Open letter to clinicians and pharmacists from Dr Berkeley Phillips MRCP, UK Medical Director, and Seema Patel MPharm, MRPharmS, Established Pharma Medical Director, Pfizer UK

There has been some discussion and media reporting about our patent for the use of Lyrica® (pregabalin) in pain over recent months. We recognise this has been the cause of concern for some of you; and we apologise if this has been the case. We hope this letter will help to bring further clarity and reassurances to all concerned.

We wish we had been able to explain this patent situation earlier and better. This was new territory for all of us and there was no system or policy in place to deal with it. We were finding our way, as was the NHS. Our intention was neither to cause confusion, nor add to your workload. As a physician and pharmacist ourselves, we appreciate the work you are all doing under many, and often conflicting, pressures.

Ultimately, Pfizer's goal is to discover and develop new medicines for patients. Like you, we want to save lives, prevent illness, and improve health and wellbeing. This also lies at the heart of our continued research and subsequent discoveries in the case of Lyrica.

Lyrica was originally developed for epilepsy. But through significant research our scientist here in Cambridge, UK, discovered that it could also help patients suffering with neuropathic pain; a common debilitating condition for which additional treatment options are welcomed by doctors and patients alike. We have conducted over 50 clinical studies involving more than 12,000 patients specifically to assess the efficacy and safety profile of Lyrica for this condition alone. It is only as a result of our investment in this additional research programme that millions of patients have had access to this important treatment to help manage their pain and improve their quality of life. It is for this discovery that Pfizer was granted the patent protecting its use in pain, which is an example of a patent for a second medical use.

The original patent for the pregabalin molecule has expired and generic versions are available in the UK for the treatment of generalised anxiety disorder and epilepsy – indications that are not patent protected. The second medical use patent for pain, however, remains in place until July 2017, subject to ongoing legal proceedings with generics companies.

As science evolves and our knowledge grows, patients will increasingly benefit from research into new uses for existing medicines. In addition to researching new molecules, we are also more regularly going back to existing medicines with new knowledge to discover if they are effective

treatments for other conditions. We need to make sure this avenue is open for scientists to continue to explore.

This means that we have to be able to protect our patents, including our second medical use patents. It is the core of any pharmaceutical business. The period for which a medicine is available to patients under patent is a critical phase in the lifecycle that fuels future innovation. Without patents and the ability to protect them, we could not discover tomorrow's treatments.

We recognise that this evolving R&D model and the forging of new ways are not without challenges for the NHS or industry. Consequently, we have been working with senior government officials and NHS policymakers in England and the devolved administrations for almost 12 months to identify the best way of supporting healthcare professionals and communicating this relatively unusual and complex patent situation. This led us first to communicate directly with CCGs, Health Boards and Superintendent Pharmacists. Following this was the much-needed central guidance issued by NHS England and senior NHS bodies within Wales and Northern Ireland, which clarifies that once a clinical decision has been made to use pregabalin for pain that it should be prescribed using the brand name, Lyrica. Generic versions can, of course, be prescribed for generalised anxiety disorder or epilepsy, and we are by no means seeking to prevent this.

We have also been liaising with prescribing software providers over the last year to see if useful additions can be made to electronic prescribing systems that could help support implementation of the NHS guidance.

We are committed to doing the right thing for patients and the NHS, and we will continue to work with policymakers to find ways of supporting implementation at a local level. We hope that any framework that is put in place as a result of this work makes things easier for all and, ultimately, ensures that patients have access to life-saving and life-changing medical innovations of the future.