European Medicines Agency

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Questions and answers on the withdrawal of the marketing authorisation application for Biferonex

interferon beta-1a

On 28 May 2009, BioPartners GmbH officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Biferonex, for the treatment of relapsing-remitting multiple sclerosis.

What is Biferonex?
Biferonex is a solution for injection that contains the active substance interferon beta-1a. It was to be available in prefilled syringes.

What was Biferonex expected to be used for?
Biferonex was expected to be used to treat adults with relapsing-remitting multiple sclerosis. Multiple sclerosis is a disease of the nerves, in which inflammation destroys the protective sheath around the nerves. Relapsing-remitting means that the patient has attacks (relapses) followed by periods with milder symptoms (remission). Biferonex was intended for patients who had experienced two or more attacks in the previous two years.

How is Biferonex expected to work?
The active substance in Biferonex, interferon beta-1a, belongs to the group 'interferons'. Interferons are natural substances produced by the body to help it fight against attacks such as infections caused by viruses. Biferonex is expected to work by modulating the activity of the immune system (the body's natural defences) and preventing relapses of multiple sclerosis.
Interferon beta-1a is produced by a method known as 'recombinant DNA technology': it is made by a cell that has received a gene (DNA), which makes it able to produce interferon beta-1a. The interferon beta-1a in Biferonex acts in the same way as naturally produced interferon beta.
Biferonex contains the same active substance as other medicines called Avonex and Rebif, which have been authorised in the European Union since 1997 and 1998, respectively. In contrast to these medicines, Biferonex is made in such a way that it does not contain the human blood protein, albumin.

What documentation did the company present to support its application to the CHMP?
The effects of Biferonex were first tested in experimental models before being studied in humans.
The company presented the results of one main study, in which Biferonex was compared with placebo (a dummy treatment) in 339 adults with relapsing-remitting multiple sclerosis. Each patient received either Biferonex or placebo for two years. The main measure of effectiveness was the reduction in the number of attacks.
The company also used information relating to Avonex, and information from the published literature on other medicines containing interferon beta.

How far into the evaluation was the application when it was withdrawn?
The evaluation had finished and the CHMP had given a negative opinion. The company had requested a re-examination of the negative opinion, but this re-examination had not yet finished when the company withdrew.

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What was the recommendation of the CHMP at that time?
At the time of the withdrawal, the CHMP had given a negative opinion, recommending that the marketing authorisation be refused for Biferonex for the treatment of relapsing-remitting multiple sclerosis.

What were the main concerns of the CHMP?
The Committee noted that there were differences between the active substance in Biferonex and other interferon beta-containing medicines available on the market. It therefore concluded that using the published studies on these interferon beta-containing medicines to support the use of Biferonex was not justified, and that studies on Biferonex itself were required.
The CHMP was also of the opinion that the results of the single pivotal study of Biferonex did not show enough evidence that the medicine was effective. Based on the information presented to the Committee, it was not clear whether this was due to the way the study was designed, the way the results were analysed, or to the medicine itself.
Therefore, at the time of the withdrawal, the CHMP was of the opinion that the benefits of Biferonex in the treatment of patients with relapsing-remitting multiple sclerosis did not outweigh its risks.

What were the reasons given by the company for withdrawing the application?
The letter from the company notifying the European Medicines Agency of the withdrawal of the application is available here.

What are the consequences of the withdrawal for patients in clinical trials or compassionate use programmes using Biferonex?
The company informed the CHMP that there are no clinical trials or compassionate use programmes ongoing with Biferonex.