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Questions and answers

Questions and answers on the supply situation of Caelyx

The European Medicines Agency has updated its recommendations on the use of Caelyx that were issued in the last two years. These recommendations followed a shortage of the medicine due to shortcomings in quality assurance identified at the manufacturing site, Ben Venue Laboratories. The Agency's Committee for Medicinal Products for Human Use (CHMP) now considers that adequate supply levels have been restored in all EU Member States and that Caelyx can now be used again without restrictions as per its licensed indications. There is no longer a need to prioritise existing patients and new patients for whom no alternative treatment is available.

What is Caelyx?

Caelyx is an anticancer medicine that contains the active substance doxorubicin hydrochloride. It is authorised for 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).

What were the previous recommendations for Caelyx[1]?

On 22 November 2011, the CHMP issued recommendations that no new patients should be started on Caelyx. This followed an inspection of Ben Venue Laboratories, where a number of sterile medicines including Caelyx were manufactured, which highlighted several problems in quality assurance of the sterilisation process of these medicines. As Ben Venue was the only manufacturing site for Caelyx and all manufacture and distribution of medicines ceased after the inspection, a shortage of Caelyx followed. The CHMP considered that Caelyx was an essential medicine for patients who had already started treatment with it and recommended that existing Caelyx stocks should therefore be used to complete treatment that had begun.

A review[2] of Caelyx and other medicines manufactured at Ben Venue followed, which, in the case of Caelyx, led the CHMP on 15 March 2012 to recommend the transfer of the manufacturing operation to an alternative site. The alternative site was authorised as a manufacturer of Caelyx in October 2012.

[1] http://www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/2011/11/WC500117926.pdf
[2] http://www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/2012/03/WC500124203.pdf

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At that time the company introduced a web-based ordering and reservation system, 'Caelyx Managed Access', to help manage the allocation of the medicine in the EU while the company built up stock to restore normal supply levels. During this period, the CHMP recommended prioritising existing patients and new patients for whom no alternative treatment was available.[3] At its April 2013 meeting, the CHMP considered that the alternative manufacturing site has produced sufficient Caelyx to restore supply levels in all EU Member States. The CHMP therefore recommended that Caelyx be used again without restrictions as per its licensed indications.

What are the new recommendations for patients and healthcare professionals?

- New patients may now be started on Caelyx. There is no longer a need to prioritise existing patients and new patients for whom no alternative treatment is available.
- Healthcare professionals will no longer need to use Caelyx Managed Access to order Caelyx for their patients. The company will contact healthcare professionals in the EU with further details.

Further information on Caelyx can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.

[3] http://www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/2012/10/WC500134460.pdf