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Press Office

Start of community reviews

CHMP meeting of 18-21 February 2013

Table 1. Start of reviews for non-centrally authorised medicines

| Name | INN | Type of procedure | Scope |
|---|------------------|------------------------------------|--|
| Thiocolchicoside-containing medicinal products for systemic use | Thiocolchicoside | Article 31 of Directive 2001/83/EC | Procedure triggered by Italy requesting an opinion of the Committee on the potential clinical impact of genotoxicity preclinical findings with thiocolchicoside-containing medicinal products. |



Table 2. Start of arbitration procedure

| Name | INN | Type of procedure | Scope |
|---|-------------------------------|---------------------------------------|---|
| Methylphenidate Sandoz Methylphenidate Hexal | Methylphenidate hydrochloride | Article 29(4) of Directive 2001/83/EC | The Committee started a referral procedure for Methylphenidate Sandoz and Methylphenidate Hexal. The procedure was initiated because of disagreements regarding the demonstration of bioequivalence under fed conditions between the generic and the reference product. |
| Simvastatin Vale and associated names | Simvastatin | Article 29(4) of Directive 2001/83/EC | The Committee started a referral procedure for Simvastatin Vale. The procedure was initiated because of disagreements regarding the demonstration of bioequivalence between the generic and the reference product. |