EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

EMA recommends approval of treatment for attention deficit hyperactivity disorder

Intuniv to be used in combination with comprehensive behavioural treatment in children and adolescents

The European Medicines Agency (EMA) has recommended granting a marketing authorisation for Intuniv (guanfacine) to treat attention deficit hyperactivity disorder (ADHD) in children and adolescents aged 6 to 17 years old for whom stimulants, another type of ADHD medicines, are not suitable or tolerated or have shown to be ineffective.

In its scientific opinion, EMA's Committee for Medicinal Products for Human Use (CHMP) stressed that Intuniv, like other medicines authorised for the treatment of ADHD, must only be used as part of a comprehensive treatment programme typically incorporating psychological, educational and social measures. The CHMP also recommended that treatment with Intuniv must be initiated under the supervision of an appropriate specialist in childhood and/or adolescent behavioural disorders.

Intuniv is the first treatment for ADHD in the European Union (EU) to be recommended through the centralised authorisation procedure.

ADHD is a chronic neurobehavioral disorder characterised by symptoms that include inattentiveness (a short attention span or being easily distracted), impulsivity, and hyperactivity (restlessness, constant fidgeting or over-activity). Most cases are diagnosed in children between the ages of 6 and 12 years.

ADHD affects a person's social interactions, psychological and behavioural development and learning activities. There is no cure for the condition, but treatment, consisting of medication and therapy, can help relieve the symptoms and make the condition much less of a problem in day-to-day life.

Since the 1950s, a class of medicines called stimulants has been the standard medication therapy for ADHD. These medicines work by increasing activity in the brain, particularly in areas that play a part in controlling attention and behaviour.

Intuniv belongs to a class of medicines with a different mechanism of action for patients who cannot take stimulants. Its active substance, guanfacine, is a selective alpha$_2$–adrenergic agonist, an agent that initiates a response from the alpha adrenergic receptors. It is expected to improve the symptoms

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of ADHD by initiating a response from neurons in regions of the brain associated with attention, organisation, planning and impulse control.

During the evaluation of Intuniv, the CHMP sought input from external experts, both clinicians and patient's representatives, and convened a meeting of its Scientific Advisory Group (SAG) on psychiatry.

The CHMP also invited the mother of an ADHD patient and a young adult affected by ADHD to share their experience during the Committee meeting. This is part of a pilot project started in September 2014 to bring patients' and carers' views and values to the assessment of medicines throughout their lifecycle.

The CHMP based its recommendation on 13 studies, including 5 pivotal studies, which provided evidence on the safety and efficacy in children and adolescents showing improvements for a number of disease parameters associated with symptom reduction. The most serious side effects were the risk of bradycardia, hypotension, syncope, somnolence and sedation and the associated risk of falls and accidents. Treatment with Intuniv was also associated with weight gain. Measures have been put in place to minimise those risks at the beginning and during treatment with Intuniv. In addition, the company will perform a post-authorisation safety study to further confirm the long term safety profile of the medicine.

The opinion adopted by the CHMP at its July 2015 meeting is an intermediary step on Intuniv's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a 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 Intuniv is Shire Pharmaceuticals Ireland Ltd.
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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