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No change to product information for breast cancer medicine Tyverb following re-assessment of data

The product information for Tyverb, a breast cancer medicine, will continue to state that no data are available on the effectiveness of Tyverb used together with an aromatase inhibitor compared with trastuzumab used with an aromatase inhibitor in patients previously treated with trastuzumab.

In July 2018, results of a study involving women with 'HR+/HER2+' breast cancer and whose disease had worsened despite previous treatment with trastuzumab were added to Tyverb's product information. The results had indicated a benefit of Tyverb over trastuzumab when each medicine was used with an aromatase inhibitor. However, in April 2019, errors were detected in the data and they were removed from the product information.

During a procedure to re-assess the data, the contract research organisation where the data were analysed was inspected. The inspection found deficiencies in the systems and procedures for managing data and concluded that data handling did not comply fully with good clinical practice (GCP). In addition, the re-analysed data do not allow a conclusion on whether Tyverb is more effective than trastuzumab when either is combined with an aromatase inhibitor.

As a result, the study results will not be re-introduced into the product information for Tyverb. There are no consequences for the current authorised uses of the medicine in the treatment of breast cancer.

More about the medicine

Tyverb is a cancer medicine used to treat patients with breast cancer expressing HER2. This means that the cancer produces a specific protein called HER2 (also known as ErbB2) on the surface of the cancer cells. Tyverb can be used in combination with capecitabine, trastuzumab or an aromatase inhibitor, depending on previous treatment and the stage of the disease.

More information about the medicine can be found on the EMA website: ema.europa.eu/medicines/human/EPAR/tyverb.

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More about the procedure

The re-analysis of data was carried out as a 'type II variation' (variation II/59). The incorrect information had previously been added to the prescribing information (in variation II/51) and subsequently removed (in variation IB/61).