EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press office

Press release

First DNA vaccine in the EU recommended for use in salmon

Clynav to protect Atlantic salmon from serious infectious disease

The European Medicines Agency (EMA) has recommended granting a marketing authorisation in the European Union (EU) for Clynav, a DNA vaccine to protect Atlantic salmon against Salmon Pancreas Disease (SPD) caused by salmon alphavirus subtype 3.

SPD is a serious infectious disease which causes damage to the heart, pancreas and skeletal muscle and can lead to the death of salmon. The disease has become established in some Member States and outbreaks of SPD cause significant losses in salmon farms in the EU.

Clynav is the first DNA vaccine to be recommended for marketing authorisation in the EU. A DNA vaccine consists of a genetic sequence that triggers the production of proteins directly in the cells of the vaccinated animal. These proteins stimulate a protective immune response, in the case of Clynav against salmon alphavirus subtype 3, thereby preventing or reducing the impact of the disease should the fish subsequently be exposed to this virus.

The vaccine has been tested in fresh water and sea water trials that showed that an intramuscular injection reduces mortality and the damage to the heart, pancreas and muscle tissue that is associated with the disease. EMA's Committee for Veterinary Medical Products (CVMP) considered that the protection provided by the vaccination is clinically relevant and provides direct benefit to the salmon in terms of improved health and welfare.

On the basis of a detailed environmental risk assessment, the committee was satisfied that any potential risk to the environment from use of the product in salmon was negligible. Likewise, as any vaccine residues are rapidly degraded in the gastrointestinal tract after ingestion, the committee concluded that vaccinated salmon are safe to eat.

Clynav was classified as a medicine for minor use minor species (MUMS) / limited market because it is intended for a disease affecting a major species (Atlantic salmon) that has a limited geographical distribution. EMA's MUMS policy aims to stimulate the development of new veterinary medicines for minor species and for diseases in major species for which the market is limited and that would otherwise not be developed under current market conditions.

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The CVMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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