European Medicines Agency

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Questions and answers on the referral for Gluscan 500 solution for injection containing fludeoxyglucose (^{18}F) 500MBq per ml

The European Medicines Agency (EMEA) has completed an arbitration procedure following a disagreement among Member States of the European Union regarding the authorisation of the medicine Gluscan 500. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Gluscan 500 outweigh its risks, and the marketing authorisation can be granted in France and in the following Member States of the European Union Germany, Poland, Portugal and Spain.
The review was carried out under an 'Article 29' referral[1].

What is Gluscan 500?

The active substance in Gluscan 500, fluodeoxyglucose (^{18}F), is a diagnostic radiopharmaceutical. It contains a substance, fluodeoxyglucose, that has been labelled with ^{18}F (fluoride-18), a radioactive form of the chemical element fluorine. When Gluscan 500 is injected in the body, the radiolabelled fluodeoxyglucose is absorbed in the same way as glucose, the main source of energy for the cells. This means that it will be absorbed differently by cells depending on their state.
Once in the cell, the radioactivity remains trapped, and can be seen on scans such as those obtained using a 'PET' (positron emission tomography) scanner.
Gluscan 500 can be used:

- in cancer medicine to help detect the location of tumours, as cancer cells use a lot of energy and will absorb more fluodeoxyglucose than non-cancerous cells;
- in cardiac medicine to help locate areas of the heart that are not taking up as much glucose as expected because of ischaemia (reduced blood supply);
- in neurology to detect specific areas within the brain of epileptic patients before surgery;
- and to locate areas of the body where there are abnormally high numbers of white blood cells (such as the sites of deep-seated infections or inflammation).

Why was Gluscan 500 reviewed?

Advanced Accelerator Applications submitted Gluscan 500 to the French medicines regulatory agency for a decentralised procedure. This is a procedure when one Member State (the 'reference Member State', in this instance France) assesses a medicine with a view of granting a marketing authorisation that will be valid in this country as well as in other Member States (the 'concerned Member States', in this instance are Germany, Poland, Portugal and Spain)[2].

However, the Member States were not able to reach an agreement and the French medicines regulatory agency referred the matter to the CHMP for arbitration on 30 January 2009.

[1] Article 29 of Directive 2001/83/EC as amended, referral on the grounds of potential serious risk to public health

[2] Fluodeoxyglucose (^{18}F) is already authorised via national procedures in the Czech Republic, Ireland and the United Kingdom.

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The grounds for the referral were concerns from the Spanish medicines regulatory agency that, while the use of fluodeoxyglucose (^{18}F) with PET in the areas of cancer, cardiac and neurology medicine were well established, its use in the diagnosis of infectious and inflammatory conditions had not been shown to be sufficiently established in the European Union, and therefore the use of Gluscan 500 as a diagnostic radiopharmaceutical in the diagnosis of these conditions should not be authorised.

What are the conclusions of the CHMP?
Based on evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that the benefits of Gluscan 500 outweigh its risks, and therefore the marketing authorisation for Gluscan 500 should be granted in all concerned Member States.

The European Commission issued a decision on 29 May 2009.

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