Veterinary Mutual Recognition Facilitation Group

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VETERINARY MUTUAL RECOGNITION FACILITATION GROUP (VMRF)

COLOSTRUM AND COLOSTRUM SUBSTITUTES

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COLOSTRUM AND COLOSTRUM SUBSTITUTES

Background

It has been agreed by the European Committee for Veterinary Medicinal Products that colostrum products fall within the scope of Directive 90/677/EEC on veterinary immunological products, when they are administered to provide passive immunity. They are therefore required to be authorised in accordance with Directive 81/851/EEC (as amended) and national legislation which implements that Directive.

Situation

Manufactured colostrum substitutes will have to be authorised. This includes colostrum from cows which have been treated to ensure that the colostrum produced will contain particular antibodies.

Pure colostrum or products containing pure colostrum, but which make no reference to immunoglobulin content, antibodies or immunity can be marketed without an authorisation and are considered to be a nutritional supplement. The term «colostrum,» is not considered medicinal.

The products will have to be authorised if medicinal claims are to be made.

Companies currently marketing colostrum or colostrum substitutes will be required according to national situations to notify the authorities whether their products:

(a) fall within the definition and therefore require authorisation;

(b) whether the company will be submitting an application or not;

(c) contain natural colostrum for which all references to immunoglobulin content, antibodies and immunity have been removed.

Mutual Recognition

Companies intending to market a colostrum product, considered to be a veterinary medicinal product in more than one member state will be required to use the mutual recognition procedure or the centralised procedure (where the product involves biotechnology or novel science).