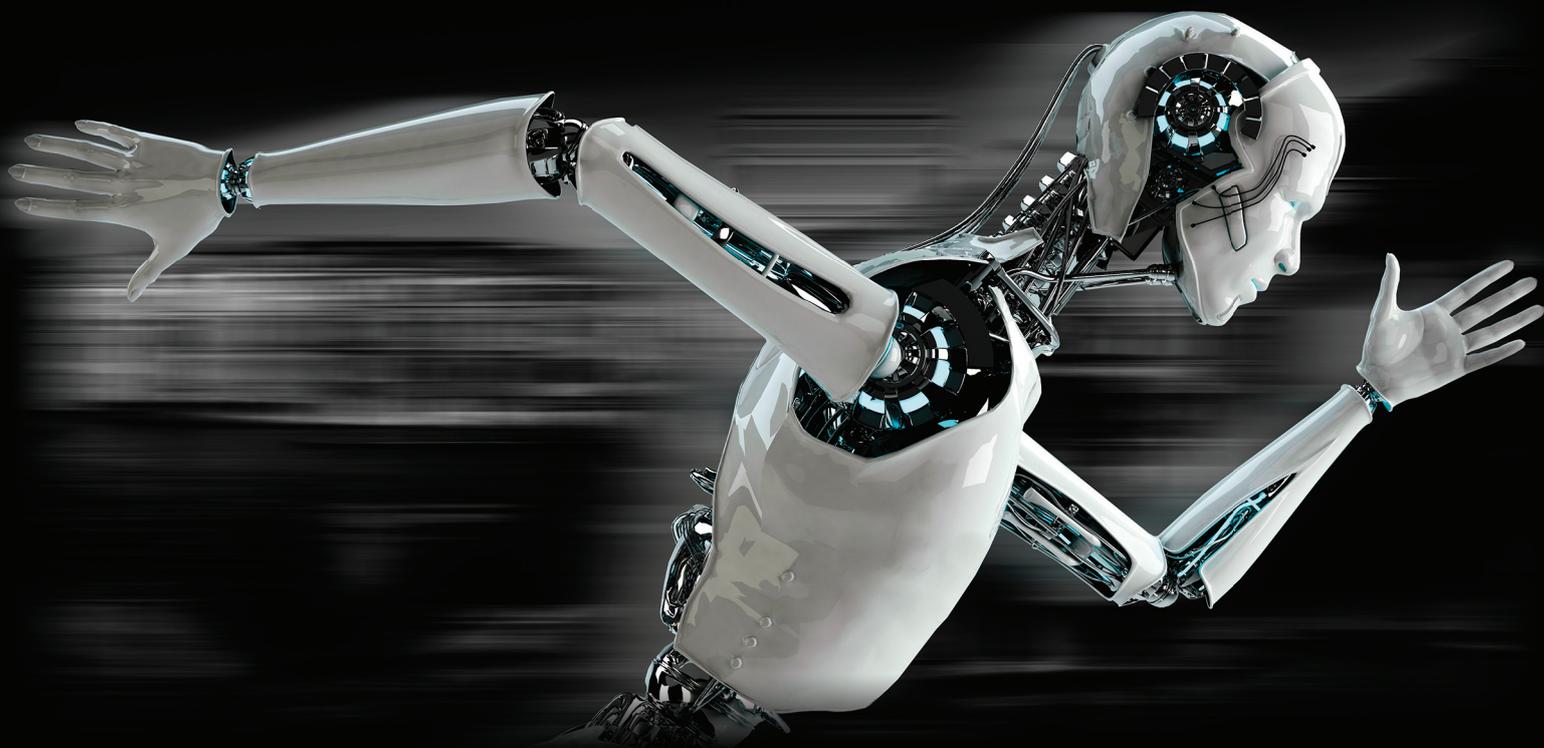


**NEW** Nobilis<sup>®</sup> H9N2+ND P



# FAST ACTING IMMUNITY

**PROMPT ACTING + MORE PROTECTION**

[www.msd-animal-health.com](http://www.msd-animal-health.com)



# THE FUTURE OF A.I. & N.D. VACCINATION HAS ARRIVED

**NEW Nobilis® H9N2+ND P** is the first Avian Influenza and Newcastle Disease Vaccine to incorporate revolutionary Pathogen Associated Molecular Pattern (PAMP) technology.

PAMP delivers an earlier onset of immunity with increased protection combined with reduced viral shedding and can be administered from day one.

IMPROVED PROTECTION WHEN ADMINISTERED BEFORE 4 WEEKS OF AGE

PROVIDES A VERY RAPID ONSET OF IMMUNITY

PROTECTS AGAINST AVIAN INFLUENZA H9N2 & NEWCASTLE DISEASE

CAN BE GIVEN AT DAY OLD AT THE HATCHERY



# AVIAN INFLUENZA

- Avian Influenza (AI) viruses (Influenzavirus, a genus of the Orthomyxoviridae family) are divided into subtypes on the basis of 18 haemagglutinin antigens (H1 - H18) and 11 neuramidase antigens (N1 - N11).

- AI viruses infecting poultry are classified in two groups, depending on the severity of the disease in poultry:

## HIGHLY PATHOGENIC AVIAN INFLUENZA (HPAI)

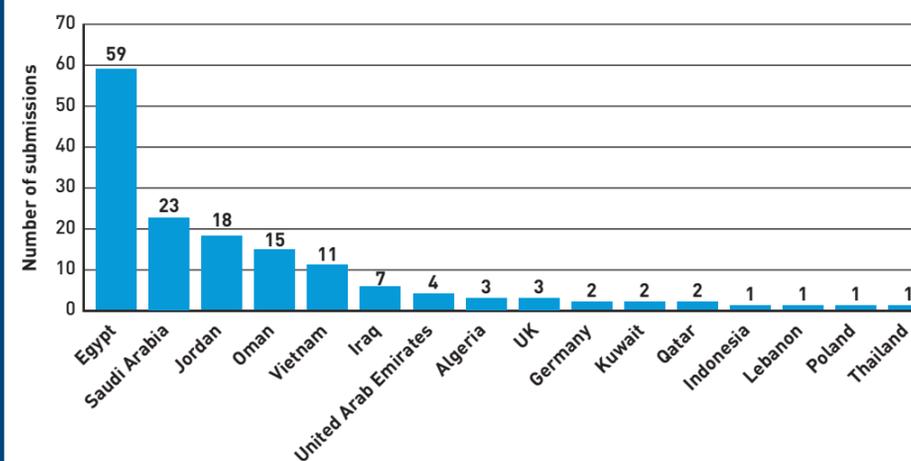
- Can cause severe clinical signs and potentially high mortality rates among poultry.
- Restricted to subtypes H5 and H7.
- Classified as a list A disease by the World Organization for Animal Health (OIE).

## LOW PATHOGENIC AVIAN INFLUENZA (LPAI)

- Typically cause few or no clinical signs in poultry.
- Concomitant infection with other organisms or suboptimal environmental conditions may cause more serious disease.

- Over the last decade (2010-19) we had 378 HPAI outbreaks worldwide - this is more than double when compared with the 2 previous decades (1990-2009):
- Vaccine based control has been established, however, the vaccines available do not induce an early, fast and high immunity - which is particularly restrictive when used in broilers.

AI SUBTYPE H9 - COUNTRIES EVALUATED (N=153) 2013-2019



Period: 14/10/2013 - 17/12/2019. N. Submissions: 153. N. Samples analyzed (by request): 182

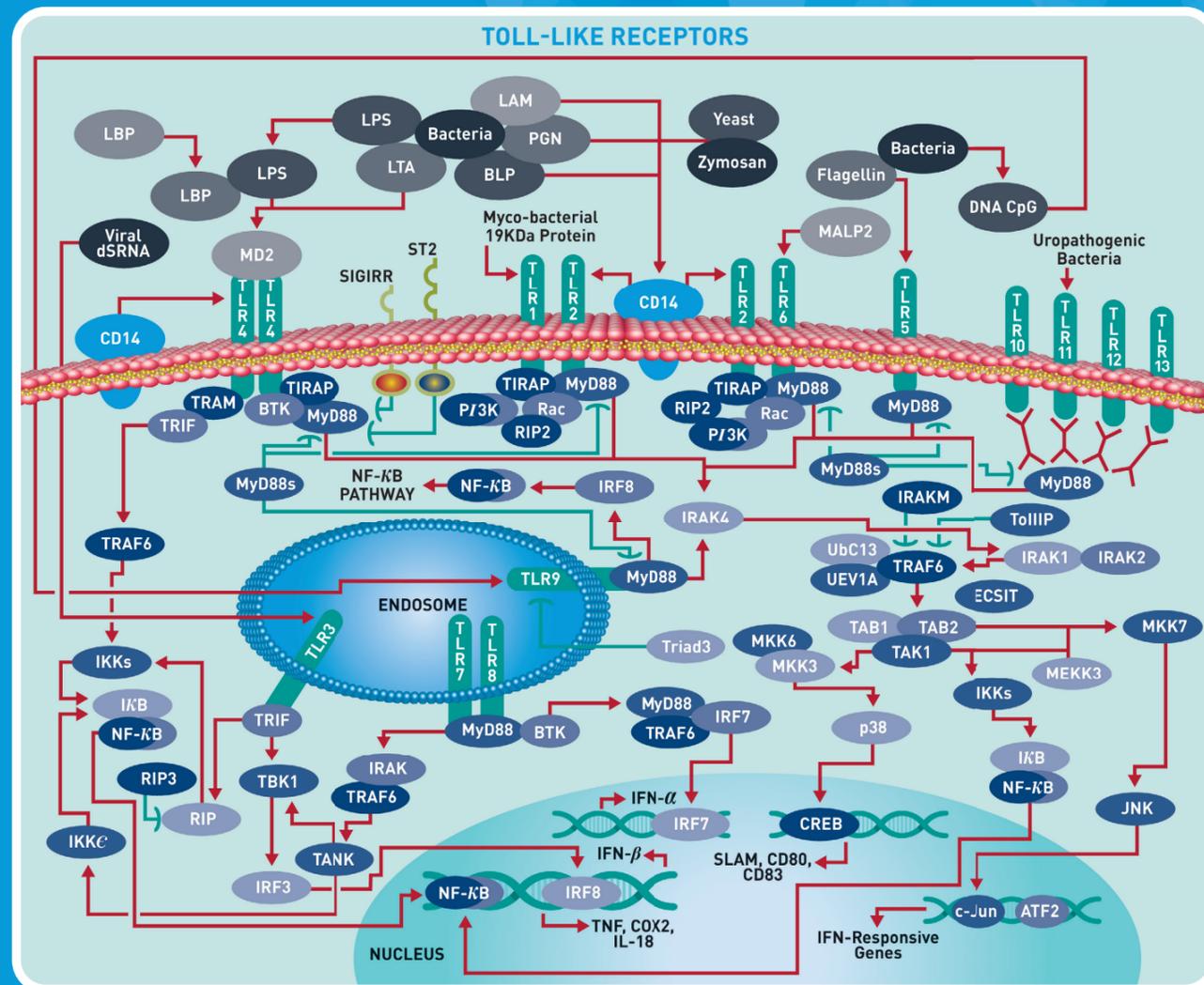
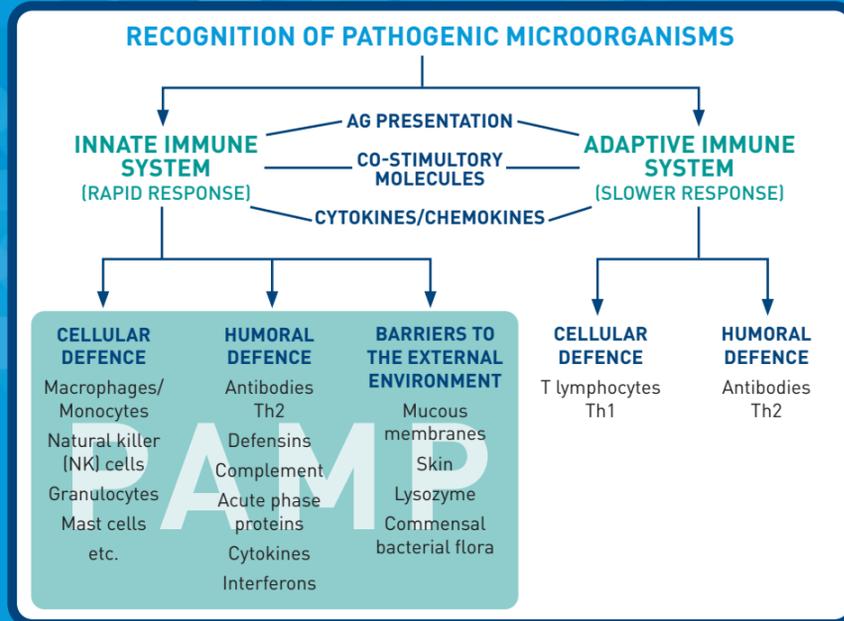
\*Data from WAHIS/OIE



# PAMPs

## PATHOGEN ASSOCIATED MOLECULAR PATTERNS

- PAMPs are small molecular motifs, conserved within a class of microbes, recognized by cells of the innate immune system.
- PAMPs are recognized by Pathogen Recognition Receptors (PRRs)
- PAMPs used in Nobilis® H9N2+ND P act as an additional adjuvant

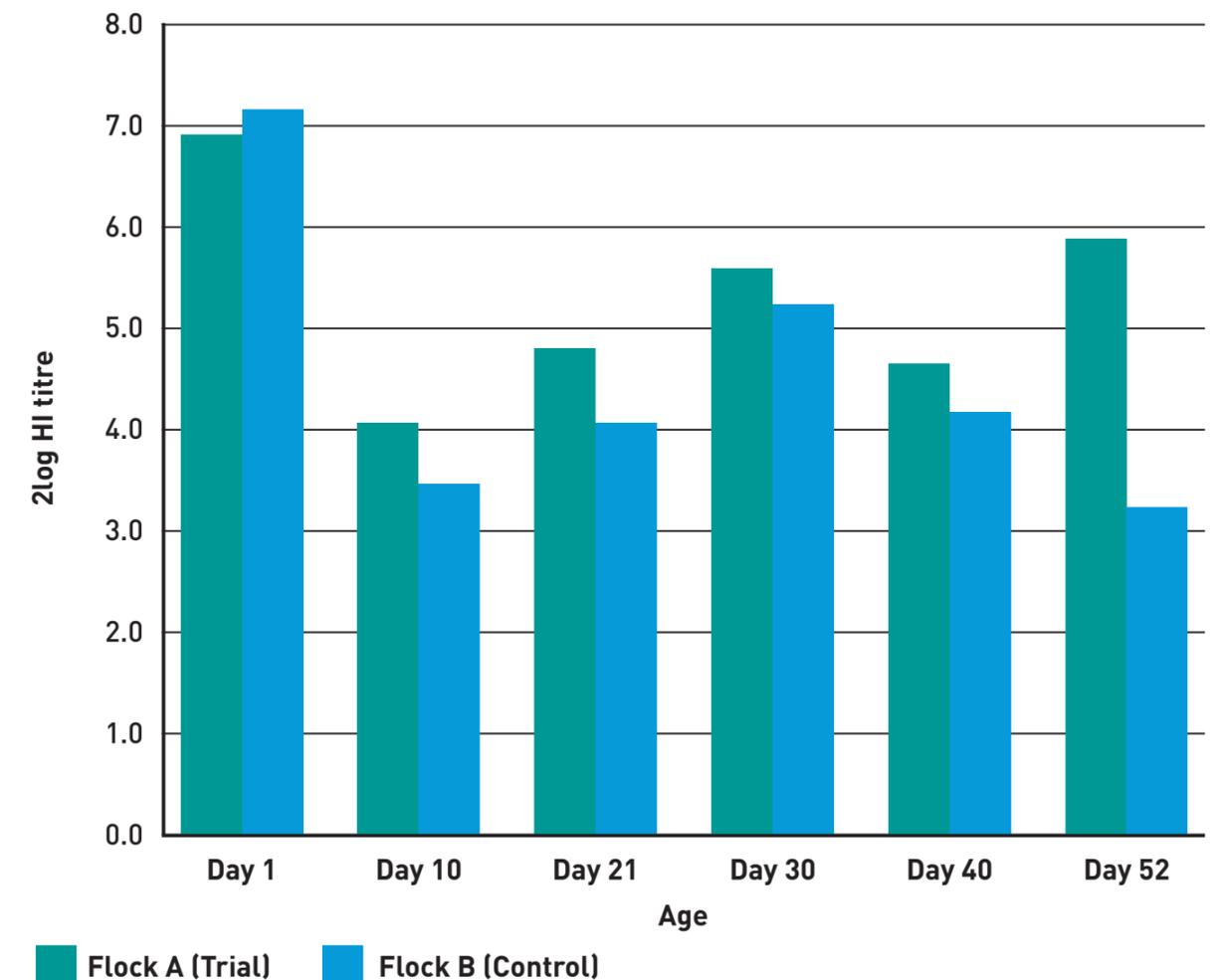


# FIELD TRIAL

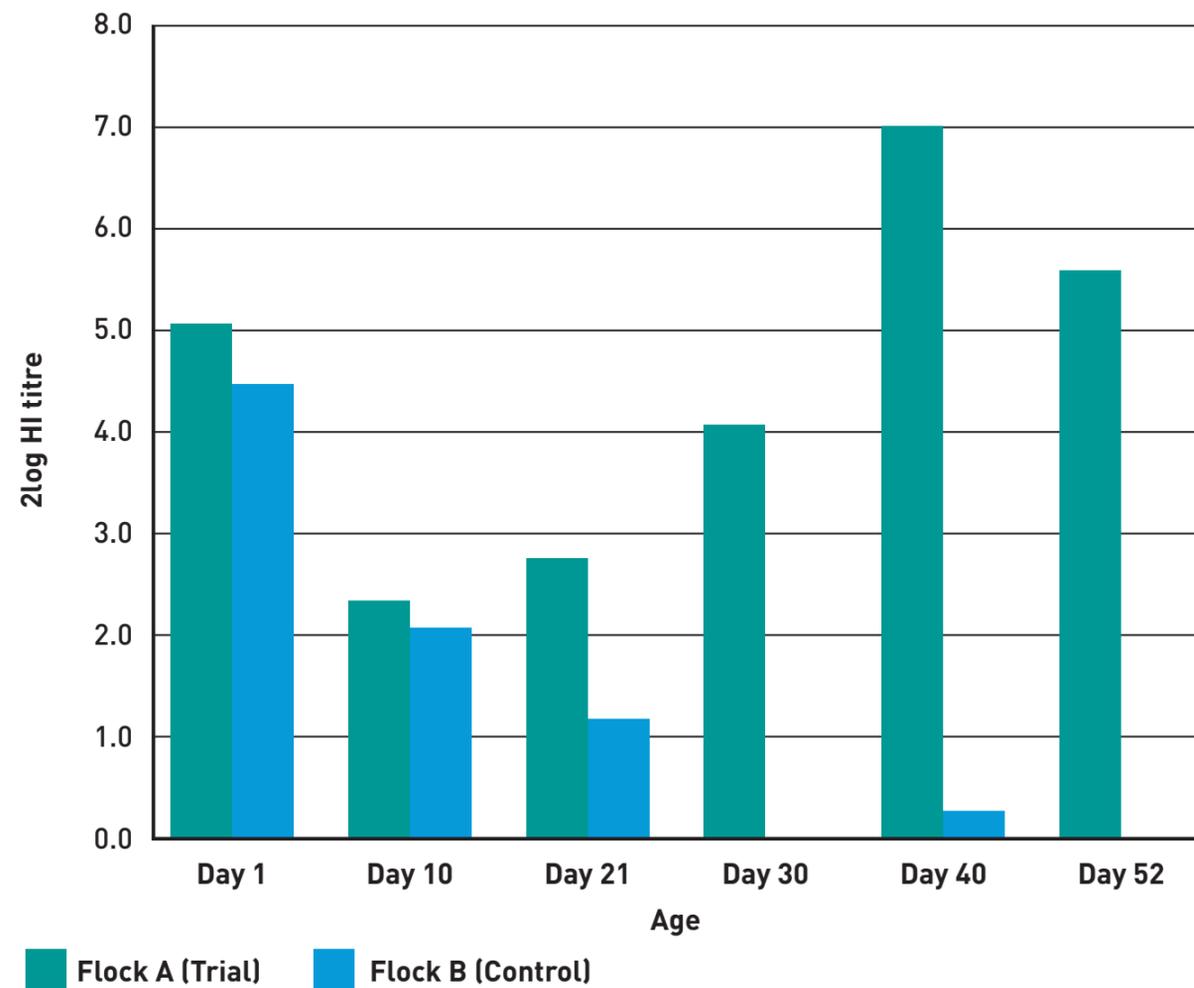
## MDA POSITIVE DAY-0 OLD CHICKS

- Field trial comparing Nobilis® Influenza H9N2+ND vs Nobilis® H9N2+ND P.
- Broilers with Maternal derived antibodies against AI (MDA+).
- Both vaccines (trial and control) were administered to the test groups by subcutaneous injection (dose per bird 0.25ml) at one day of age. At the same time the vaccination program against Newcastle Disease and Infectious Bronchitis was completed with a live vaccine given at day of age by coarse spray.
- The vaccines were given at the hatchery.
- The products were administered according to the manufacturer's indications.

## ND SEROLOGY IN MDA+ BROILERS



## H9N2 SEROLOGY IN MDA+ BROILERS



**FOR BOTH AI AND ND,  
THE NOBILIS® H9N2+ND P  
GROUP DEMONSTRATED  
EARLIER AND HIGHER  
INDUCED IMMUNITY**

# Nobilis® H9N2+ND P

## SUMMARY OF PRODUCT CHARACTERISTICS

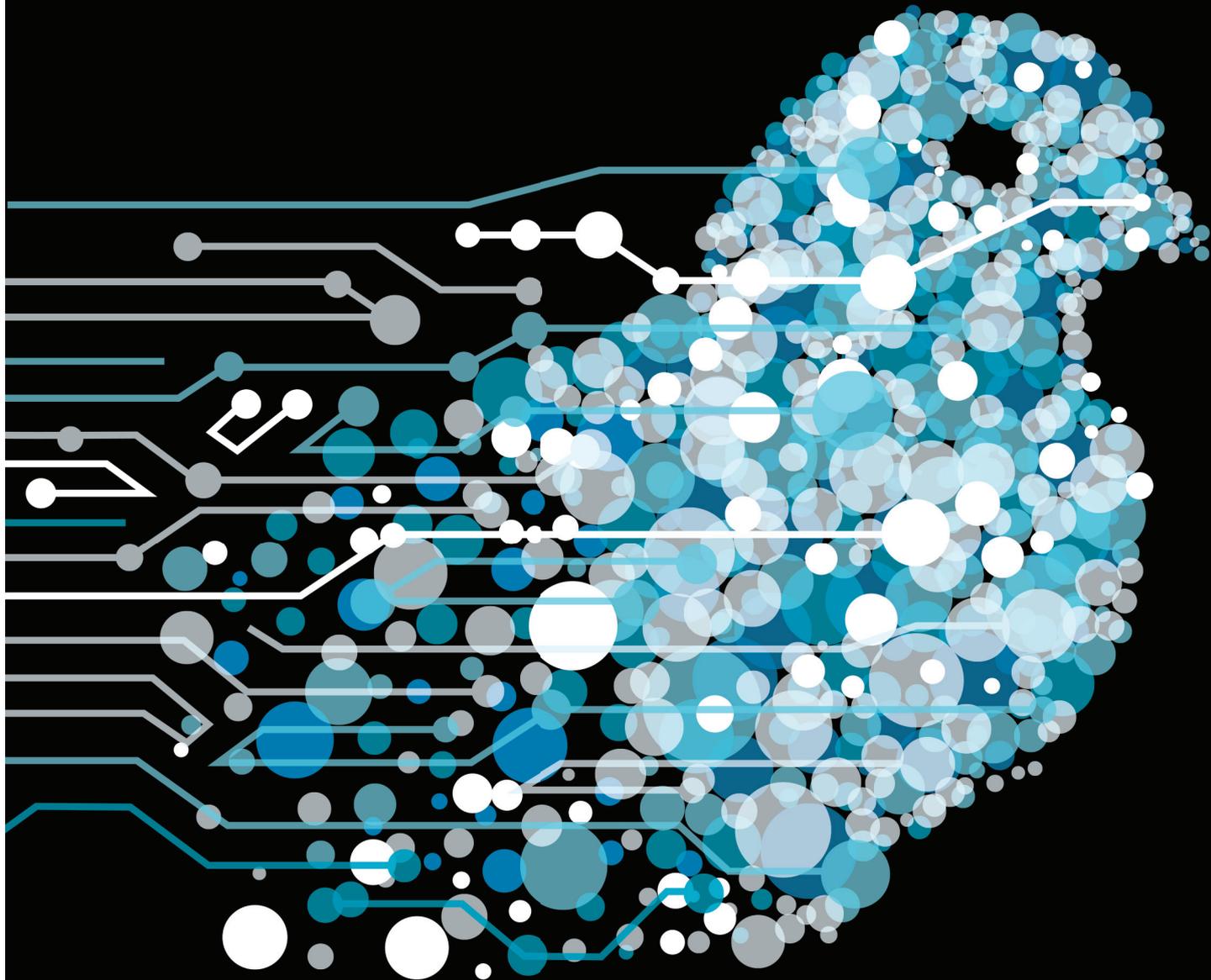
- 1. NAME OF THE VETERINARY MEDICINAL PRODUCT**  
Nobilis® H9N2+ND P emulsion for injection for chicken
- 2. QUALITATIVE AND QUANTITATIVE COMPOSITION**  
Each dose of 0.25 ml contains:  
**Active substances:**  
Inactivated Avian Influenza Virus, Type A,  $\geq 8.0 \log_2$  HI<sup>1</sup>  
Subtype H9N2 (strain A/CK/UAE/415/99)  
Inactivated Newcastle Disease Virus  $\geq 4.0 \log_2$  HI units per 1/50th dose<sup>1</sup> or containing  $\geq 50$  PD<sub>50</sub> units  
**Adjuvant:**  
Liquid light paraffin  
Immunostimulant
- 3. PHARMACEUTICAL FORM**  
Emulsion for injection.  
Homogenous white to nearly white emulsion after shaking.
- 4. CLINICAL PARTICULARS**
  - 4.1 Target species**  
Chicken
  - 4.2 Indications for use <specifying the target species> (if appropriate)**  
For active immunisation of chickens against Avian Influenza Virus, Type A, Subtype H9 and against Newcastle Disease Virus.  
**Avian Influenza Virus**  
Onset of Immunity: 2 weeks  
Duration of Immunity: 7 weeks  
**Newcastle Disease Virus**  
Onset of Immunity: 3 weeks  
Duration of Immunity: 7 weeks
  - 4.3 Contraindications**  
Do not administer intramuscularly as this can lead to local reactions. Do not administer later than 4 weeks of age, as vaccination close to onset of lay can lead to a transient reduction in egg production.
  - 4.4 Special warnings**  
None
  - 4.5 Special precautions for use**  
**Special precautions for use in animals**  
Vaccinate only healthy animals.  
**Special precautions to be taken by the person administering the veterinary medicinal product to animals**  
**To the user:**  
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.  
**To the physician:**  
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.
  - 4.6 Adverse reactions (frequency and seriousness)**  
In laboratory studies trials:  
Transient, small local reactions at the injection site (redness, hardness) are a very common observation.  
The frequency of adverse reactions is defined using the following convention:  
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)  
- common (more than 1 but less than 10 animals in 100 animals)  
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- 5. IMMUNOLOGICAL PROPERTIES**  
Pharmacotherapeutic group: inactivated viral vaccine.  
ATC vet code: QI01AA.  
The product stimulates the development of active immunity in chicken against Avian Influenza Virus, Type A, Subtype H9 and Newcastle Disease Virus.
- 6. PHARMACEUTICAL PARTICULARS**
  - 6.1 Incompatibilities**  
Do not mix with any other veterinary medicinal product.
  - 6.2 Shelf life**  
Shelf life of the veterinary medicinal product as packaged for sale: 2 years.  
Shelf life after first opening the immediate packaging: 10 hours.
  - 6.3 Special precautions for storage**  
Store in a refrigerator (2°C-8°C).  
Do not freeze.  
Protect from light.
  - 6.4 Nature and composition of immediate packaging**  
Plastic vials of 250 ml (1000 doses) or 500 ml (2000 doses), are closed with a rubber stopper and sealed with a cap.  
Not all pack sizes may be marketed.
  - 6.5 Special precautions for the disposal of unused medicinal product or waste materials derived from the use of such products**  
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
- 7. MARKETING AUTHORISATION HOLDER**  
Intervet International BV  
Wim de Körverstraat 35  
5831 AN Boxmeer  
The Netherlands

<sup>1</sup> As determined in the *in vivo* potency test in chickens.

Registration file / December 2017

**NEW** Nobilis® H9N2+ND P

# THE FUTURE IS NOW AVAILABLE



**PROMPT ACTING + MORE PROTECTION**