

German suspension of 'Rumalon' to be decided soon

A decision on Robapharm's appeal of the German Health Office's (BGA) suspension of its animal-derived antiarthritic product, 'Rumalon', is expected shortly.

The BGA provisionally suspended the product until the end of the year, on the basis of adverse effects reported from Hungary, and extended the suspension on the basis of a document it had produced itself.

The adverse reports entail pain at injection site, elevated body temperature and leg pain, which Robapharm believes to be related to 2 batches contaminated with pyrogens. However, the BGA believes that the product has an immunotoxicity problem.

Robapharm has submitted data in defence of the product to a German court, and a decision is expected shortly. 'Rumalon' has also been suspended in France and Portugal.

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