



**Media Statement**

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**Pfizer Statement Regarding Positive European Commission Decision for Champix® (varenicline) Marketing Authorisation Renewal<sup>1</sup>**

Pfizer Inc. (NYSE: PFE) has received the European Commission Decision to renew the marketing authorization (MA) for Champix® (varenicline tartrate) for a further five year period for the treatment of smoking cessation in adults.<sup>1</sup> In the U.S., varenicline is known as Chantix®, and is indicated as an aid to smoking cessation treatment in patients aged 18 and older.

The Decision ratifies the Committee for Medicinal Products for Human Use (CHMP) positive opinion, which considered that the overall benefit-risk balance of varenicline remains positive.<sup>2</sup>

When initially granted, a marketing authorisation in the EU is valid for five years and can be renewed upon application. Varenicline was first approved in the EU in 2006, and its MA renewal for a further five-year period was based on the CHMP review of the pertinent product safety and efficacy data. As with many medicines, varenicline continues to be studied in various patient populations, and the EMA stated that continual safety profile monitoring would be necessary. After five years, an application for further renewal will be required.

Smoking is one of the world's major threats to public health. It has been estimated that there are more than 1.3 billion smokers globally.<sup>3</sup> and the World Health Organization (WHO) has estimated

that approximately 5.4 million people died worldwide from tobacco related illnesses in 2006.<sup>4</sup>

The currently approved Champix EU labelling is available on the EMA website.

### **About CHANTIX**

CHANTIX was approved by the FDA in May 2006 as an aid to smoking cessation treatment in adults 18 and older. CHANTIX has been shown to increase the likelihood of abstinence from smoking for as long as one year compared to treatment with placebo. Adults who smoke may benefit from quit smoking support programs and/or counseling during their quit attempt. It's possible that patients might slip up and smoke while taking CHANTIX. If patients slip up, they can stay on CHANTIX and keep trying to quit. Nearly 13 million people have been prescribed CHANTIX worldwide.

### **IMPORTANT SAFETY INFORMATION**

Some people have had changes in behavior, hostility, agitation, depressed mood, suicidal thoughts or actions while using CHANTIX to help them quit smoking. Some people had these symptoms when they began taking CHANTIX, and others developed them after several weeks of treatment or after stopping CHANTIX. If you, your family or caregiver notice agitation, hostility, depression or changes in behavior, thinking, or mood that are not typical for you, or you develop suicidal thoughts or actions, anxiety, panic, aggression, anger, mania, abnormal sensations, hallucinations, paranoia or confusion, stop taking CHANTIX and call your doctor right away. Also tell your doctor about any history of depression or other mental health problems before taking CHANTIX, as these symptoms may worsen while taking CHANTIX.

Some people can have serious skin reactions while taking CHANTIX, some of which can become life-threatening. These can include rash, swelling, redness, and peeling of the skin. Some people can have allergic reactions to CHANTIX, some of which can be life-threatening and include: swelling of the face, mouth, and throat that can cause

trouble breathing. If you have these symptoms or have a rash with peeling skin or blisters in your mouth, stop taking CHANTIX and get medical attention right away.

The most common side effects include nausea (30 percent), sleep problems, constipation, gas and/or vomiting. If you have side effects that bother you or don't go away, tell your doctor. You may have trouble sleeping, vivid, unusual or strange dreams while taking CHANTIX. Use caution driving or operating machinery until you know how CHANTIX may affect you.

CHANTIX should not be taken with other quit smoking products. A lower dose of CHANTIX may be necessary in patients with kidney problems or who get dialysis.

Before starting CHANTIX, patients should tell their doctors if they are pregnant, plan to become pregnant, or if they take insulin, asthma medicines, or blood thinners. Medicines like these may work differently when patients quit smoking.

### **About Smoking**

Tobacco use is a risk factor for six of the eight leading causes of death in the world, including heart disease, cancer, and chronic obstructive pulmonary disease.<sup>5,6</sup> Smoking-related illness is the leading preventable cause of death in the United States, killing more than 443,000 people each year.<sup>7,8</sup>

For more information, please visit:

[www.pfizer.com/files/products/uspi\\_chantix.pdf](http://www.pfizer.com/files/products/uspi_chantix.pdf) for [full Prescribing Information](#) and [http://www.pfizer.com/files/products/ppi\\_chantix.pdf](http://www.pfizer.com/files/products/ppi_chantix.pdf) for [Patient Medication Guide](#).

The EU Summary of Product Characteristics (SmPC) may be found at:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000699/human\\_med\\_000696.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001d124](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000699/human_med_000696.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001d124)

## **Pfizer Inc: Working together for a healthier world™**

Founded in 1849, Pfizer is the world's premier biopharmaceutical company taking new approaches to better health. We discover, develop, manufacture and deliver quality, safe and effective prescription medicines to treat and help prevent disease for both people and animals. We also partner with healthcare providers, governments and local communities around the world to expand access to our medicines and to provide better quality health care and health system support. At Pfizer, more than 80,000 colleagues in more than 90 countries work every day to help people stay happier and healthier longer and to reduce the human and economic burden of disease worldwide.

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### **References**

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3. Tobacco Addiction, Disease Control Priorities Project, April 2006
4. Tobacco Free Initiative (TFI), World Health Organization (WHO). Facts and Figures About Tobacco, June 2007
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6. Mathers CD, Loncar D. Projections of global mortality and burden of disease from 2002 to 2030. PLoS Medicine, 2006;3(11):e442. (Additional information obtained from personal communication with CD Mathers).
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8. Centers for Disease Control and Prevention. Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses- United States, 2000-2004. MMWR. 2008; 57(45); 1226-1228