20 November 2015
EMA/765377/2015
EMEA/H/C/003858

Questions and answers

Refusal of the marketing authorisation for Solumarv (insulin human)

On 19 November 2015, the Committee for Medicinal Products for Human Use (CHMP) recommended the refusal of the marketing authorisation for the medicinal product Solumarv, intended for the treatment of diabetes.

The company that applied for authorisation is Marvel Lifesciences Ltd. It can request a re-examination of the opinion within 15 days of receipt of notification of this negative opinion.

What is Solumarv?

Solumarv is a medicine that contains the active substance human insulin. It was to be available as a solution for injection.

Solumarv was developed as a biosimilar medicine. This means that it was intended to be similar to a biological medicine (the 'reference medicine') already authorised in the European Union (EU). The reference medicine for Solumarv in this application was Humulin S.

For more information on biosimilar medicines, see the question-and-answer document here.

What was Solumarv expected to be used for?

Solumarv was expected to be used to treat patients with diabetes who require insulin to control their blood sugar levels.

How is Solumarv expected to work?

Diabetes is a condition in which the body does not produce enough insulin to control the level of blood sugar or in which the body is unable to use insulin effectively. Solumarv was intended as a replacement for the insulin made by the body.

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

What did the company present to support its application?

The company presented results of studies in healthy people designed to show that Solumarv is similar to its reference medicine Humulin S in terms of biological activity and how the body handles the medicine. Two additional studies in patients with type 1 and type 2 diabetes compared the safety and effectiveness of Solumarv and Humulin S.

What were the CHMP's main concerns that led to the refusal?

The CHMP's main concern was that the company did not define the manufacturing process for Solumarv in sufficient detail. As such, it was not possible to show that Solumarv used in clinical studies was representative of batches intended for the market and that its quality was comparable to Humulin S's.

The CHMP concluded that Solumarv could not be approved as a biosimilar of Humulin S and recommended that it be refused marketing authorisation.

What consequences does this refusal have for patients in clinical trials or compassionate use programmes?

The company informed the CHMP that there are no clinical trials or compassionate use programmes affected by the Committee's opinion.