Press release of the National Agency for Medicines and Medical Devices on recall from wholesale distributors of CILEST 0,250mg/0,035mg, tablets

Following information received via the Rapid Alert System from the Belgian drug competent authority as well as from the marketing Authorisation Holder (Johnson & Johnson d.o.o.), the National Agency for Medicines and Medical Devices has decided on recall from wholesale distributors of all CILEST 0,250mg/0,035mg, tablets batches manufactured as of January 2011.

The decision has been prompted by identification by the Belgian manufacturer of a quality defect in certain product batches (out-of-specification result under the "dissolution time" parameter) concerning one of the two active substances in the medicinal product composition. This quality defect may be conducive to diminished contraceptive effect. This is unlikely because the tablet is administered once a day only; in addition, the test performed by the company during 1 January 2009-31 December 2012 has shown a decrease in the number of reports submitted as regards lack of efficacy and emergence of pregnancies.

Given the possibility that the medicine may not be available for a certain time, the Agency hereby recommends users of Cilest tablets to seek alternative treatment from their physician.

This precautionary recall on wholesale distribution level of all CILEST 0,250mg/0,035mg, tablets batches manufactured as of January 2011 is underway in all countries where this medicinal product is distributed, other EU member States included.