Bundesamt für Sicherheit
im Gesundheitswesen

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PHV-issue: Misoprostol

Sehr geehrte Damen und Herren,

Nach der Fertigstellung der Misoprostol-PSUSAs (PSUSA/00010378/201705, PSUSA/00010354/201705) kam das CMDh zu dem Schluss, dass Ergebnisse aus den PSUR Assessments für alle Arzneimittel, die den Wirkstoff Misoprostol enthalten relevant sind. (Siehe auch CMDh Press release vom 22.-24. Jänner 2018: http://www.hma.eu/249.html)

Auszug aus dem Report from the CMDh meeting held on 22-24 January 2018

Misoprostol containing products (combination and mono substance products)

In the framework of the PSUSA for mifepristone / misoprostol, the PRAC considered that the risk of uterine ruptures would also be relevant to be included in the medicinal products containing misoprostol as single agent, as the indications, dosage and use are similar to the fixed dose combination products.

Likewise, in the framework of the PSUSA for misoprostol (gynaecological indication - termination of pregnancy), the PRAC considered that the risk of teratogenicity and the proposed variations would also be relevant to be included/revised in the fixed dose combinations of mifepristone/misoprostol as the indications, dosage and use are similar to the mono substance products.

Valid for all medicinal products containing misoprostol