

Annex A - Discussion paper on novel formulations of supplement compounds designed to increase oral bioavailability

# Questions for the Committee

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161. Members are asked to please consider the following questions:

- i) What further and/or specific information would Members like to see regarding novel formulations of supplement compounds?
- ii) Would Members like to see a more detailed study (i.e., exposure assessment and risk characterisation) of one or more of the included cases? Which

pharmacokinetic parameters and calculations would be most useful?

iii) Would Members find further case studies/examples useful? If so, are there any specific formulations and/or supplement compounds of interest to the COT?

iv) Do Members believe purchasing a report reviewing the (projected) market trends for novel supplement formulations would aid in future evaluation of the risks associated with these formulations? If so, what kind of report do Members consider would be most useful? The reports identified in the current paper are each in the price range of £2,000 - £4,000. Beyond the reports indicated in this paper, are there any other data that would be deemed particularly valuable?

v) Regarding the toxicological evidence presented related specifically to novel formulations of supplements, what kinds of information would Members consider necessary for allowing meaningful evaluation of their safety?

vi) Do Members consider that, where they exist, current HBGVs are protective for supplements formulated in the novel ways discussed in this paper? If not, what information would the Committee like to see to derive HGBVs in the future?

vii) Would Members like to see more detailed information regarding conflicts of interest in the presented studies or a subset thereof?

viii) Do Members have any other comments and/or questions about the paper in general?

**Secretariat, April 2023**