Subject: Summary report of expert meeting on pharmacovigilance in the context of the review of the veterinary medicinal products legislation

On 29 May 2012, an expert meeting took place on pharmacovigilance. The meeting was held under Chatham House rules and objective of this meeting was to gather experts’ inputs for the impact assessment and for the drafting of the legal proposal. Participants were invited based on their expertise and received a discussion paper on pharmacovigilance shortly before the meeting.

Ten experts participated in the meeting. The discussion mostly focused on the advantages and disadvantages of the current pharmacovigilance system and possible amendments: the scope of pharmacovigilance, the different categories of adverse reactions in pharmacovigilance, the type of reporting and means of providing information, signal detection, the organisation and implementation of inspections, the scope, development and maintenance of pharmacovigilance database(s) and access to them, the sharing of information between parties, the responsibilities and tasks of actors, regulatory tools for action, and transitional provisions.

The participants agreed to have a risk-based approach for pharmacovigilance in the future and to develop a veterinary pharmacovigilance better adapted to the characteristics of the veterinary sector. However, views differed as to how these principles should take shape in practice, in particular in relation to the tasks and responsibilities of the different actors. Another key question discussed was the level of events or accuracy that the new veterinary pharmacovigilance system has to detect.

The group agreed that environmental and residue violation events should be better covered by other systems, but no EU-wide alternatives appear to exist.

Both the duplication of tasks by actors in the system and the repetition of providing and collecting similar information repeatedly surfaced in the discussion. Also frequently mentioned were the differences in the way European pharmacovigilance requirements are implemented by Member States. In general the participants favoured a harmonised, proportionate pharmacovigilance system in the future. The development of an EU pharmacovigilance database was supported by the participants; it was pointed out that actors should be able to continue using their own databases for signal detection. Surveillance should be based in principle on the active substance, and the establishment of a masterfile should be made possible. There was no agreement on the access of actors to the new EU database and how the quality of the input should be ensured.

Clearly different views were expressed on several items in the discussion paper, for example the organisation and implementation of inspections and the need to report on events in third countries.