



European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

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COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS

PUBLIC SUMMARY OF NEGATIVE OPINION FOR ORPHAN DESIGNATION OF chelidonii radix special liquid extract for the treatment of pancreatic cancer

On 10 October 2007, the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on orphan designation of chelidonii radix special liquid extract for the treatment of pancreatic cancer. A negative decision was issued by the European Commission on 4 December 2007.

The sponsor applied for orphan designation on the basis of the life-threatening nature and the rarity of the condition, as well as an assumption of potential significant benefit over currently available methods of treatment.

The negative opinion is based on the following element:

- Satisfactory methods of treatment of the condition have been authorised in the Community and the sponsor has not provided sufficient justifications that chelidonii radix special liquid extract may be of significant benefit to those affected by the condition, over currently authorised treatments for pancreatic cancer, neither through a clinically relevant advantage in terms of efficacy or safety nor through a significant contribution to patient care.

Requests for designation as orphan medicinal products are made for investigational products. Absence of orphan designation does not preclude the development of this product, in particular through clinical trials, and subsequently the possibility of obtaining a marketing authorisation if quality, safety and efficacy are demonstrated.

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