Malta, 23 January 2009
Circular No. P02/2009

Re: The EMEA recommends new contraindications for Fareston (toremifene)

The European Medicines Agency (EMEA) has recommended that Fareston (toremifene), from Orion Pharma, should not be used in patients at risk of prolonged QT intervals or other heart problems.

The EMEA's Committee for Medicinal Products for Human Use (CHMP) reviewed Fareston, because of concerns that its use could lead to a prolongation of the QT interval in patients taking the medicine. The QT interval is a measure of the time between the start of the Q wave and the end of the T wave in the heart's electrical cycle. Patients with prolonged QT intervals are at risk of developing ventricular arrhythmias (dangerous irregular and fast heartbeats).

Fareston has been authorised in the European Union (EU) since 1996. It is authorised as hormone treatment for hormone-dependent metastatic breast cancer in postmenopausal women.

Completing the review of the available data during its 19-22 January 2009 meeting, the CHMP concluded that the benefits of Fareston are greater than its risks, but that its use should be restricted. The CHMP recommended that Fareston should no longer be used in patients with:

- prolonged QT intervals;
- electrolyte disturbances, particularly hypokalaemia (low blood potassium levels);
- clinically relevant bradycardia (abnormally slow heart rate);
- clinically relevant heart failure with reduced left-ventricular ejection fraction (inability of the heart to pump enough blood to the rest of the body);
- a history of symptomatic arrhythmias (abnormal heart rhythm).

In addition, the CHMP also recommended that Fareston should not be used together with other medicines that prolong the QT interval.

Doctors should prescribe Fareston according to the updated product information. Patients who are taking Fareston and have any questions or concerns should talk to their doctor or pharmacist.

The EMEA's recommendation has been sent to the European Commission for the adoption of a legally binding decision.

The Medicines Authority has participated in these discussions held at the EMEA and is in agreement with the full **press release** and **Q&A document** issued by the EMEA, attached here for your perusal.