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

London, 19 March 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
QUTENZA

International Nonproprietary Name (INN): ***capsaicin***

On 19 March 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Qutenza 179 mg cutaneous patch intended for the treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain. The applicant for this medicinal product is NeurogesX, Inc .

The active substance of Qutenza is capsaicin, a medicinal product belonging to other local anaesthetics (ATC code: N01BX04). Capsaicin is a selective agonist of the transient receptor potential vanilloid 1 receptors (TRPV1). Persistent stimulation of the TRPV1 receptors leads to the desensitisation of sensory neurons responsible for pain transmission (nociceptors) resulting in pain relief.

The benefits with Qutenza are its ability to reduce pain related to dysfunction or damage of neurons (neuropathic pain) after single 30-minute application to the feet in HIV-associated neuropathy (HIV-AN) and single 60-minute application to locations other than feet in post-herpetic neuralgia (PHN). The most common side effects are transient capsaicin-related application site reactions including burning, pain, erythema, pruritus.

A pharmacovigilance plan for Qutenza, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: “the treatment of peripheral neuropathic pain in non-diabetic adults either alone or in combination with other medicinal products for pain”. It is proposed that Qutenza is administered by a physician or by a health care professional under the supervision of a physician.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Qutenza and therefore recommends the granting of the marketing authorisation.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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