



Fees for Product Safety Update Reports Submission of Veterinary Medicinal Products Not Marketed

According to item a), 2nd paragraph of Decree-Law No. 148/2008 of July 29, is mandatory the 6-month product safety update report submission (PSUR) for Veterinary Medicinal Products from granting the authorization to the beginning of the marketing or until the expiration of two years after the start of marketing.

PSUR submission is subject to the same fee as other PSUR submitted for national veterinary medicines, varying with the type of procedure in accordance with section 10.1 of the Annex to Portaria No. 1444/2008 of 12 December. See item "Fees for Periodic Safety Update Reports of Veterinary Medicines Submission by National, Mutual Recognition and Decentralized Procedures".