Informative Note

Spanish Agency of Medicinal Products and Medical Devices
AEMPS

INFORMATIVE NOTE CONCERNING THE INTERPRETATION OF THE "INCOMPATIBILITIES" SECTION OF SUMMARY PRODUCTS CHARACTERISTICS (SPC) FOR VETERINARY MEDICINAL PRODUCTS (VMPS)

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Category: INDUSTRY, VETERINARY MEDICINAL PRODUCTS
Reference: MVET, 3_vi/2017

According to the current version of Quality Review of Documents (QRD), the section 6.2. Main "Incompatibilities" of the SPC, the following must be included:

- ***<Not applicable>***
- ***<In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products>***
- ***<Do not mix with any other veterinary medicinal product>, except <diluent, solvent or other component> <recommended> <supplied> <for use with the veterinary medicinal product>***
- ***<None known>***

This section must be understood as follows:

a) In section 6.2 of SPC all main physical or chemical incompatibilities recorded during the compatibility studies made on the VMPs with other products with which they could be mixed shall be included (e.g. feed additives).

b) **< Not applicable >**
This must be chosen when the incompatibility is not relevant because of the pharmaceutical form (e.g. solid oral pharmaceutical forms).

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c) **<In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products>**
This must be chosen when the compatibility with other VMPs had not been demonstrated or no studies had been carried out (e.g. parenterals, premixes and products for administration in drinking water).

d) **<Do not mix with any other veterinary medicinal product>, except <diluents, solvent or other component> <recommended><supplied> <for use with the veterinary medicinal product>**
This must be chosen for immunological because mixing with other products different from the recommended diluents or components is not allowed, except in the case of compatibility studies having been carried out.

e) **< None known>**
This must be chosen when compatibility studies have been carried out and no incompatibilities have been described for this VMP.
For safety reasons, the suitable sentences must be used in SPCs of premixes and VMPs for administration in drinking water. The MAHs who's VMPs do not have the QRD current sentences in section 6.2 of the SPC and section 12 of the leaflet, must apply for one of the following variations:

1. **Type IB C.II.z.** when the appropriate sentences in sections 6.2 and 12 are included without any additional studies having to be assessed.

2. **Type II C.I.4.,** when compatibility studies are attached.

In both cases the exemption of 95% of the normal fee, according to Article 121.5 of the Legislative Royal Decree 1/2015, of 24 July, will apply.

If the respective variation application is not submitted **within six months from the next day following the publication of this letter**, the procedure for a temporary suspension of the marketing authorization will begin , in compliance with Articles 51.1.i) and 52 of the Royal Decree 1246/2008. The suspension will be lifted when the variation is satisfactorily solved.

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