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EMA concludes safety review of Uptravi

Medicine can continue to be used according to the prescribing information

The European Medicines Agency (EMA) has completed the review of Uptravi (selexipag) which was initiated following 5 patient deaths in France. EMA confirms that the medicine can continue to be used by both new and existing patients, according to the current prescribing information. No changes to the prescribing information are considered necessary following the review.

Uptravi is used to treat pulmonary arterial hypertension (PAH, a life-threatening condition involving abnormally high blood pressure in the arteries of the lungs). During the review of the medicine, EMA's Pharmacovigilance Risk Assessment Committee (PRAC) closely examined the 5 fatal cases. In addition, the PRAC studied relevant safety data that have been collected since the medicine started to be marketed, as well as data from clinical trials and comparisons with data from other PAH medicines.

The PRAC concluded that the data examined do not suggest any increase in mortality with Uptravi, and the death rate in patients taking Uptravi is in line with observations for other PAH medicines.

No specific regulatory action is considered necessary for Uptravi at this time. The safety of Uptravi will continue to be monitored, and emerging data from ongoing and planned studies will be carefully evaluated as they become available.

More about the medicine

Uptravi is a medicine called a prostacyclin receptor agonist used for the long-term treatment of pulmonary arterial hypertension. It is authorised for use in combination with other medicines called endothelin receptor antagonists (ERAs) and/or phosphodiesterase type 5 (PDE-5) inhibitors when these medicines do not work well enough, or on its own in patients who cannot take these other treatments. The medicine was authorised centrally in the EU in May 2016. For further information about Uptravi, see here.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

More about the procedure

The review of Uptravi has been carried out in the context of a safety signal. A safety signal is information on a new or incompletely documented adverse event that is potentially caused by a medicine and that warrants further investigation.

The review was carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which has now reached its conclusions.