



Our Reference: 014953

9th May 2016

Rebecca Snook
Coroners Deputy First Officer
H M Coroners Court
The Phoenix Centre
L/Cpl Stephen Shaw MC Way
Heywood
OL10 1LR

13 MAY 2016

Dear Ms Snook

Re Nadine Alexandra Brookes-Walker (your Ref: 56281)

Following the letter dated 17th November 2015 from your colleague [REDACTED] and our subsequent correspondence with yourself and [REDACTED] this letter constitutes Takeda's response to the Regulation 28 report.

Matters of concern:

With regard to your specific comment 'warning regarding the seriousness of the consequences of using damaged fentanyl patches may not be apparent to the patient from the packaging' and your request for 'action to be taken to prevent future deaths' we would like to bring to your attention section 3 of the Matrifen patient information leaflet (PIL) where the following is mentioned:

- Inspect the patch for any damage.
- Do not use the patch if it has been divided, cut or looks damaged.

Given the need to balance completeness with brevity and understandability in the compilation of PILs, our current view is that the current information presented in the Matrifen leaflet adequately addresses the issue of damaged patches.

Furthermore, as we are required to ensure that the PIL for Matrifen is consistent with that of the brand leader product Durogesic, marketed by Johnson & Johnson, we have requested that they conduct a review to determine whether any changes are required to the product information as a result of this incident. I understand that this is still under investigation.

In addition kindly be informed that the product information for Fentanyl patches (which include Matrifen) have recently been extensively reviewed by the Medicines and Healthcare Products Regulatory Agency (MHRA) to ensure the safety warnings are adequate. Last review was conducted in April 2015.

Lastly, we can confirm that this incident has been reported to the MHRA via the yellow card scheme.

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Should you require any additional information regarding this report, please do not hesitate to contact [REDACTED] Deputy Drug Safety Officer on [REDACTED]

Yours sincerely



[REDACTED]
UK and Ireland Medical Director

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