ANNEX I

NAME, PHARMACEUTICAL FORM, STRENGTH OF THE MEDICINAL PRODUCTS, ANIMAL SPECIES, ROUTES OF ADMINISTRATION, AND MARKETING AUTHORISATION HOLDER/ APPLICANT(S)

Member State	Marketing Authorisation Holder/Applicant	Product invented name	Pharmaceutical form	Strength	Animal species	Frequency and route of administration	Recommended dose
Ireland	ECO Animal Health Ltd. 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	Ecomectin 18.7 mg/g Oral Paste for Horses	Oral Paste. A white homogenous paste	Ivermectin 18.7 mg/g	Horses	The paste is given by oral route.	One syringe division of paste per 100 kg body weight (based on a recommended dosage of 200 microgram ivermectin per kg body weight).
Belgium	As above	Ivermax 18.7 mg/g Oral Paste for Horses	As above	As above	As above	As above	As above
Cyprus	As above	Tizoval 18.7 mg/g Oral Paste for Horses	As above	As above	As above	As above	As above
Czech Republic	As above	Vetimec 18.7 mg/g Oral Paste for Horses	As above	As above	As above	As above	As above
Denmark	As above	Ecomectin 18.7 mg/g Oral Paste for Horses	As above	As above	As above	As above	As above
Finland	As above	Ecomectin 18.7 mg/g Oral Paste for Horses	As above	As above	As above	As above	As above

Member State	Marketing Authorisation Holder/Applicant	Product invented name	Pharmaceutical form	Strength	Animal species	Frequency and route of administration	Recommended dose
France	As above	Divamectin 18.7 mg/g Oral Paste for Horses	As above	As above	As above	As above	As above
Germany	As above	Tizoval 18.7 mg/g Oral Paste for Horses	As above	As above	As above	As above	As above
Greece	As above	Tizoval 18.7 mg/g Oral Paste for Horses	As above	As above	As above	As above	As above
Hungary	As above	Ecomectin 18.7 mg/g Oral Paste for Horses	As above	As above	As above	As above	As above
Italy	As above	Tizoval 18.7 mg/g Oral Paste for Horses	As above	As above	As above	As above	As above
The Netherlands	As above	Ivermax 18.7 mg/g Oral Paste for Horses	As above	As above	As above	As above	As above
Norway	As above	Tizoval 18.7 mg/g Oral Paste for Horses	As above	As above	As above	As above	As above

Member State	Marketing Authorisation Holder/Applicant	Product invented name	Pharmaceutical form	Strength	Animal species	Frequency and route of administration	Recommended dose
Portugal	As above	Ecomectin 18.7 mg/g Oral Paste for Horses	As above	As above	As above	As above	As above
Spain	As above	Ecomectin 18.7 mg/g Oral Paste for Horses	As above	As above	As above	As above	As above
Sweden	As above	Ecomectin 18.7 mg/g Oral Paste for Horses	As above	As above	As above	As above	As above
United Kingdom	As above	Animec 18.7 mg/g Oral Paste for Horses	As above	As above	As above	As above	As above

ANNEX II

SCIENTIFIC CONCLUSIONS

SCIENTIFIC CONCLUSIONS

1. Introduction and background

Ecomectin 18.7 mg/g Oral Paste for Horses is intended to be used in horses for the treatment of nematode or arthropod infections caused by *Strongylus vulgaris, Strongylus edentatus, Strongylus equinus,* Small strongyles (including benzimidazole resistant strains): *Cyathostomum spp, Cylicocyclus spp., Cylicodontophorus spp., Cylicostephanus spp., Gyalocephalus spp.,* Ascarids: *Parascaris equorum,* Pinworms: *Oxyuris equi*m, Neck threadworms: *Onchocerca spp,* Stomach bots: *Gasterophilus spp*

Ireland notified the EMEA on 4 July 2007 that the Co-ordination Group for Mutual Recognition and Decentralised Procedures - Veterinary (CMD(v)) failed to reach an agreement regarding Ecomectin 18.7 mg/g Oral Paste for Horses. Pursuant to Article 33(4) of Council Directive 2001/82/EC, as amended, the matter has been referred to the CVMP.

The referral relates to the concerns raised by Germany that this veterinary medicinal product may present a potential serious risk to public health on the following grounds:

An environmental risk was detected during the risk assessment Phase II Tier A for dung fauna organisms. No adequate data for Tier B were provided by the applicant to assess the long-term effects on dung fauna organisms caused by the use of the product.

The referral procedure started on 11 July 2007. The time frame agreed by the CVMP on 11 July 2007 was 58 days.

On the basis of the grounds for referral, the points considered by the CVMP were:

1. The Marketing Authorisation Holder should provide complete information submitted to the Reference Member State and the CMD(v) in respect to environmental risk assessment;
2. The Marketing Authorisation Holder should provide an updated Environmental Risk Assessment according to the CVMP guidelines on the matter, including any justification for exemption of Phase II;
3. The Marketing Authorisation Holder should discuss and propose, if considered appropriate, possible risk mitigation measures to be included in the SPC of the product.

These points were included in the List of Questions that the Committee for Veterinary Medicinal Products adopted on 11 July 2007. The List of Questions was sent to the Marketing Authorisation Holder.

The Marketing Authorisation Holder submitted written responses to the List of Questions on 12 September 2007. Oral explanations were heard on 10 October 2007.

2 Information in respect to environmental risk assessment

The Marketing Authorisation Holder provided the following information:

- An updated Environmental Risk Assessment
- The complete information submitted to the Reference Member State and the CMD(v) in respect to environmental risk assessment.

2.1 Updated Environmental Risk Assessment according to the CVMP guidelines on the matter, including any justification for exemption of Phase II

The Marketing Authorisation Holder provided an updated environmental risk assessment. A separate file for justification of exemption from phase II was not specifically given. However some consideration to this is given on the document that can be summarised as follows:

Ecomectin 18.7 mg/g Oral Paste for Horses is a generic product and as such an environmental risk assessment is now required under Directive 2001/82, as amended.

The Marketing Authorisation Holder considers that the guidelines were written primarily for new molecules where the risk to the environment has not been characterized and that it is not the case for ivermectin-containing veterinary medicinal products that have been in extensive worldwide use for nearly 25 years and that real risk or detrimental environmental effect attributable to ivermectin-based veterinary medicinal products would have been observed.

The Marketing Authorisation Holder considers it inconceivable that the risks posed to the environment associated with the use of Ecomectin 18.7 mg/g Oral Paste for Horses in particular are any greater than those posed by other ivermectin-based products, particularly as the concentration of the active ingredient and the proposed usage regime is identical to that of the reference and other similar products.

The applicant considers that the level of use in horses in terms of animal numbers and dose level, compared to other pasture animals (cattle and sheep) is low and that consequently the use in the horse will have limited impact on the environment. Based on this, the applicant argued that the horse should be classed as "minor use/minor species" and that no Phase II risk assessment is required. In addition, he considers that since this is a generic, there will not be an additional risk to the environment. The applicant does not provide a formal justification for exemption of Phase II.

The PEC in soil were calculated for intensively reared animals and pasture animals, according to the CVMP Guideline on Environmental Impact Assessment for Veterinary medicinal Products in Support of the VICH Guidelines GL6 and GL38 (EMEA/CVMP/ERA/418282/2005-corr).

PEC_{SOIL}- Intensively reared animals = 1.036 µg.kg^{-1}

PEC_{SOIL}- Pasture animals = 0.48 µg.kg^{-1}

For two soil exposure scenarios the PEC_{SOIL} values did not exceed the 100 µg/kg threshold value as stated in the VICH Guideline for Phase I assessments of veterinary medicines. Despite this, Step 16 of the Phase I decision tree would indicate that a Phase II assessment is required for a product of this nature i.e. ecto/endoparasiticide for major species.

The applicability of the following question of the VICH GL6 was considered:

Question 4 - Is the VMP intended for use in a minor species that is reared and treated similarly to a major species for which an EIA *(Environmental Impact Assessment)* already exists?

The product under referral is intended for horses only. Although oral paste is not used in major species (cattle, sheep, pigs), oral forms exist. Ivermectin-containing products are widely used in these species. Horses are reared under similar conditions to livestock or, alternatively to housed livestock such as pigs, for which species ivermectin has a well-established use, orally and by other routes of administration.

The use of Ecomectin 18.7 Oral Paste for Horses does not result in an increase of the exposure to the environment compared to products for major species and therefore the conclusions of their environmental impact assessment is applicable for this product for horses.

No risk mitigation measures are considered appropriate.

3 Conclusions and recommendations

The Committee concludes that, since the product is intended for use in a minor species (horses) that is reared and treated similarly to a major species, the conclusions on the Environmental Risk Assessment of the major species apply, the product should be exempt from providing a Phase II assessment and that no risk mitigation measures should be included in the SPC of the product.

ANNEX III

SUMMARY OF PRODUCT CHARACTERISTICS, LABELLING AND PACKAGE INSERT

The valid Summary of Product Characteristics, labelling and package leaflet are the final versions achieved at day 90 during the Coordination group procedure.