Státní zdravotní ústav

Šrobárova 49/48
Praha 10
100 00

Minority opinion on the application for approval of the active substance of Mecetronium ethyl sulphate (MES) – PT 1

30 September 2022 – CZCA

The BPC agreed by a majority of votes on non-approval of MES. The chief reason for this conclusion was lack of data which prevented WGs to conclude on ED properties. The applicant proposed to use 2-gen study with ADBAC which is in the public domain (i.e. published in a scientific journal). ECHA expert on legal issues expressed a view that such study is, as a whole, protected by Copyright law (the Berne Convention). While we agree that copyright protects scientific works alongside literary and artistic works etc., we are not sure, without further analyses, if the study cited by the applicant constitutes a scientific work, as a whole or in part. In our opinion, a study performed according to well established principles usually reflected in relevant guidelines, cannot be protected by copyright as a whole. What can be protected is e.g. an original interpretation of the study results. Such interpretation may, in some cases, reflect the creative and original spirit, of its author. Even if this is the case, the outcome of the study is not protected by copyright. In our opinion, a two generation study cited by the applicant is likely to have been performed in accordance with the relevant guidelines, perhaps with some deviations. Therefore, without further analyses, we consider it unlikely that this study results are protected by copyright. In our opinion this merits further discussion at the EC level where the above issues should be addressed.

Apart from the copyright, the use of this study without a written permission of its owner could constitute an unfair business. This is why studies submitted in dossiers for the a.s. are protected for 10 years. As follows from the above, such studies can hardly be protected under the Copyright law. Therefore, the law maker provided for a 10-year protection to strike the balance between the rights of the data owner and the rights of the competitors to do business. In our opinion, the following questions should be discussed at the EC level: 1) Is the 10 year protection applicable for the published 2-geneneration reprotox. study? 2) if the 10 year protection is not applicable, does the use of the study, without LoA, for regulatory purposes constitute unfair business, where more conditions must be fulfilled in a cumulative manner? 3) If LoA is need at which stage it is necessary (i.e. is it enough for the applicant to have it just before they start making profit?)

In conclusion: Before the above issues are properly addressed we cannot agree with the non-approval of the substance as such non approval is not in line with a just and transparent process.