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Introduction in autogenous poultry vaccines

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Agenda

- What are autogenous vaccines?
- How to get an autogenous vaccine
- Regulatory aspects

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Autogenous Vaccines



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Wordings

- Autogenous Vaccines (AV)
- Custom Made Vaccines (CMV)
- Tailor Made Vaccines
- Farm Specific Vaccines
- Autovaccines
- **It's all the same !**

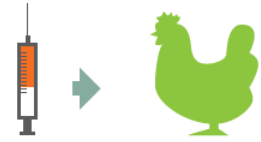
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Definition



Veterinary Medicines Directorate (VMD)

- “Manufactured from pathogens or antigens obtained from an animal/s to be used for the treatment of that animal and/or other animals within the same epidemiological unit or in the same rearing chain.”
- inactivated
- “veterinary surgeon has confirmed a need and fully justified the use of the autogenous vaccine in preference to a UK authorised product”

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Reasons for CMV

- Re-occurring problems in the farm
- Reduction of morbidity and mortality
- No/limited options of therapy
- Reduction of antibiotic use
- No effective licensed vaccine available

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Regulatory

- Production and use of CMVs are allowed only if
 - no licensed product in the market
or
 - licensed product not available
or
 - licensed product without efficacy (e.g. different serotypes)

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General procedure

isolate from a
particular farm



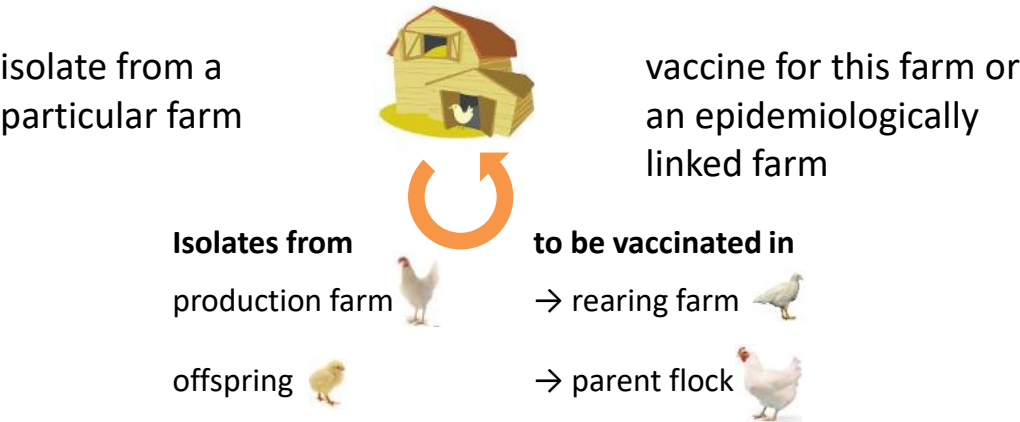
vaccine for this farm or
an epidemiologically
linked farm

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General procedure

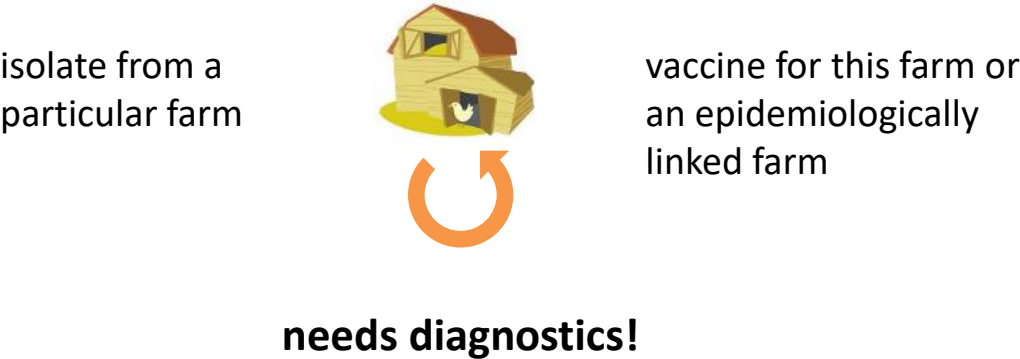


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General procedure



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General procedure

- Identify and isolate the causing pathogen(s) (pathology, isolation; invasive isolates!)
- Differentiate from pathogen(s) in authorized products (serotyping, virulence-factors, sequencing phylogenetic and divergence analysis)



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Flexibility of products

- Chicken (layers, breeders)
 - Turkey (fattening, breeders)
 - Waterfowl (fattening, breeders)
 - Gamebirds
 - Pigeons
 - Zoo birds
-
- (swine, ruminants, rabbits, fish, ...)

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Flexibility of products

Bacterial (and viral) CMVs for poultry

- | | | |
|-------------------|------------------|------------------|
| • Avibacterium | • ORT | • (Reovirus |
| • Brachyspira | • Pasteurella | • Adenovirus |
| • Bordetella | • Pseudomonas | • Influenzavirus |
| • (Campylobacter) | • Riemerella | • IBV |
| • Clostridium | • Salmonella | • Rotavirus) |
| • Coenonia | • Staphylococcus | |
| • Erysipelothrix | • Streptococcus | |
| • E. coli | • Enterococcus | |
| • Gallibacterium | • ... | |
| • Mycoplasma | | |

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Flexibility of products

- Combination of antigens
- Diverse isolates per antigen
- Choose of adjuvants (oil, aluminium hydroxide)
- Volume per dose



Tailor made product
Designed specifically to your needs!

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Limitations

- Protection wears off over time
- Protection can be overcome by high infectious pressure, stress, ...
- Limited cross-protection to other (sero-)types
- Same as with commercial vaccines
- Continuous monitoring and update recommended!

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Order the vaccine



- Decide on adjuvants
 - Oil
 - stronger tissue reaction
 - longer lasting depot effect
 - slower "release" of antigen
 - AIOH
 - watery
 - milder tissue reaction
 - faster elimination
- Decide on volume/dose
 - 0.2ml, 0.3ml or 0.5ml
- Decide on number of vaccinations

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Vaccine production process

- Vaccine order
- Thawing of isolates
- Propagation of isolates
- Inactivation
- Mixing antigens and adjuvants
- Bottling
- Labeling and packing
- Sterility control (2 weeks!)
- On-Farm-Safety Test
- Batch release



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Vaccination



- By injection
- i.m. or s.c. (depending on poultry species and age)
- Time point of vaccination(s) usually:
 - Parent stock: until 4 weeks prior to start of lay
 - Chicken layers: during rearing, until 2 weeks prior movement
 - Fattening turkeys: < 7 wph

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Vaccination



- On-Farm-Safety-Test (OFST)
 - a double dose of vaccine
 - to be conducted on the site of use of the vaccine
 - before use of the vaccine batch in the entire group of animals.
- Batch Release

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Monitor vaccination success

- Inactivated vaccine → not detected by PCR
- Serology → limited informative value
- Best: look at flock production data!
 - e.g.
 - mortality
 - egg production rate
 - clinical disease
 - ...

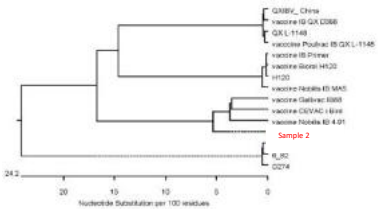
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Monitor vaccination success

- In case disease occurs again:
 - take samples for diagnostics!
 - is it still the same strain?
 - if not → update of the vaccine!



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Regulatory aspects



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Regulatory

- Globally used
- Country specific registration process
 - United Kingdom: Veterinary Medicines Directorate (VMD)

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Regulatory

- United Kingdom: VMD
 - Autogenous Vaccine Authorization
 - High safety standards in production
 - Regular re-inspections by VMD
 - Approval of antigens and adjuvants

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Regulatory

- Production and use of CMVs are allowed only if
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or
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Regulatory

- EU: harmonization
 - so far, multidiverse situation
 - ≠ commercial vaccines
 - Individual products
 - Small batch sizes
 - isolates are non-GMP
- special GMP guidelines

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New (EU) Regulation 2019/6

7.1.2019

EN

Official Journal of the European Union

L 4/43

REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 11 December 2018
on veterinary medicinal products and repealing Directive 2001/82/EC

Article 2

Scope

1. This Regulation shall apply to veterinary medicinal products prepared industrially or by a method involving an industrial process and intended to be placed on the market.
2. In addition to the products referred to in paragraph 1 of this Article, Articles 94 and 95 shall also apply to active substances used as starting materials in veterinary medicinal products.
3. In addition to the products referred to in paragraph 1 of this Article, Articles 94, 105, 108, 117, 120, 123 and 134 shall also apply to inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals in an epidemiological unit and used for the treatment of that animal or those animals in the same epidemiological unit or for the treatment of an animal or animals in a unit having a confirmed epidemiological link.

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Summary



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Summary

Keep in mind

- autogenous vaccines are individually manufactured products
- production process takes about **5-8 weeks!**
(novel isolates may prolong the process!)



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Summary



- CMV can significantly
 - support flock health and economical outcome
 - reduce the need of antibiotics
- continuous diagnostics are crucial to update a vaccine

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Thanks!

Questions?

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