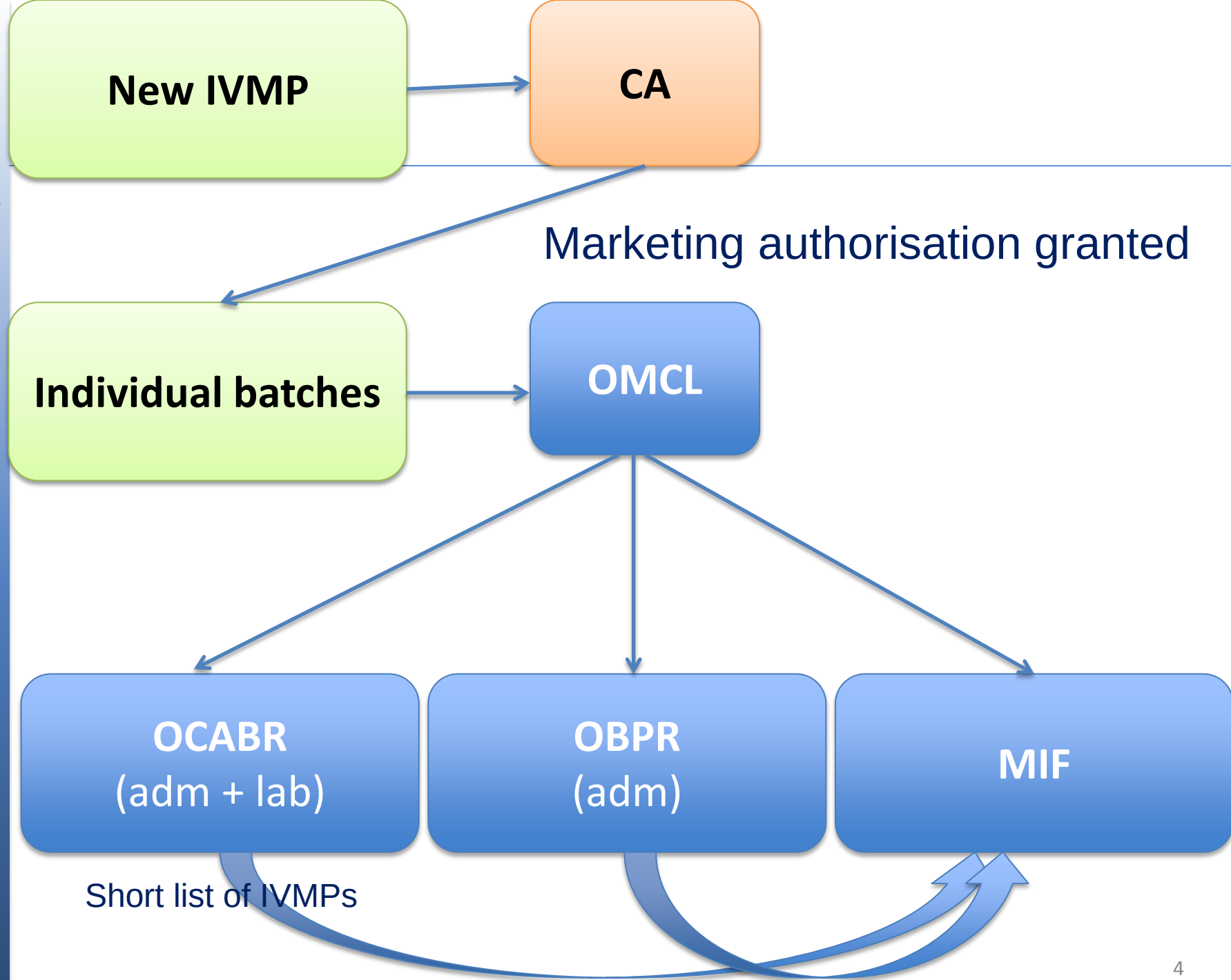
Support the Competent Authorities in controlling the quality of medicinal products on the market for the human patient and/or animals

- public institution
- laboratory testing
- independent from manufacturers or MAH
- Veterinary Batch Release Network (VBRN)



Role of OMCLs for IVMPs

- Batch release (OBPR, OCABR)
- Post marketing surveillance
- centralised authorised product (CAP) testing
- Pre-authorisation analysis
- Support investigation of pharmacovigilance cases, quality defects
- Test of counterfeit/illegal products
- Support GMP inspections as experts
- Support the evaluation of the quality part of the dossiers
- Support in the framework of Ph. Eur.
- Research and development (e.g.: 3Rs)
- ...



ANNEX I

Short list of IVMPs for which a restricted test list for OMCLs has been agreed and list of associated guidelines for OMCLs

IVMPs listed alphabetically

Short list of IVMPs for which a restricted test list for OMCLs has been agreed	Exempted Categories (eg live, inactivated, recombinant etc.)	Relevant guideline(s)
IVMP's against <u>Aujeszky's Disease</u>	none	PA/PH/OMCL (03) 7 DEF 2CORR PA/PH/OMCL (03) 8 DEF 2CORR
IVMPs against Brucellosis	none	PA/PH/OMCL (03) 23 DEF 2CORR
IVMPs against Equine Influenza	none	PA/PH/OMCL (04) 4 DEF 2CORR PA/PH/OMCL (14) 81 R
IVMPs against Infectious Bovine <u>Rhinotracheitis</u>	none	PA/PH/OMCL (03) 9 DEF 2CORR PA/PH/OMCL (03) 6 DEF 2CORR
IVMPs against Newcastle Disease	none	PA/PH/OMCL (02) 3 DEF 2CORR PA/PH/OMCL (02) 4 DEF 2CORR
IVMPs against Rabies	none	PA/PH/OMCL (11) 209 DEF 2CORR PA/PH/OMCL (04) 05 DEF 2CORR
IVMPs against Swine Erysipelas	none	PA/PH/OMCL (03) 11 DEF 2CORR PA/PH/OMCL (03) 10 DEF 2CORR
<u>Brucellin Preparations</u>	none	PA/PH/OMCL (04) 119 DEF 2CORR
Tuberculin PPD, Avian	none	PA/PH/OMCL (14) 126 DEF
Tuberculin PPD, Bovine	none	PA/PH/OMCL (14) 125 DEF

Emergency cases - Belgium

- o Authorised or non-authorised product?
- o Cascade-system for (non-) food producing animals
- o Special batch release/permit procedure
- o Autovaccin

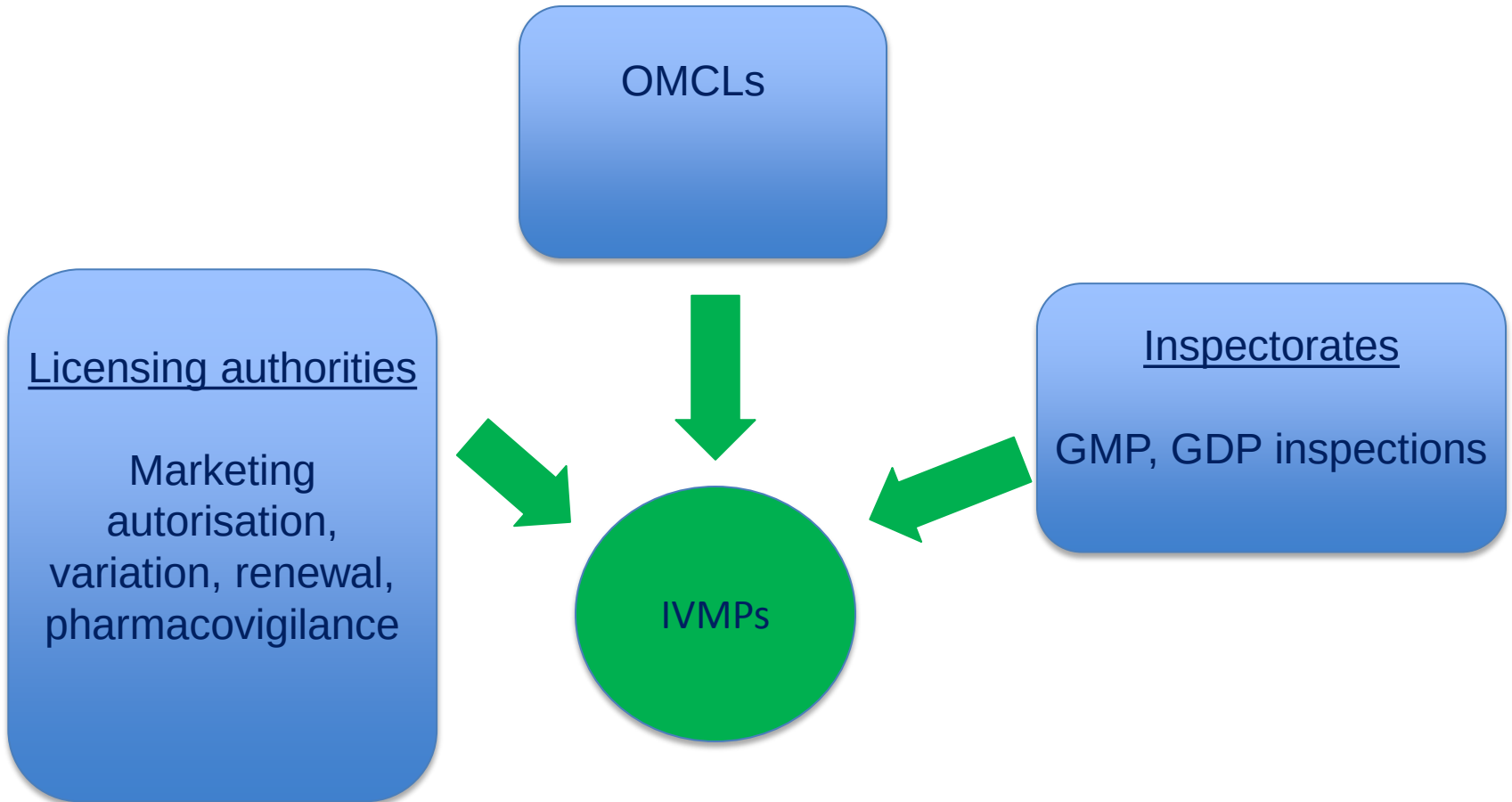
Further steps

- o **Certificate of Analysis**
- o Marketing **authorisation** needed
- o **Reflection needed**: submit LSD vaccins for laboratory testing by OMCLs during pre-marketing evaluation? If so, potential ways to go:
 - Putting on **OCABR short list**: risk assessment – via VBRN – product specific guidelines (PA/PH/OMCL (12) 43)
 - Temporary testing of products **not on the restricted list** - via VBRN (PA/PH/OMCL (11) 75)



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Different branches, different roles, same goal



Courtesy of VBRN Advisory Group

More information

- o National veterinary Competent Authorities (**NCA**) in the EEA:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000167.jsp&mid=WC0b01ac0580036d65
- o National Official Medicines Control Laboratories (**OMCL**) for IVMPs:
https://www.edqm.eu/sites/default/files/annexiv-contactlist_network_competent_authorities_ivmps-december2016.pdf
- o **OCABR / OBPR** for IVMPs: website EDQM
<https://www.edqm.eu/en/veterinary-biologicals-634.html>



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Thank you for your attention



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