INDIVIDUAL REGISTRATION OF VETERINARY DRUG AND PRODUCTS WITH DIFFERENT PACKAGING MATERIALS

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For purposes of clarification on the registration of Veterinary Drug and Products (VDAP) using different packaging materials, the following guidelines are hereby provided for the information and guidance of all concerned:

- Products using packaging of different materials should have separate registration.

- The packaging materials should give information on the construction of the container, with a list of the different components, the type of materials used in the different parts, and the nature of the polymers. If the official standards/pharmacopeia include requirements concerning the type of material used, it must be documented that these requirements will be complied with.

For plastics, the name of the material, name of the manufacturer, chemical structure, and physico-chemical properties shall be presented. For polymers intended for containers of liquid and semi-liquid drug preparation, appropriate detailed information must be provided. Complete composition, including possible polymerization residues, stabilizers, plasticizers, colouring agents etc., shall be stated. The maximum permitted content shall be indicated. A report on toxicity may be required. Technical properties of the material relevant to the proposed use shall be stated (sterilizability, permeability, transparency, resistance etc.)

Detailed information is required about the technical construction of non-standardized containers, eg. aerosol containers, spray packs, etc.)

- A new report of stability studies to justify claimed shelf-life must be provided for changes or additional packaging material employed.

Conceivable changes in the chemical, pharmaceutical or biological properties of the product during storage must be described. Changes in concentration of the preservative(s) antioxidant(s) and changes due to interaction with the container must also be considered.

Reports must specify the initial values, storage conditions, type of container and batch number. Based on this, the manufacturer shall propose a shelf life and if necessary any storage directions applicable.

For compliance.

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