



26 April 2018  
EMA/219594/2018  
Press Office

## Start of community reviews

CHMP meeting of 23-26 April 2018

**Table 1. Start of arbitration procedure**

Name	INN	Type of procedure	Scope
Diclofenac Sodium Spray Gel 4 % w/w Cutaneous Spray, Solution	diclofenac sodium	Article 29(4) of Directive 2001/83/EC	A referral procedure was initiated for Diclofenac Sodium Spray Gel 4 % w/w Cutaneous Spray, Solution and associated names. The procedure was initiated because of disagreements regarding the benefit-risk ratio.
Paclitaxel Hetero	paclitaxel	Article 29(4) of Directive 2001/83/EC	A referral procedure was initiated for Paclitaxel Hetero and associated names. The procedure was initiated because of disagreements regarding the benefit-risk ratio.



**Table 3. Start of scientific review**

Name	INN	Type of procedure	Scope
Gentamicin containing medicinal products (solution for infusion/solution for injection)	gentamicin	Article 5(3) of Regulation (EC) No 726/2004	A procedure was initiated by EMA asking for a scientific opinion to the Committee whether a specification should be introduced regarding the histamine levels in gentamicin-containing medicinal products (solution for infusion/solution for injection).