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Questions and answers

Positive opinion on the marketing authorisation for Sialanar (glycopyrronium bromide)

Outcome of re-examination

On 21 July 2016, the Committee for Medicinal Products for Human Use (CHMP) recommended the granting of the marketing authorisation for Sialanar for treating severe drooling in children and adolescents with neurological conditions. The company that applied for authorisation is Proveca Limited.

On 28 April 2016, the CHMP had originally adopted a negative opinion on Sialanar in a wider patient group, which included patients with mild or moderate drooling. At the request of the applicant, the CHMP started a re-examination of its opinion. Following the re-examination, the CHMP adopted a final positive opinion on 21 July 2016 recommending the granting of a marketing authorisation in the restricted group of patients with severe drooling.

What is Sialanar?

Sialanar is a medicine that contains the active substance glycopyrronium bromide. It is to be available as a solution to be taken by mouth.

What is Sialanar to be used for?

Sialanar is for treating severe drooling caused by the inability to control saliva spillage and excessive salivation in children and adolescents (aged 3 years and above) with neurological conditions, such as cerebral palsy, epilepsy and neurodegenerative diseases.

How does Sialanar work?

The active substance in Sialanar, glycopyrronium bromide, works by blocking receptors in the salivary glands known as muscarinic receptors. These receptors trigger the production of saliva when activated by the nerves from the brain. By blocking the receptors, the medicine is expected to help reduce the amount of saliva produced by the glands and so reduce the risk of drooling.

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What did the company present to support its application?

The main data supporting the application came from two published studies, which compared glycopyrronium bromide with placebo (a dummy treatment) in 77 children with neurological conditions and severe drooling. These studies measured improvements in patients' drooling symptoms using a standard rating scale known as mTDS (modified teachers drooling scale).

What were the CHMP's main concerns that led to the initial negative opinion?

In its initial recommendation to refuse authorisation, the CHMP noted that there was a lack of adequate data on the medicine's risks as well as insufficient toxicology data from non-human studies. As a consequence, the data provided were insufficient to show that glycopyrronium bromide is acceptably safe for treating drooling in patients with neurological conditions. Finally, the CHMP noted that Sialanar was not shown to improve quality of life.

What happened during the re-examination?

During the re-examination, the CHMP consulted a group of experts in the field and considered, among other things, the possible effects of Sialanar in different patient groups, particularly those with severe drooling.

What were the conclusions of the CHMP following the re-examination?

The CHMP agreed with the expert group's conclusion that available data justify using Sialanar for short-term treatment in children and adolescents with severe drooling. To help prescribers and carers use the medicine as safely as possible in these patients, the Committee also recommended educational material for them with information about the medicine and its risks.

The Committee was satisfied that the benefits of Sialanar outweigh its risks in the restricted group of patients and recommended that it be granted marketing authorisation.