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The recommendations in this document were valid during the supply shortage of Caelyx which was resolved in April 2013. For the updated recommendations see here.

Recommendations on the use of Caelyx (doxorubicin hydrochloride)

The European Medicines Agency is aware of a shortage of the anticancer medicine Caelyx in several EU Member States linked to manufacturing problems at Ben Venue Laboratories, USA. The Agency's Committee for Medicinal Products for Use (CHMP) is recommending that patients already receiving treatment with Caelyx may continue their treatment but that no new patients should start treatment with this medicine.

What is Caelyx?

Caelyx is an anticancer medicine that contains the active substance doxorubicin hydrochloride. It is available as a concentrate to be made up into a solution for infusion (drip into a vein).

Caelyx is used in the treatment of the following cancers: metastatic breast cancer, advanced cancer of the ovary, Kaposi's sarcoma (a cancer of the blood vessels) in patients with acquired immune deficiency syndrome (AIDS), and multiple myeloma (a cancer of the cells in the bone marrow).

The active substance, doxorubicin hydrochloride, has been available since the 1960s. In Caelyx, it is contained within 'pegylated liposomes' (tiny fatty spheres that are coated with a chemical called polyethylene glycol). This reduces the rate at which it is broken down, allowing it to circulate in the blood for longer.

What is the cause of the supply problem and how long will it last?

On 7-11 November 2011, an inspection of Ben Venue Laboratories, where a number of sterile medicines including Caelyx are manufactured, highlighted several problems in quality assurance of the sterilisation process of these medicines. The November 2011 inspection was conducted as a follow-up to a previous inspection in March 2011, which had resulted in supply problems with Caelyx.

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During the November inspection, Ben Venue decided to cease all manufacture and distribution of medicines from its site. Ben Venue is the only manufacturing site for Caelyx. As a result, supply problems are expected to last for the foreseeable future.

What are the recommendations of the CHMP?

Having considered that Caelyx is an essential medicine for patients who have already started treatment with it and that Ben Venue is the only source of this medicine, the CHMP is recommending the following:

- No new patients should be started on Caelyx and existing Caelyx stocks should only be used to complete treatment that has been initiated.
- Healthcare professionals should monitor treated patients intensively and report immediately any relevant safety concerns (including sepsis or suspected sepsis) that could be evidence of a quality assurance problem with the sterilisation process.
- Non-anthracycline anticancer medicines may be considered as an alternative treatment for patients who haven't yet started treatment with Caelyx.
- Medicines containing non-liposomal and non-pegylated forms of doxorubicin are not bioequivalent to Caelyx (they do not produce the same levels of the active substance in the blood) and should only be used as an alternative after a consideration of their benefits and risks to the individual patient.

The Committee will continue to monitor the safety of Caelyx. The Committee has also agreed that the company should provide a letter to the healthcare professionals in the EU, explaining the supply situation in their countries together with the CHMP recommendations.

The current European public assessment report for Caelyx can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.