

## Direct Healthcare Professional Communication

14<sup>th</sup> October 2021

### **CHAMPIX (varenicline) - lots to be recalled due to presence of impurity N-nitroso-varenicline above the acceptable intake limit**

Dear Healthcare Professional,

Pfizer, in agreement with the European Medicines Agency (EMA) and Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

#### **Summary**

- **All CHAMPIX (varenicline) batches that were found to contain levels of N-nitroso-varenicline above the acceptable level of intake set at both EMA and MHRA level are being recalled at pharmacy and wholesale level.**
- **Based on the available data, there is no immediate risk to patients currently taking this medication.**
- **The recall will result in further shortages of CHAMPIX (earlier recall of several batches took place across Europe in July 2021).**
- **For patients who are already on CHAMPIX, it may not be possible to complete treatment and prescribing healthcare professionals may consider switching treatment to an alternative.**
- **Alternatives may include nicotine replacement therapy (NRT) and bupropion.**
- **Healthcare professionals should also take into account the need to consider dose tapering, as the summary of product characteristics (SmPC) states that "At the end of treatment, discontinuation of CHAMPIX was associated with an increase in irritability, urge to smoke, depression and/or insomnia in up to 3% of patients."**
- **Healthcare professionals should advise patients undergoing treatment not to discontinue CHAMPIX without consulting them, and to discuss any questions or concerns with their prescribing healthcare professional.**

## ***Background on the safety concern***

CHAMPIX (varenicline) is indicated for smoking cessation in adults.

Test results have identified the levels of N-nitroso-varenicline in Champix to exceed the acceptable intake (AI) level.

N-nitroso-varenicline is a nitrosamine. Nitrosamines are classified as probable human carcinogens (substances that could cause cancer). Nitrosamines can be found at very low levels in water and foods, including cured and grilled meats, dairy products and vegetables. Nitrosamine impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time.

Upon request from MHRA, Pfizer Ltd are recalling as a precautionary measure all Champix (varenicline) batches that were found to contain levels of N-nitroso-varenicline above the acceptable level of intake set by both EMA and MHRA. The recall is at pharmacy and wholesale level.

## ***Call for reporting***

Please report suspected adverse drug reactions (ADRs) or suspected defective medicines to the MHRA through the Yellow Card scheme.

You can report via:

- the Yellow Card website: <https://yellowcard.mhra.gov.uk/>
- the free Yellow Card app available from the Apple App Store or Google Play Store.
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals.

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

Suspected adverse drug reactions may also be reported to Pfizer Medical Information on 01304 616161.

## ***Company contact point***

If you have any questions about this letter or for more information about CHAMPIX (varenicline) please contact Pfizer Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS or Telephone: 01304 616161

Yours sincerely,

**Dr Berkeley Phillips**

**UK Medical Director**