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VIAGRA CONNECT (SILDENAFIL) GRANTED RECLASSIFICATION BY THE UK MHRA AS A NON- PRESCRIPTION, PHARMACY- SUPPLIED TREATMENT FOR ERECTILE DYSFUNCTION IN MEN AGED 18 AND OVER

28/11/17

Pfizer Ltd, Walton Oaks, UK – 28 November 2017 – Pfizer announced today that the UK's Medicines and Healthcare products Regulatory Agency (MHRA) has granted the reclassification of Viagra Connect (sildenafil) as a non-prescription, Pharmacy (P) medicine for the treatment of the symptoms of erectile dysfunction in men aged 18 and over.

Viagra Connect is the first medicine for erectile dysfunction to be reclassified from Prescription Only Medicine (POM) to Pharmacy (P) status in the UK; following an extensive and detailed review process, which included a public consultation (medicines in the UK are classified as POM; P; or General Sales List [GSL] which means they are available in retail stores such as supermarkets and newsagents).

Pfizer is currently working on plans for the launch of Viagra Connect in the UK in the spring of 2018. In the interim, the company will be implementing an extensive training and education programme within pharmacies. When available, supply of the product will depend on pharmacists' assessment of its suitability for each man presenting with symptoms of erectile dysfunction (ED).

Dr Berkeley Phillips, UK Medical Director, Pfizer Ltd said: "The availability of Viagra Connect in pharmacies from next year will offer men who are eligible for the product a new and

convenient way to access sildenafil, a commonly prescribed treatment for erectile dysfunction.¹ We understand some men may avoid seeking support and treatment for this condition ^{2,3}, so we believe giving them the option to talk to a pharmacist and buy Viagra Connect could be a real step forward in encouraging more men into the healthcare system. As erectile dysfunction may be a sign of an underlying condition such as diabetes, high blood pressure, or heart disease², there could also be a wider benefit to public health in the long term.⁴ We hope that this forthcoming new opportunity to purchase a genuine treatment via pharmacy will also reduce the likelihood of men turning to potentially ineffective and dangerous counterfeits from illicit sources."

Dr David Edwards, GP with a special interest in sexual dysfunction and past President of the British Society of Sexual Medicine said: "In my clinical experience a man's ability to attain and maintain an erection is of paramount importance to him. When erection difficulties do occur, emotional and physical closeness between a man and his partner can diminish, leaving a man with a sense of isolation and lacking confidence in day to day life.

A new initiative that enables men to go to a pharmacy to get help for their ED is welcome. The Royal Pharmaceutical Society has pointed out that pharmacists are ideally placed to handle conversations with men about the condition. Almost all pharmacies already have a consulting room that is private making it an 'okay place' for men to attend. Anything that will deter men from buying 'dodgy', often counterfeit drugs without any contact with a healthcare professional, is to be applauded."

Additional information

- In order to purchase Viagra Connect, men aged 18 and over will need to answer questions from the pharmacist about their symptoms, their general health, and any other medications they are taking, so that the pharmacist can determine whether Viagra Connect is suitable for them
- Pharmacists should advise men to follow up with their doctor at their earliest convenience within 6 months of first being supplied the product, so that any potential underlying conditions or risk factors associated with erectile dysfunction can be investigated. In cases where pharmacists believe the product is unsuitable for clinical reasons, they should advise men to see their doctor for further assistance
- Pfizer is committed to patient safety, and to ensuring that Viagra Connect is supplied in a way that supports patient safety and improves patient health
- In addition to Viagra Connect, Viagra (VIAGRA 25mg, 50mg, 100mg film-coated tablets) will remain available as a prescription medicine

-ENDS-

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ABOUT VIAGRA CONNECT

Viagra Connect is indicated in adult men with erectile dysfunction (ED), which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. Viagra Connect contains the active ingredient sildenafil, which belongs to a group of medicines called phosphodiesterase type 5 (PDE 5) inhibitors. It works for men with ED by helping to relax the blood vessels in the penis, allowing blood to flow into the penis when sexually stimulated.⁵

Viagra Connect is contraindicated in the following:

- Hypersensitivity to the active substance or to any of the excipients
- Nitrates and nitric oxide donors (such as amyl nitrite)
- ritonavir (a highly potent P450 enzyme inhibitor)
- guanylate cyclase stimulators, such as riociguat,
- men for whom sexual activity may be inadvisable, and these patients should be referred to their doctor. This includes patients with severe cardiovascular disorders such as a recent (6 months) acute myocardial infarction (AMI) or stroke, unstable angina or severe cardiac failure.
- patients with severe hepatic impairment, hypotension (blood pressure < 90/50 mmHg) and known hereditary degenerative retinal disorders such as retinitis pigmentosa
- patients who have loss of vision in one eye because of non-arteritic anterior ischaemic optic neuropathy (NAION)
- patients with anatomical deformation of the penis (such as angulation, cavernosal fibrosis or Peyronie's disease)
- women
- men without erectile dysfunction
- men under 18 years of age

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At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. In the UK, Pfizer has its business headquarters in Surrey and is a major supplier of medicines to the NHS. To learn more about our commitments, please visit us at www.pfizer.co.uk

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