



Our Reference: 015380

4th April 2016

Mr John Pollard
Senior Coroner
H M Coroner South Manchester
Coroners Court
1 Mount Tabor Street
Stockport
SK1 3AG

Dear Mr Pollard

Re Irene Ann PEARSON (Deceased) (your Ref: JSP/ER/01780-2015)

Following your officer's phone call with Meera Pithia on 30th March 2016, this letter constitutes Takeda's response to the Regulation 28 report.

Item 1:

With regard to your specific comment concerning the lack of clarity over heat exposure, we would like to bring your attention the fact that the first page of the Matrifen patient information leaflet displays a list of 'Important things you need to know about Matrifen transdermal patches'. This comprises 7 bullet points highlighted in bold text, including '**do not expose the patches to a heat source (such as a hot water bottle)**'. Given the need to balance completeness with brevity and understandability in the compilation of patient information leaflets, our current view is that the information presented in the Matrifen leaflet adequately addresses the issue of exposing patches to heat sources.

However, we have reported this matter to Johnson and Johnson, who own the brand leader product Durogesic, and have requested that they conduct a review to determine whether any changes are required to the product information as a result of this incident. We are obliged to ensure that the product information leaflet for Matrifen is consistent with that for Durogesic.

We can confirm that this incident has been reported to the Medicines and Healthcare Products Regulatory Agency (MHRA). For your information, we can additionally confirm that the product information for Fentanyl patches (which include Matrifen) has recently been extensively reviewed by the MHRA to ensure the safety warnings are adequate.

Item 2:

With regard to your request for us to define 'prolonged' and 'hot', I am afraid we are not able to do this as we do not have sufficient data on heat exposure and fentanyl absorption to determine what an appropriate duration or temperature would be.

Takeda UK Ltd.

Building 3, Glory Park, Glory Park Avenue, Wooburn Green, Buckinghamshire HP10 0DF United Kingdom
Tel: +44(0) 1628 537900 • Fax: +44(0) 1628 526615 • www.takeda.co.uk



Furthermore, since rate of absorption will vary by person, depending on dosage, age and body weight for example, giving advice in terms of exact duration and temperature would be inappropriate.

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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