REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** 1. Teva ~~Pharmaceutical Industries~~ UK Ltd 2. 3.
1	**CORONER** I am Elaine Moloney, Assistant Coroner for the Coroner area of Manchester North
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroner's and Justice Act 2009 and Regulations 28 and 29 of the Coroners (Investigations) Regulations 2013
3	**INVESTIGATION and INQUEST** On the 5th May 2015 I commenced an investigation into the death of Nadine Brookes-Walker (age 32 years), for whom the cause of death was given as being that of 1a) Fentanyl Toxicity and at an Inquest held at Rochdale Coroners Court Heywood on 5 November 2015 the conclusion of "Accidental overdose of prescribed medication" was given.
4	**CIRCUMSTANCES OF DEATH** **Mrs Brookes-Walker had an extensive medical history dating back to her birth and for the last 4 years was using Fentanyl patches prescribed by her GP for relief of pain, which was severe. She was using one patch every 72 hours. Her uncle, [redacted], who lived with her, gave evidence at the Inquest that he had applied a new patch to her shoulder the night before she died. He stated that he had difficulty removing it from its package and there had been previous like occasions when the patches would stick to the inside of the packaging, requiring force to remove them. The toxicologist giving evidence to the hearing, [redacted], gave evidence that if this caused the patch to become damaged it was likely that an excessive amount of fentanyl was released into Ms Brookes-Walker's body. I concluded from the whole of the evidence that it was more likely than not that the patch had become inadvertently damaged whilst being removed from its packaging and this had led to a fatal amount of fentanyl being administered to Mrs Brookes-Walker. [redacted] stated in evidence that he was not aware of any danger arising from use of damaged patches and that he could not recall any warnings on the packaging regarding this. Furthermore, there had been occasions when all 5 patches contained within a single box were difficult to remove from their package, suggesting there may be a manufacturing fault in some batches.**
5	**CORONER'S CONCERNS** During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you. The **MATTERS OF CONCERN** are as follows:- Warning regarding the seriousness of the consequences of using damaged Fentanyl patches may not be apparent to the patient from the packaging

6	**ACTION SHOULD BE TAKEN** **In my opinion action should be taken to prevent future deaths and I believe each of you respectively have the power to take such action.**
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely . I, the Coroner, may extend the period. Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.
8	**COPIES and PUBLICATION** I have sent a copy of my report to the Chief Coroner and to the following Interested Persons namely:- [redacted] [redacted] [redacted], mother of the deceased I am also under a duty to send the Chief Coroner a copy of your response. The Chief Coroner may publish either or both in a complete or redacted or summary from. He may send a copy of this report to any person who he believes may find it usefulor of interest. You may make representations to me the coroner at the time of your response, about the release or the publication of your response by the Chief Coroner.
9	Date: 16 November 2015 Signed: