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Forms and electronic submissions in Albania

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Abstract

Regulation no.73 of 3 February 2009 on the Registration of Medicinal Products in the Republic of Albania prepared pursuant the Law No.9323 of 25 November 2004 on Medicinal Products and Pharmaceutical Service amended is the document that regulates registration of medicinal products in Albania. A lot of changes need to be made in order to upgrade to the EU legislation that Albania aims to adapt.

Up to date there are no forms defined in legislation to be filled by pharmaceutical companies or their representatives for the application for new registration or renewal of the marketing authorization, even though almost all companies submit with needed documentation Application forms as well. In practice, there are no templates for these forms for submission by representatives of pharmaceutical companies. There is only one approved template for Variation applications which is filled by pharmaceutical companies or their representatives before submission. There are standard forms for new registration, renewal or variation application that are filled by registration specialists of the National Center for Drugs Control (NCDC) after the preliminary evaluation of the documentation.

With exception of the documentation that is foreseen in the Regulation no.73 of 3 February 2009 on the Registration of Medicinal Products in the Republic of Albania to be in original or notarized, all the documentation may be presented as hard copy or in electronic version (CD).

eCTD is not applicable in Albania. There are no defined rules and no foreseen date for implementation of eCTD.

Biography

Ledia Çikopana has completed her M.Pharm. at the age of 23 years from Tirana University, Faculty of Medicine, Department of Pharmacy and at the age 30 years the MBA from Tirana University, Faculty of Economics. She is the Regulatory associate and responsible person for Quality and Pharmacovigilance at the Representative office in Albania of Krka, a well known generic pharmaceutical company.