European Medicines Agency
Press office

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PRESS RELEASE
EPAR summaries for the public: A further step for the provision of better information about medicines

As part of its commitment to providing useful and understandable information about medicinal products, the European Medicines Agency (EMEA) has begun publishing summaries of European public assessment reports (EPARs) that are specially written to be understandable by patients and members of the general public.

These 'EPAR summaries for the public' are shorter, non-technical versions of the full EPARs the Agency currently publishes for centrally authorised medicinal products. Each EPAR summary provides information about how the medicine works, its indications, how it was studied, its benefits and risks, and the reasons why it received a positive recommendation for authorisation from the EMEA. The summaries are written in a question-and-answer format, and are intended to give the general public adequate information to understand the basis for the granting of the marketing authorisation.

The publication of EPAR summaries is one of the new provisions introduced in the revised EU pharmaceutical legislation concerning the availability of better information about medicines. Implementation of this new initiative has already begun, with the publication today of EPAR summaries for the newly authorised products Ionsys and Yttriga.

Initially, EPAR summaries for the public will only be published for newly authorised medicines, but, over time, will be published retroactively for all centrally authorised products on the market. They will be prepared for both human and veterinary medicines, and will be made available in all official EU languages.

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NOTES

1. European public assessment reports reflect the scientific conclusions reached at the end of the centralised evaluation process. They are made available to the public by the EMEA after deletion of commercially confidential information.
2. A reflection paper on EPAR summaries for the public is available here.
3. EPARs and EPAR summaries will be updated throughout the authorisation period as changes to the original terms and conditions of the authorisation are made.
4. The EMEA has started a project to replace existing EPAR abstracts (module 1) with EPAR summaries for all human medicinal products that are already authorised; the project is expected to be finalised by the end of 2006. As each summary is prepared, the marketing-authorisation holder will be informed and will have the opportunity to see it before publication. Summaries are initially being prepared for products used for conditions affecting the 'alimentary tract and metabolism' (ATC group A).
5. The EPAR summary for Ionsys is available here; that for Yttriga is available here.
6. EPARs can be found at http://www.emea.eu.int/htms/human/epar/a-zepar.htm (human medicines) and http://www.emea.eu.int/htms/vet/epar/epar.htm (veterinary medicines).
7. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: http://www.emea.eu.int

Media enquiries only to:
Martin Harvey Allchurch
Tel.: (44-20) 74 18 84 27, E-mail: press@emea.eu.int