Referral to the Coordination Group under Article 35 of Regulation (EU) No 528/2012

Executive summary

Type of referral: Referral to the Coordination Group of a disagreement on conclusions of the assessment report in accordance with Delegated Regulation (EU) No 492/2014 on the renewal of authorisations subject to mutual recognition in accordance with Regulation (EU) No 528/2012

Case type: Application of renewal of national authorisation (NA-RNL)

Reference Member State (rMS): Italy

Initiating concerned Member State (iCMS): Sweden

Other Concerned Member States (CMSs): Bulgaria, Germany, Romania, Belgium, France, Ireland.

Product type(s): 14

Active substance(s): Difenacoum

Brief summary of the point of disagreement:

Detailed results of storage stability tests are missing in the PAR.

Outcome of the discussion within the Coordination Group (CG):

The CG members agreed by consensus on 7 March 2018 by written procedure:

The results of storage stability tests will be included in the PAR. The active substance is proven to be stable up to 24 months.

The product meets the condition for granting an authorisation in Article 19(1)(d) of the BPR. This formal referral is therefore closed.