



Datum: 23.04.2019
Kontakt: Ing. Veronika Heimlich, B.Sc.
T: +43 505 55-36247
E-Mail: pv-implementation@basg.gv.at
Unser Zeichen: PHV-11968266-A-190415
Ihr Zeichen:

PHV-issue: Imatinib

Sehr geehrte Damen und Herren,

Nach der Fertigstellung des Imatinib-PSUSAs (C(2019) 2603) kam das CMDh zu dem Schluss, dass die Produktinformation auf dem aktuellen Stand zu halten ist.
(Siehe auch CMDh Press release meeting held on 28-30 January 2019: <http://www.hma.eu/249.html>)

Auszug aus dem Report from the CMDh meeting held on 28-30 January 2019

Medicinal products containing imatinib

During the assessment of the PSUSA on imatinib, the PRAC noted that information related to some risks of Glivec as approved during recently finalised variations (II/100; II/102; II/104; II/106; II/108; II/109) are not reflected in the product information of all products. In accordance with Article 16 of Regulation 726/2004 and Article 23 Directive 2001/83/EC, the marketing authorisation holder(s) are reminded of the obligation to keep the product information up 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 established in accordance with Article 26, and/or the CMDh webpage.

Valid for all imatinib containing medicinal products