Bristol-Myers Squibb Pharmaceuticals uc

Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 T867, Ireland.
Tel: +353 (0)1 483 3625 Medical Information: 1800 749 749

04 March 2020

Dear Sir / Madam,

Re: SUSTIVA (efavirenz) 600 mg film-coated tablets
EU/1/99/110/009
Notification of Product Shortage

Bristol-Myers Squibb Pharmaceuticals uc (BMS) regrets to inform you that we are facing a temporary stock shortage of SUSTIVA (efavirenz) 600 mg film-coated tablets. This is due to short-dated stock (expiry date 10 Feb 2020) together with a production interruption at the active substance manufacturing plant, which has created a delay to the next supply for 600 mg film-coated tablets.

We expect re-supply of the 600 mg film-coated tablets to resume 30 April 2020. During this period, we have a finite amount of 50 mg, 100 mg and 200 mg SUSTIVA (efavirenz) hard capsules. We therefore would like to ask hospitals to prioritise the ordering of SUSTIVA (efavirenz) hard capsules for patients who are in the greatest need of this product.

This interruption in supply may require health providers to switch patients to alternative treatment options. These alternatives may have a different efficacy and safety profile and close supervision of the patient by the healthcare provider will be required. For product information on alternatives, you may wish to contact the manufacturers of these products.

BMS recognises the importance of SUSTIVA (efavirenz) to patients and is doing everything that we can to minimise the interruption in supply.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of a medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance website: www.hpra.ie. Adverse events should also be reported to BMS via telephone at 1800 749 749 or via email at medical.information@bms.com.

Company Contact Point
If you have any further questions or require additional information, please contact the BMS Medical Information department at 1800 749 749 or via email at medical.information@bms.com.

Bristol-Myers Squibb is committed to the safety and efficacy of our products, and to the manufacture of products of the highest quality. BMS will continue to monitor and seek whatever opportunities exist to accelerate this timetable. We appreciate your patience as we work through this issue.

Bristol-Myers Squibb Pharmaceuticals uc

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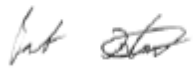
Yours Sincerely,



Pat Fortune
Associate Director Market Access Ireland

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Date: March 2020