

9 August 2016 EMA/327935/2010-Rev.1 Veterinary Medicines Division

Principles for ensuring the confidentiality of data supplied to the European Surveillance of Veterinary Antimicrobial Agent Consumption (ESVAC) project

The European Commission has requested the European Medicines Agency (the 'Agency') to develop a harmonised approach for the collection, analysis and reporting of data on the sales and use in animals of veterinary antimicrobial agents in EU Member States. This will be achieved by the operation of the of the European Surveillance of Veterinary Antimicrobial Agent Consumption (ESVAC) activity during which the Agency will collate the data collected by participating EU Member States and supplied in response to specific calls for data.

The revision of the principles for ensuring the confidentiality of data takes into consideration the ESVAC Interactive Database which is available for public access.

The Agency, in accordance with the terms of reference of its task, will adopt practices and procedures to ensure that the following principles are applied:

- 1. Data published by the Agency, either on web pages or as part of scientific or other publications, will not contain, or in any other way disclose, any commercially confidential information on specific veterinary products.
- 2. Commercial confidentiality will be maintained by publishing only aggregated data, where aggregation is carried out a level sufficient to ensure that the sales of any one product cannot be identified.
- 3. Before publication of data by the Agency, including publication of data into the Interactive Database, members of the ESVAC activity ask to the Member States to confirm in writing that the material does not disclose commercially confidential information.
- 4. The Agency will not circulate any data provided to ESVAC from one Member State (or country) to another Member State (or country). Any requests for such information will be redirected to the Member State concerned.
- 5. In general, ESVAC data will be published after publication at Member State level where relevant, otherwise the Member States will be informed in advance.

The same principles will apply to data provided to ESVAC by other European countries that are not part of the European Union.

