

TITLE

CODEINE AND BREASTFEEDING, WHAT ARE THE LATEST DATA IN PHARMACOVIGILANCE AND EMA REGULATION

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Exclusive maternal breastfeeding has been recommended for the newborn and the infant by WHO since 2003 and its practice has been on the increase. We have evidence that breastfeeding benefits are all the more important as the infant was born before term. There seems to be a contradiction then between the possibility of breastfeeding and the fact of taking medication without causing serious adverse effects in the infant. Nearly all health care professionals agree to propose breastfeeding after a detailed analysis of the benefit/risk balance concerning the medication taken by the mother. But most prescribers have access only to the drug dictionary containing summaries on the product characteristics (SmPC) i.e. the legal marketing authorization data. On March 10 and 11, 2009 a founder seminar bringing together 40 professionals from France, Belgium and Canada took place at the "Institut de Puériculture" in Paris. Codeine, though a molecule authorized by the AAP (American Academy of Pediatrics), had caused the death of a breastfed newborn. This observation has been confirmed in the course of a pharmacovigilance research which underlines 35 cases of brain toxicity due to codeine via breastfeeding. In 2008 our team published a case of neonatal intoxication through propoxyphen. It is a priority to obtain a regulatory, coherent and gradual approach from the health authorities concerning drugs and breastfeeding. These data - above all safety data- will allow the prescriber to be confident enough while taking charge of a breastfeeding woman when he must prescribe a drug such as a common analgesic.