EPIRUBICIN

RECOMMENDED CHANGES TO THE PRODUCT INFORMATION

The following changes to the product information of medicinal products containing the active substance epirubicin are recommended:

Summary of product characteristics

Several sections of the SmPC (especially 4.2):

"Epirubicin" should be revised to "epirubicin hydrochloride" relevant places. In each sentence containing a direct dosage recommendation for epirubicin use, "epirubicin" should be replaced by "epirubicin hydrochloride".

Section 4.4 and section 4.5

A warning should be revised (new underlined) as follows:

Because the half-life of trastuzumab is approximately 28-38 days ~~4-5 weeks~~, trastuzumab may persist in the circulation for up to ~~20-25~~ 27 weeks after stopping trastuzumab treatment. Patients who receive anthracyclines such as epirubicin after stopping trastuzumab may possibly be at increased risk of cardiotoxicity. If possible, physicians should avoid anthracycline-based therapy for up to ~~25~~ 27 weeks after stopping trastuzumab. If anthracyclines such as epirubicin are used, the patient's cardiac function should be monitored carefully.

Section 4.8

Update of frequencies in 4.8 following Innovator routine review of safety database and clinical trial information.

The innovator anticipates completing this review by 3Q2015 and submitting variations thereafter. Other MAH's are recommended to update the SmPC and submit variations when the innovator SmPC update has been completed.