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1 March 2017

Dear Miss Brown

RE: RAYMOND CHARLES WOODWARD, DECEASED, date of death 19/02/16 (Ref: 113062)

Further to my letter dated 7 December 2016 regarding the inquest into the death of Raymond Charles Woodward, I can confirm that the Summary of Product Characteristics (SmPC) for Buscopan Ampoules has been updated to more clearly communicate and minimise this risk of serious adverse reactions in patients with underlying cardiac disease. Section 4.4 of the SmPC has been revised with the following warning:

*Buscopan Ampoules can cause tachycardia, hypotension and anaphylaxis, therefore use with caution in patients with cardiac conditions such as cardiac failure, coronary heart disease, cardiac arrhythmia or hypertension, and in cardiac surgery. Monitoring of these patients is advised. Emergency equipment and personnel trained in its use must be readily available.*

We have also communicated these new recommendations to healthcare professionals through an article in our MHRA newsletter, Drug Safety Update, which is available at <https://www.gov.uk/drug-safety-update>

Yours sincerely



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