



Ian Allen & Nickie O'Neill, Commercial Medicines Unit, NHS England, Quarry House, Leeds LS2 7UE

Dear Mr Allen and Ms O'Neill,

We are writing to express our alarm at the difficulty that men are facing in getting access from pharmacists to the off-patent treatment bicalutamide, as well as several other generic treatments.

Bicalutamide is a hormone therapy that men rely on to help them fight prostate cancer. Prostate cancer requires testosterone to grow and bicalutamide is an anti-androgen that stops testosterone from reaching cancer cells. It can slow or shrink the cancer. For some men, any break in treatment poses the risk that their cancer may start to grow again, potentially in an aggressive way. As you can imagine, this is causing a great deal of concern and anxiety for men on this treatment regime.

We are aware that bicalutamide is not the only generic treatment affected by this problem. However, the cause of the problem remains unclear to us. It appears that in the summer of 2017, regulators forced four generic medicine manufacturers to suspend their production. This has the knock-on effect of reducing supply and so increasing prices. The British Generic Manufacturers Association has suggested that this problem will last for "a small number of months". We understand that some sites are being re-audited in the next few weeks, although we do not know if production will restart immediately.

While the suspension of production may be the root cause, there have been major complicating factors with the delay in the time taken to introduce higher prices through the concessionary prices scheme, the inadequacy of the concessionary prices scheme to deal with supply shortages lasting for more than one month and increased pressures on UK prices due to the weakness of the pound.

An article in the Health Service Journal on 5<sup>th</sup> December 2017 suggested that the Department of Health and NHS England are aware of the issue and discussing 'potential mitigations' to reduce the risk faced by CCGs. We are disappointed that these 'potential mitigations' appear to focus on cost and ignore the impact of this problem on patients and we would like to see an early resolution of this issue to ensure continuity of treatment for patient benefit. We would also like lessons to be learned from this episode with the introduction of better systems to inform patients and pharmacists of potential shortages and to keep them informed to reduce patient anxiety. We would be happy to work with you to address this.

Yours sincerely.

Angela Culhane

Chief Executive, Prostate Cancer UK

Roger Wotton

Chairman, Tackle Prostate Cancer

Cc: Steve Brine, Parliamentary Under Secretary of State, Department of Health Sue Sharpe, Chief Executive, Pharmaceutical Services Negotiating Committee