ANNEX III

LIST OF THE OBLIGATIONS REFERRED TO IN ARTICLE 136(1)

(1) the obligation, as an applicant, to provide accurate information and documentation as referred to in Article 6(4);

(2) the obligation to provide, in an application submitted in accordance with Article 62, the data referred to in point (b) of paragraph 2 of that Article;

(3) the obligation to comply with the conditions referred to in Articles 23 and 25;

(4) the obligation to comply with conditions included in the marketing authorisation of the veterinary medicinal product, as referred to in Article 36(1);

(5) the obligation to introduce any necessary variation to the terms of the marketing authorisation to take account of technical and scientific progress and enable the veterinary medicinal products to be manufactured and checked by means of generally accepted scientific methods, as provided for in Article 58(3);

(6) the obligation to keep up to date the summary of product characteristics, package leaflet and labelling with current scientific knowledge, as provided for in Article 58(4);

(7) the obligation to record in the product database the dates when its authorised veterinary medicinal products are placed on the market and information on the availability for each veterinary medicinal product in each relevant Member State and, as applicable, the dates of any suspension or revocation of the marketing authorisations concerned, as well as data relating to the volume of sales of the medicinal product, as provided in Article 58(6) and (11) respectively;

(8) the obligation to provide within the time limit set at the request of a competent authority or the Agency any data demonstrating that the benefit-risk balance remains positive, as provided for in Article 58(9);

(9) the obligation to supply any new information which may entail a variation to the terms of the marketing authorisation, to notify any prohibition or restriction imposed by the competent authorities of any country in which the veterinary medicinal product is marketed, or to supply any information that may influence the evaluation of the risks and benefits of the medicinal product, as provided for in Article 58(10);

(10) the obligation to place the veterinary medicinal product on the market in accordance with the content of the summary of the product characteristics and the labelling and package leaflet as contained in the marketing authorisation;

(11) the obligation to record and report suspected adverse events for their veterinary medicinal products, in accordance with Article 76(2);

(12) the obligation to collect specific pharmacovigilance data additional to the data listed in Article 73(2) and to carry out post-marketing surveillance studies in accordance with Article 76(3);

(13) the obligation to ensure that public announcements relating to information on pharmacovigilance concerns are presented objectively and are not misleading and to notify them to the Agency, as provided for in Article 77(11);

(14) the obligation to operate a pharmacovigilance system for the fulfilment of pharmacovigilance tasks, including maintenance of a pharmacovigilance system master file in accordance with Article 77;

(15) the obligation to submit, at the request of the Agency, a copy of its pharmacovigilance system master file(s), as provided for in Article 79(6);

(16) the obligation to carry out signal management process and to record the results and outcomes of that process in accordance with Article 81(1) and (2);

(17) the obligation to provide to the Agency all available information relating to the Union interest referral, as referred to in Article 82(3).