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QUESTIONS AND ANSWERS ON THE EMEA'S ACTION REGARDING THE SAFETY OF CHAMPIX

What is Champix?

Champix contains the active substance varenicline. It is available as tablets, which are used in adults to help them stop smoking.

Champix has been authorised by the European Commission in September 2006 and is marketed within the European Union in Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Luxembourg, the Netherlands, Portugal, Slovenia, Slovakia, Spain, Sweden and the United Kingdom. It is also authorised and marketed in Iceland and Norway.

What is the issue with Champix safety?

There have been reports of 'suicidal ideation' (thinking about committing suicide) and suicide attempts in people taking Champix. It is very difficult to know if this is due to Champix, as the act of stopping smoking itself can make people depressed, especially if they already have a mental health problem. Depression is often associated with suicidal thoughts.

What action is the EMEA taking?

The European Medicines Agency (EMA) is reviewing the reports it has received on patients who have developed suicidal ideation or attempted suicide while taking Champix. The Committee for Medicinal Products for Human Use (CHMP) and its Pharmacovigilance Working Party discussed the available information and its impact on the use of Champix during their December 2007 meetings. They noted that the product information for Champix currently does not contain any warning about suicidal thoughts.

What are the consequences of the EMEA's action for patients and doctors?

- Doctors are already aware of the risk of using Champix in patients who have an underlying mental illness. They also need to be aware of the possibility that patients who are trying to stop smoking can develop symptoms of depression, and they should advise their patients accordingly.
- Patients who are taking Champix and develop suicidal thoughts should stop their treatment and contact their doctor immediately.

Are there any further steps?

The CHMP has agreed on the changes to the product information¹, and they have asked the company to implement them via a change (variation) to the marketing authorisation. This will start next week. Further advice will be given to healthcare professionals and patients as appropriate.

¹ The CHMP has recommended that the following wording be inserted in the warning section of the SPC:

'Depressed mood may be a symptom of nicotine withdrawal. Depression, including suicidal ideation and suicide attempt, has been reported in patients undergoing a smoking cessation attempt. These symptoms have also been reported while attempting to quit smoking with Champix. Clinicians should be aware of the possible emergence of significant depressive symptomatology in patients undergoing a smoking cessation attempt, and should advise patients accordingly.'