EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 October 2016
EMA/706959/2016
Inspections Human Medicines Pharmacovigilance Division
Committees and Inspections Department

Scientific recommendation on classification of advanced therapy medicinal products

Article 17 – Regulation (EC) No 1394/2007

Disclaimer: This document is a summary for public release of a scientific recommendation on classification of advanced therapy medicinal products. The original text adopted by the Committee for Advanced Therapies (CAT) has been redacted to delete commercially confidential information.

The present scientific recommendation refers exclusively to the case as presented to the European Medicines Agency (EMA) without prejudice to future evaluations by the Agency.

It is stressed that the scientific recommendation on advanced therapy classification does not amount to any endorsement of the plausibility of the product, including the mode of action or therapeutic indication(s) claimed by the applicant.

Brief description (or name when available) of the active substance(s)

The product includes two active substances i.e. two plasmids encoding for synthetic, non-functional consensus E6 and E7 antigens of human papilloma virus types 16 and 18.

Brief description of the finished product

Solution for injection.

The product is to be administered by intramuscular injection followed by electroporation using a separate stand-alone device.

Proposed indication

Treatment of HPV-16 and -18 related high-grade squamous intraepithelial lesions (HSIL) of the cervix and vulva.

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EMA/CAT conclusion

The committee adopted on 7 October 2016 the following scientific recommendation.

On the basis that the product:

- contains an active substance which consists of a recombinant nucleic acid administered to human beings with a view to adding a genetic sequence,
- its therapeutic effect relates directly to the product of genetic expression of this sequence,
- the product is used to induce an immune response that results in elimination of the neoplastic cells which constitute HPV-16 and -18 related high-grade squamous intraepithelial lesions (HSIL) of the cervix and vulva,

the EMA/CAT considers that the Product falls within the definition of a gene therapy product.