Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

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PHV-issue: Anästhetika

Sehr geehrte Damen und Herren,

Das CMDh kam zu dem Schluss, dass in den Produktinformationen von Anästhetika folgende Informationen (siehe Anhang) sinngemäß enthalten sein müssen. (Siehe auch CMDh Press release held on 17-19 September 2018: http://www.hma.eu/249.html)

Auszug aus dem CMDh Press release (Report from the CMDh meeting held on 17-19 September 2018)

General anaesthetics and sedatives

Following a Drug Safety Communication by the FDA for a warning about repeatedly or prolonged use of general anaesthetics and sedative drugs in children younger than 3 years of age and in pregnant women during the third trimester and the risk of neurodevelopment disorders in children, the CMDh, following consultation of PRAC and SWP, agreed on the below wording to be implemented in the SmPC of concerned medicinal products, if a similar wording is not already included.

The concerned active substances are: desflurane, enflurane, etomidate, esketamine, halothane, isoflurane, ketamine, propofol, sevoflurane, thiopental, methohexital. All pharmaceutical forms are concerned.

For sedatives (midazolam and dexmedetomidine) no text is proposed as for these compounds no convincing data are available, and there are not sufficient grounds for extrapolating the class effect of anaesthetics to sedatives.

SmPC wording to be implemented:

Section 4.6

Studies in animals have shown reproductive toxicity (see section 5.3).

Section 5.3

Published studies in animals (including primates) at doses resulting in light to moderate anaesthesia demonstrate that the use of anaesthetic agents during the period of rapid brain growth or synaptogenesis results in cell loss in the developing brain that can be associated with prolonged cognitive deficiencies. The clinical significance of these nonclinical findings in not known.

Product information updates should be implemented for existing MAs within 3 months via a type IB variation, unless a similar wording is already included.