

Responsibility of submission of information in accordance with requirements of Article 89(3)

December 11th, 2019

BE-CA has been questioned on the responsibility of information submission for the list of existing and new products for NA-APP and UA-APP in order to prolong the existing authorizations according to article 89 (3) of the BPR.

During the CG-36, CG-37 and CG-38 meetings, MSs, COM and stakeholders discussed whose responsibility is to inform MSCAs of existing products on the market under art. 89(3) which is supported by an authorisation application if they wish to maintain the transitional products on the market.

The CG members agreed that the responsibility lies with the applicant who introduced the NA-APP or UA-APP dossier as registered in R4BP-3. It was also agreed that where several marketing companies are involved in an application and/or where one or more companies rely on another company or consultant to act as an applicant, it is the applicant's responsibility to collaborate and coordinate to ensure that all products are clearly identified in the application using the ECHA supporting document "List of existing_new products for NA_UA processes".