Bundesamt für Sicherheit
im Gesundheitswesen

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PHV-issue: ACE-Inhibitoren

Sehr geehrte Damen und Herren,

Nach der Fertigstellung mehrerer PSUSAs wurde das CMDh darauf aufmerksam gemacht, dass sicherheitsrelevante Informationen aus früheren Verfahren der Originatoren nicht in die Produktinformationen aller Arzneispezialitäten (Monoprodukte und Kombinationen) aufgenommen wurden.
Gemäß Artikel 23 der Richtlinie 2001/83 / EG werden die Inhaber der Genehmigung für das Inverkehrbringen an die Verpflichtung erinnert, die Produktinformationen entsprechend den derzeitigen wissenschaftlichen Erkenntnissen, einschließlich der Schlussfolgerungen der Bewertung und der Empfehlungen, die am Europäischen Arzneimittel-Webportal veröffentlicht wurden, aktuell zu halten.
Siehe auch: "Report from the meeting held on 12-14 December 2016"
(http://www.hma.eu/249.html)

Medicinal products containing ACE inhibitors

Following the finalisation of several PSUSAs, the CMDh was made aware that information from previously finalised procedure(s) by the originators is not reflected in the product information of all products (single active substance products and combinations).

For quinapril and quinapril / hydrochlorothiazide (HCT), this relates to the addition of warnings regarding increased risk of angioedema with ACE inhibitor use and concomitant mTOR inhibitor or concomitant DPP-IV inhibitor therapy, risk of severe hyperkalaemia with the coadministration of ACE inhibitors and trimethoprim-containing products as well as warnings regarding drug interactions such as concomitant use of ACE inhibitors and NSAIDs and an increased risk of reduced kidney function and concerning quinapril / HCT only concomitant use of thiazides with digoxin or gout medications.

For captopril / HCT, this relates to the outcome of the Renin-angiotensin-system (RAS)-acting agents Article 31 referral (EMEA/H/A-31/1370) and the outcome of previously finalised procedure(s) CMDh/PhVWP/031/2011 related to use in pregnancy and lactation and of the worksharing PSUR FR/H/PSUR/005/002 related to the adverse events glaucoma and myopia.

In addition, the PRAC considered that the risk of angioedema in case of concomitant use with mTOR inhibitors and the risk of hyperkalaemia in case of concomitant use with co-trimoxazole as recommended for the combination captopril / HCT would also be relevant to be included in the product information of the captopril single agent as well as in that of all other ACE inhibitors, as it is a class effect.

In accordance with Article 23 Directive 2001/83/EC the marketing authorisation holder(s) are reminded of the obligation to keep the product information to date with the current scientific knowledge, including the conclusions of the assessment and recommendations made public by means of the European medicines web-portal.
The CMDh requests concerned MAHs to harmonise the product information on these aspects using variation worksharing procedures, where possible.