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Press Office

## Start of community reviews

CHMP meeting of 21-24 October 2013

**Table 1. Start of benefit-risk review**

| Name  | INN   | Type of procedure                  | Scope  |
|---|---|------------------------------------|--|
| Caustinerf arsenical and Yranicid arsenical | ephedrine hydrochloride, lidocaine and arsenous anhydride | Article 31 of Directive 2001/83/EC | Article 31 triggered by the France for ephedrine hydrochloride, lidocaine and arsenous anhydride containing medicinal products for topical use, based on genotoxicity data and published literature. |



**Table 2. Start of arbitration procedure**

| Name                         | INN                                | Type of procedure                     | Scope  |
|------------------------------|------------------------------------|---------------------------------------|--|
| Nanotop and associated names | Human albumin, denatured (NanoHAS) | Article 29(4) of Directive 2001/83/EC | The Committee started a referral procedure for Nanotop and associated names. The procedure was initiated because of disagreements regarding the quality and efficacy of the product. |

**Table 3. Start of harmonisation procedure**

| Name                            | INN                    | Type of procedure                  | Scope   |
|---------------------------------|------------------------|------------------------------------|---|
| EMLA creme and associated names | lidocaine / prilocaine | Article 30 of Directive 2001/83/EC | The Committee started a harmonisation exercise for EMLA creme and associated names. The review was triggered by Germany, due to the need of harmonisation of the Summary of Product Characteristics across Member States. |