EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Media and Public Relations

Press release

New long-lasting implant to treat opioid dependence

EMA's human medicines committee (CHMP) has recommended granting a marketing authorisation in the European Union (EU) for Sixmo (buprenorphine) as a substitution treatment for opioid dependence. Sixmo is an implant that releases low levels of buprenorphine into the patient's body for six months. It is indicated in clinically stable adult patients who require no more than 8 mg per day of sublingual (i.e. administered under the tongue) buprenorphine, within a framework of medical, social and psychological treatment.

Opioid use disorder (OUD) is an important public health problem. It is characterised by compulsive use of prescribed opioid medications or illicitly-obtained opioids, such as heroin. This may cause significant mental, physical and social distress, as well as transmission of infectious diseases, unintentional overdose, criminal activity and incarceration.

Standard treatment of OUD aims at reducing illicit opioid use, and usually involves long-term treatment with substitution opioid therapy, such as methadone or buprenorphine, as well as psychological and social counselling.

The active substance of Sixmo is buprenorphine. It consists of four small rods that are implanted in the patient's upper arm by a trained physician under local anaesthetic and continuously deliver buprenorphine for six months. This new method of administration could enhance adherence to the treatment and reduce the potential for misuse or accidental overdoses in the home, as well as the risk of accidental ingestion of buprenorphine by others, especially children.

The safety and efficacy of Sixmo were studied in three pivotal trials, in a total of 626 adult patients. One of the trials enrolled OUD adults who were considered clinically stable by their treating physician. The results demonstrated that 96.4% of patients in the Sixmo group responded to treatment, compared to 87.6% of patients treated with sublingual buprenorphine.

The most common adverse events associated with this medicine were headache, constipation and insomnia. These are normally associated with the active substance buprenorphine. The most common adverse reactions due to the insertion and removal techniques were pain, severe itching and haematoma at the implant site. In some patients implant breakages occurred.

Physicians must be competent in minor surgery and have received focused training on the insertion and removal of Sixmo prior to its use.

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The applicant is required to perform an additional study in patients in Europe to further evaluate the risks associated with the insertion and removal of the implants.

The opinion adopted by the CHMP is an intermediary step on Sixmo's path to patient access. The opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once the marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role/use of this medicine in the context of the national health system of that country.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Sixmo is L. Molteni & C. dei Fratelli Alitti Società di Esercizio S.p.A.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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