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Sicherheit im
Gesundheitswesen
BASG

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Unser Zeichen: PHV-100843634-A-220331
Ihr Zeichen:

PHV-issue: Lithium

Sehr geehrte Damen und Herren,

Nach der Fertigstellung des Empagliflozin-PSUSAs (C(2014)3539) kam das CMDh zu dem Schluss, dass Ergebnisse aus dem PSUR Assessment für alle Arzneimittel (außer Diagnostika), die Lithium enthalten relevant sind.

Bei der Umsetzung in die Produktinformation der betroffenen Arzneyspezialitäten beachten Sie auch den CMDh Press release (Meeting vom 14-16 December 2021): <http://www.hma.eu/249.html>



Auszug aus dem Report from the CMDh meeting held on 14-16 December 2021

Products containing lithium (excluding diagnostic medicinal products)

In the framework of the PSUSA on empagliflozin, the PRAC considered that the drug-drug interaction with lithium would also be relevant to be included in products containing lithium (excluding diagnostic medicinal products) in order to inform that co-administration of empagliflozin with lithium may lead to decreased lithium concentrations which may lead to a reduction in effectiveness of lithium.

The product information of products containing lithium should be amended as such:

SmPC section 4.5

Interactions which decrease serum lithium concentrations:

Co-administration of the following drugs with lithium may lead to decreased lithium concentrations and a risk of loss of efficacy:

- **empagliflozin**
- ...

Package Leaflet, section 2:

These medicines may decrease the amount of lithium in your body meaning it will not work as well:

- **empagliflozin (used to treat diabetes or heart failure)**
- ...

The same timelines as for the present PSUSA would apply in accordance with the guidance on implementing variations.