Amsterdam, DD MM YYYY

Ref:

[Committee for Advanced Therapies]

[Committee for Medicinal Products for Human Use]

Consultation of GMO authorities under Article 6(3) of Regulation (EU) No 726/2004

As previously communicated by EMA, a marketing authorisation application for [name of product (INN)] has been received by the European Medicines Agency. The [Committee for Advanced Therapies] [Committee for Medicinal Products for Human Use] considers that the product contains or consists of genetically modified organisms (“GMOs”).

Please find attached a copy of the ERA Rapporteur assessment report together with Module 1.6.2.

Thank you for considering the ERA Rapporteur assessment report, in particular your comments are welcomed on the risk minimisation measures.

Deadline for the consultation: [add date]