Are Autogenous vaccines relevant for pigs in Denmark

Af
Hans-Jørgen Riising

Konsulent ved DTU-Veterinærinstituttet

Are Autogenous vaccines relevant for pigs in Denmark

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DTU-Vet

- Statens Veterinære Serumlaboratorium started serum- and vaccineproduction in 1909.
- DTU-VET stopped production of Autogenous vaccines in 2009.

Law regarding Pharmaceuticals LOV nr 1180 af 12/12/2005

§ 2. …a pharmaceutical …. is any product

1)…. Used for treatment or prevention of diseases in humans or animals or

2) Can be given to humans or animals …. in order to establish an immunological effect….

§ 3. This Law covers pharmaceuticals for humans and animals.

§7. A pharmaceutical may only be sold or given out in this country, if a marketing authorisation has been given by Sundhedsstyrelsen or EMEA……

Law regarding Pharmaceuticals LOV nr 1180 af 12/12/2005

§11. Despite the description in §7 marketing authorisation is not required for the following pharmaceuticals:

1)…

2) Inactivated or non-inactivated immunological pharmaceuticals for animals prepared from pathogenic organisms or antigens extracted from an animal or an animal herd and used on the location for treatment of the same animal or herd.

Law regarding Pharmaceuticals

LOV nr 1180 af 12/12/2005

§30. ….. DTU-VET can after application, under speical conditions and in limited amounts sell or hand-out sera, vaccines, specific immunoglobulins and other immunological test substances, that do not have a marketing authorisation.

Sundhedsstyrelsen must be informed about each sale or hand-out.

Requirement of GMP

Sundhedsstyrelsen requires that all vaccines intended for use in Denmark must be produced in pharmaceutical companies who works according to GMP.

GMP-1

(Good Manufacturing Practice)

International set of rules that must be followed by pharmaceutical companies

Requirements:

Total traceability in all Processes.

Description of Personal and Organisation.

Written instructions for all work processes.

Working sheets for all activities

Signature for each process step performed

All documents have to be kept in Archive.

How Danish Farmers get their vaccines

- Herd with Disease problem

Herd veterinarian examines animals and take samples

Herd veterinarian makes diagnosis and

Samples Examined at LAB i

Vaccination plan A **if no A →** **Vaccination plan B**

Vaccination plan A
Marketed vaccine available in DK

Vaccination plan A
Herd-vet. makes prescription to the Herd owner (CHR nr.)

Vaccination plan A
Herd owner buys vaccine at Pharmacy and treat his animals

Vaccination plan B
No marketed vaccine in DK. Non registered IR-vaccine wanted

Vaccination plan B
Herd-vet. ask for spec. permission at DTU-VET

DTU-VET vaccine comittee

Vaccination plan B
Herd-vet. receive permission for IR-vaccine from DTU-VET

Vaccination plan B
IR-vaccine requested from Dianova to CHR nr.

Vaccination plan B
Herd owner receives IR-Vaccine from Dianova and treat animals

How §30 is used

DTU-VET gives –after application- the herd veterinarian permission to use in the specific herd:

- IR-vaccine = vaccine without Danish marketing authorisation

- Autovaccine = Autogenous vaccine based on a bacterium isolated in the specific herd

IR-vaccine -1

IR-vaccine = vaccine without Danish marketing authorisation.

Vaccines where the vaccine producer has omitted to ask for a Danish marketing autorisation i.e. due to :

- The disease has not been diagnosed in Denmark
- The Danish market is not of commercial interest.
- The documentation material is not in accordance with EU-standards.

IR-vaccines -2

How are IR-vaccines selected and distributed

1) The herd veterinarian request DTU-VET about an IR-vaccine against a specific disease.
2) DTU-VET investigates the need and risk and if possible vaccine exists.

   Primarily we look for a vaccine with Marketing Authorisation in another EU-country.

   Secondarily in N-America or elsewhere.
3) If we find a suitable vaccine, we contact the vaccine producer (through the Danish representative) and ask for a summary of the documentation material.
4) The documentation is examined by DTU-VET.

IR-vaccines -3

5) If the vaccine is accepted, DTU-VET buys the required amount of vaccine.

6) The vaccine is released by the QP after inspection and accept of the product and the batch record.

7) The herd practitioner send to DTU-VET an applicat. for use of the vaccine in a specific herd (CHR nr.)

8) Dianova invoices and ship the vaccine to the herd (CHR.nr.) The vaccine is kept cool during transport.

Sundhedsstyrelsen is informed about the delivery.

Requirements for vaccines development, production and approval

Activity	Step	MF-vacc	IR-vacc	Auto-vacc
Characteris. of agent	Develop.	++	++	++
Defin. of antigen	Develop.	++	+	0
Optimisat. antigen konc.	Develop.	++	+	0
Selection of adjuvant	Develop.	++	+	0
100%, 33%, 10% vacc.prep.	Develop.	++	+	0
Descrip. vaccine composition	Product.	++	++	++
Lab. & Field test	Efficacy	++	++	0
Safety test	Safety	++	++	0
Quality controls	Safety	++	+	0
Test for sterility	Safety	++	++	++
Test for identity	Safety	++	+	0
PSUR (Per.Safe.Updat.Report)	Safety	++	+	0

Riising Vet. Consult, tlf. 40988886
hj.riising@gmail.com

Steps by production and use of Autogenous vaccine

Activity	Who acts	Requirement
Investigat./Sampling	Herd-veterinarian	Correct material
Lab.diagnose	Lab-veterinar.	Correct lab.diagnose
Disease diagnosis	Herd-veterinarian	Correct clinical Diagnose
Request of Autovaccine	Herd-veterinarian	Autovaccine requested
Autovaccine order	QP-DTUVET	Autovac. ordered by vacc-prod.
Product. of Autovaccine	Vaccine producer	Vaccine is produced
Autovac. received in DK	QP-DTUVET	Inspect. of Vacc. + Batch Record
Autovac. to CHR.nr.	Dianova	Vacc. Shipped in cooler.
Autovaccine received	Herd owner	Vaccine paid & Animals vaccin.

Severe side effect occurs

Responsibility if side effects occur after use of Auto-vaccine

Activity	Who acts	Results	Responsibility
Investigat./Sampling	Herd-veterinar.	Process correct	No responsibility of Final Vaccine.
Lab.diagnose	Lab-veterinar.	Process correct	No responsibility of Final Vaccine.
Disease diagnosis	Herd-veterinar.	Process correct	No responsibility of Final Vaccine.
Request of Autovaccine	Herd-veterinar.	Process correct	No responsibility of Final Vaccine.
Autovaccine order	QP-DTUVET	Process correct	No responsibility of Final Vaccine.
Production of Autovac.	Vaccine producer	Process correct	No responsibility of Final Vaccine.
Autovac. received in DK	QP-DTUVET	Process correct	No responsibility of Final Vaccine.
Autovac. to CHR.nr.	Dianova	Process correct	No responsibility of Final Vaccine.
ceiv. & Paid	Herd owner	Process correct	No responsibility of Final Vaccine.

Side-effect occurs

All Losses accumulate here

Riising Vet. Consult, tlf. 40988886
hj.riising@gmail.com

conclusion -1

A Vaccine with Marketing Autorisation is a **Pharmaceutical**.

The composition, safety and efficacy is examined and approved by Sundhedsstyrelsen.

An Autogenous Vaccine **may** act as a Pharmaceutical.

The composition is known. However, the strength, safety and efficacy has **NOT** been investigated.

It is important that the **HERD-owner** knows the **difference** between a vaccine with Marketing Autorisation and an Autogenous Vaccine

conclusion-4

- In reality it is the **Herd-owner** who takes all responsibility when using an autogenous vaccine.

  Only if severe failure during production or handling of the Autogenous vaccine has been proven, **may be** other persons can be responsible for failure by the final vaccine.

- Under the present Danish law Autogenous vaccines do not have bright future in Denmark.

Thank you for listening