From the Chief Medical Officer Dr Michael McBride



HSS(MD) 32/2020

FOR ACTION

Chief Executives, Public Health Agency/Health and Social Care Board/HSC Trusts/ NIAS
GP Medical Advisers, Health & Social Care Board
All General Practitioners and GP Locums (for onward distribution to practice staff)
OOHs Medical Managers (for onward distribution to staff)

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Our Ref: HSS(MD) 32/2020

Date: 5 May 2020

PLEASE SEE ATTACHED FULL CIRCULATION LIST

Dear Colleague

YELLOW CARD REPORTING SITE FOR HEALTHCARE PRODUCTS USED IN CORONAVIRUS (COVID-19)

The Medicines and Healthcare products Regulatory Agency (MHRA) has today launched a dedicated Yellow Card reporting site for healthcare products that are used in Coronavirus (COVID-19) treatment to be easily reported: https://coronavirus-yellowcard.mhra.gov.uk/

Healthcare professionals, patients and carers are asked to report all suspected side effects to medicines or medical device adverse incidents related to COVID-19 treatment. This also includes medicines that patients and healthcare professionals are using off-label to treat COVID-19. Reporting for clinical trials should be in line with the trial protocols.

Reporting will enable the MHRA to rapidly identify new and emerging side effects and medical device issues which may not have been previously known about, including diagnostic tests for COVID-19. This includes any medicines taken by patients to manage long-term, or pre-existing conditions that may influence the disease or have any potential interactions. The MHRA is closely monitoring any new or emerging safety signals in relation to medicines and medical devices used in patients with COVID-19.

Any healthcare product used in the treatment of COVID-19 can be reported, this includes medical devices such as ventilators and respiratory support devices, testing kits, certain protective personal equipment that are classified as medical devices, as



well as medicines that are being used in COVID-19 treatment. For more information on what to report please go to https://coronavirus-yellowcard.mhra.gov.uk
During the pandemic, Yellow Card reporting for suspected side effects has decreased, especially from healthcare professionals. The Yellow Card scheme continues to operate as usual and safety concerns should still be reported to the MHRA. Further information on Yellow Card reporting during the pandemic can be accessed here: https://www.gov.uk/guidance/the-yellow-card-scheme-guidance-for-healthcare-professionals

We appreciate that healthcare professionals are under pressure at this challenging time, but reporting remains essential both to understand the safety of existing medicines and medical devices used in treating COVID-19, and to identify new safety issues. Thank you for your support.

Yours sincerely

DR MICHAEL McBRIDE Chief Medical Officer

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MRS CATHY HARRISON Chief Pharmaceutical Officer

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Director of Nursing, Public Health Agency

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Joe Brogan, Assistant Director of Integrated Care, HSCB

Michael Donaldson (for distribution to all General Dental Practitioners)

Trade Union Side

This letter is available on the Department of Health website at

 $\frac{https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications}$

