I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a **letter of intent** by AB Science S.A. on 24 July 2006, the Committee for Medicinal Products for Veterinary Use (CVMP) accepted on 14 September 2006 that Masitinib – AB Science was eligible for the centralised procedure under Article 3(2)(a) of Regulation (EC) No 726/2004 as the product contains a new active substance which was not authorised in the Community.

On 14 February 2007, the CVMP confirmed that the data requirements in the appropriate CVMP guidelines on "**Minor-Use-Minor-Species (MUMS)** data requirements" would be applied when assessing the application. MUMS Status was granted for the following reasons:

- The total incidence of canine mast cell tumours grade 2 or 3 in dogs is very low.
- Mast cell tumours might be (but are not always) a life-threatening condition.
- The CVMP considered the estimated target population treatable with Masivet as being low.

The **Rapporteur and Co-Rapporteur** appointed by the CVMP were:
Rapporteur: Reinhard Kroker (later replaced by Cornelia Ibrahim) from Germany; Co-Rapporteur: Karolina Törneke from Sweden.

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 27 February 2007.
- The procedure started on 14 March 2007.
- The Rapporteur's Assessment Report was circulated to all CVMP Members on 22 May 2007. The Co-Rapporteur's critique was circulated to all CVMP Members on 6 June 2007.
- During its meeting in July 2007 the CVMP agreed on a consolidated List of Questions.
- The Applicant submitted the responses to the CVMP consolidated List of Questions on 14 February 2008.
- The Rapporteurs circulated their joint Assessment Report on the applicant's responses to the List of Questions to all CVMP Members on 17 March 2008.
- During their plenary meeting held from 15-17 April 2008, the CVMP decided that an Oral Explanation was required and agreed a List of Outstanding Issues.
- During their plenary meeting held from 13 – 15 May 2008, the CVMP considered the responses given by the applicant in writing and at an Oral Explanation (13 May 2008).
- On 15 May 2008, the CVMP, having considered the overall data submitted and the scientific discussion within the Committee, recommended the refusal of the granting of a marketing authorisation for Masivet.

3. Steps taken for the re-examination of the opinion

The **Rapporteur and Co-Rapporteur** appointed by the CVMP for the re-examination procedure were Rory Breathnach from Ireland and Cristina Muñoz Madero from Spain.

- The applicant submitted written notice to the EMEA on 27 May 2008 to request the re-examination of the Masivet CVMP opinion and to consult an Ad-Hoc Expert Group (AHEG) in this re-examination.
- During its meeting on 17 – 19 June 2008, the CVMP appointed Rory Breathnach from Ireland as Rapporteur and Cristina Muñoz Madero from Spain as Co-Rapporteur and confirmed the List of Participants for an AHEG.
- The detailed grounds for the re-examination request were submitted by the applicant on 20 July 2008. The re-examination procedure started on 21 July 2008.
- The joint Rapporteur's and Co-Rapporteur's Assessment Report was circulated on 25 July 2008.
- On 6 August 2008, the CVMP adopted a List of Questions for the AHEG (written procedure).
- During a meeting of the CVMP Ad-hoc Expert meeting on 14 August 2008, experts were convened to consider the grounds for re-examination. During this meeting the applicant presented an oral explanation. A report of this meeting was forwarded to the CVMP.
- The Rapporteur and Co-Rapporteur's final recommendation was circulated to all CVMP members on 2 September 2008.
- On 16 September 2008, the applicant presented an oral explanation before the CVMP.
- During the meeting on 16 – 18 September 2008, the CVMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a final Opinion recommending the granting of a Marketing Authorisation for Masivet.