Ministero della Salute
Dipartimento della Sanità Pubblica Veterinaria,
della Sicurezza Alimentare e degli Organi Collegiali
per la Tutela della Salute
Direzione Genmerale della Sanità Animale
e dei Farmaci Veterinari

As a general comment I would like to underline that we agree to all options which would ensure a simplification of the existing mechanisms, but with absolutely no impact on public health. Nevertheless the fact that authorities from different Member States have different working potentials must be taken into account when considering measures which in principle are satisfactory but which would require a highly efficient level of organisation with enough resources at disposition. As an example, we believe that extremisation of the simplification process in the direction of do and tell would not ensure that all the variations will be evaluated by authorities, with consequent implementation of changes which authorities have not evaluated.

With reference to the specific consultation items, please find below our responses:

Consultation item 1
We totally agree that disharmonisation in the dossier content will inevitably bring problems in the handling of a worksharing. We are experiencing this problem at the moment with informal worksharing procedures where companies “insert” extra modifications than those contained in the standard package in order to take into consideration differencies present at national level. In these cases we have had to ask for extra information with additional complexity factors to be taken into account.

Consultation item 2
In principle option (a) would be preferable but option (b) is most probably the easiest way from the point of view of feasibility

Consultation item 3
We agree to the principle that the deadline for adoption of Commission decisions amending MA must be driven by public health considerations

Consultation item 4
In principle we would support any variation which could have an impact on the quality, safety and efficacy of the product to be adopted within shorter deadlines.
We agree with the principle that variations , independently of their nature (type IA, IB or type II) should be cathegorised in respect to their potential impact on public health, with timings adjusted accordingly.

Consultation item 5
As already said in the introduction of this message, although in principle the do and tell approach could be regarded as a simplification of procedures, existing differencies between MS should be taken into consideration, as well as the potential of authorities (in terms of resources) to cope with the short times given by the regulation. Therefore we would not be happy to see a much further relaxation of the existing requisites and the inclusion of further variations in the do and tell cathegory. Moreover we believe that the new legislation should take into account and describe the cases in which variations evaluated after their

implementation are found not compliant with the requirements/conditions of the regulation and the classification guideline. In these cases it must be pointed out clearly to the companies that enforcement actions can be taken by member states, with measures ranging up to suspension of the implementation of the variations and batch recall for batches produced according to the variation. It must also be considered that it is not easy to identify exactly which variations would fall into the cathegory of "changes having impact on public health"

Consultation item 6
We agree with the introduction of specific deadlines for changes to PIL significant from a public health standpoint. To our knowledge this issue is dealt very differently by different member states. We are of the opinion that a clear subdivision must be made of changes into different cathegories according to how critical they are from a public health point of view, and assigning to each cathegory a well defined timeline for implementation of the variation in PIL.

Consultation item 7
We are of the opinion that a mechanism should be put in place in order that in any case regulatory authorities should have the information related to VMP updated in every moment, so that it is exactly known which are the characteristics of the VMP present on the market. This can only be obtained by a prompt variation of the SPC, independently of the type of variation.

Consultation item 8
We agree to extend the time limit for the assessment of complex grouped variations.