



NOTIFICATION

Addendum

The following communication, dated November 2016, is being circulated at the request of the delegation of the Brazil.

This addendum aims at informing that the Brazilian Health Regulatory Agency (ANVISA) issued the Resolution RDC Nº 120, 3 November 2016 (published in the National Gazette (DOU) in 4 November 2016), amending the Ordinance RDC 73 /2016, and approving the rules for drug labelling that have to be registered at ANVISA to be marketed in Brazil.

The Draft Resolution nº 46/2009, notified under the document G/TBT/N/BRA/327 - technical regulation that determines the rules for drug labelling that have to be registered at Anvisa for commercialization in Brazil - was published by Anvisa as Resolution RDC nº 71/2009, 22 December 2009.

On 16 June 2011, Anvisa published Resolution RDC nº 26/2011, which suspends the requirements for the adaptation period of drug labelling rules established by Resolution RDC Nº 71, 22 December 2009.

On April 8/2016 Anvisa published the Ordinance Resolution RDC Nº 73, 7 April 2016 in order to reword the Resolution RDC 71/2009 (art. 43), regarding the drugs labelling with post-registration changes.

Lastly, On November 4 2016, Anvisa published the Resolution RDC nº 120, 3 November 2016, which changes the Article 35 of the RDC 73/2016.

The full text is available only in Portuguese and can be downloaded at:

<http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=04/11/2016&jornal=1&pagina=53&totalArquivos=124>