DGV
Direcção Geral
de Veterinária

Direcção de Serviços de Medicamentos e Produtos de Uso Veterinário

Comments from the Veterinary Portuguese authorities - Direcção Geral de Veterinária

Public consultation paper 'Better regulation of Pharmaceuticals: Towards a simpler, clearer and more flexible framework on variations'.

1 - Scientific recommendation on "unforeseen" variations:

•In these cases where no classification exists, non-listed changes should be Type II and in case of disagreement, discussions on classification can also take place in CMD(v)

2 - List of Variations (guideline in annex)
•List of Variations – possibly to be in separate guidance rather than in Regulation itself– we support this proposal as it will allow and easier updating to reflect experience/scientific progress.

3 - "Do and Tell
Concept – what does it mean immediately?"

Annual report - We foresee the following risks.
- 1- non compliance with the guideline conditions- we will have to contact the MAH to submit the correct application?What can we legally do?
- In this case the burden will be bigger than what we have at this moment;
- 2 – applying a variation nationally not legal (for example a name that already exists or that cannot be for language reasons accepted;
- 3 – for NCA the workload of checking annually the conditions applied is bigger than checking one by one.

Nevertheless we could agree with this proposal if the annual report only refers to one MA and only for well identified and classified variations to be agreed upon in later discussions.

4 - Type IB by default

We do not agree with this proposal..
We still prefer to have Type II by default and to increase and better identify the Type IB variations, with possibility of a reduced timetable.

5 - Grouping of variations

We can accept but only the principle of the same MAH, same variation for different products.

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Concept – Legal problem – Either way(EMEA/CMDv) the scientific recommendation is not binding as the Regulation and Directive at this stage do not give legal competence neither to EMEA nor to Cmdv on this matter .The mandate would have to be changed.

Nevertheless we would prefer to have a temporary acting RMS with CMDv coordination.

- Downgrading-On what grounds? The NCA are the responsible ones so they have to be able to say no or to disagree to an EMEA opinion. What is the sense of submitting to the NCA a minor variation only because a non binding opinion has been issued by an entity which doesn't have a legal mandate to do so?