# WRITTEN STATEMENT

# BY

# THE WELSH GOVERNMENT

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| **TITLE** | **The publication of the Independent Medicines and Medical Devices Safety Review** |
| **DATE** | **15 July 2020** |
| **BY** | **Vaughan Gething MS, Minister for Health and Social Services** |

In February 2018 the Secretary of State for Health and Social Care announced an Independent Medicines and Medical Devices Safety Review to be led by Baroness Julia Cumberlege into concerns raised in three specific areas affecting women’s health, the anti-epileptic drug sodium valproate, the hormone pregnancy test primodos and the use of surgical mesh. The review team’s report “First Do No Harm” was published on 8 July 2020.

[https://www.immdsreview.org.uk/downloads/IMMDSReview\_Web.pdf](https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.immdsreview.org.uk%2Fdownloads%2FIMMDSReview_Web.pdf&data=02%7C01%7CNatalie.Harris%40gov.wales%7C3a3590c68c15485e62f708d8231a54f1%7Ca2cc36c592804ae78887d06dab89216b%7C0%7C0%7C637297943297981523&sdata=FMrpTpezeJG%2FpzQPkBo%2FxplpgtBXl3yvniowJU9YmDk%3D&reserved=0)

I welcome the report which has exposed significant failings in patient safety and UK - wide regulation and its recommendations.

The review team held extensive discussions with patients who experienced the complications following the use of hormone pregnancy tests, sodium valproate and surgical mesh procedures. Although the review focused on the healthcare system in England, many women from Wales submitted details of similar failures within Wales’ healthcare service and the review team undertook a visit to Cardiff where Welsh patient groups gave evidence.

I am pleased that the review team has listened to the patient groups’ experiences and would like to thank those from Wales who came forward to give evidence and bravely shared their highly personal stories. I am also grateful to those women for their persistence in bringing these issues to our attention and for keeping my officials and I abreast of their campaign’s objectives.

The described failings are widespread and have affected women throughout the UK and also across the world, in Europe, North America and across the Pacific region. The specific failings identified relate to regulatory oversight, a lack of scientific evidence on the effects of hormone pregnancy tests, sodium valproate and surgical mesh, the absence of data to record problems and, most worryingly, a perceived lack of compassion and interest in doing anything timely to reduce patients’ problems and concerns in spite of ample evidence of life-altering suffering.

I am deeply sorry for the harm that has been caused and apologise to women in Wales for a system wide failure of the healthcare service.

If there is a silver lining to this dark story, it is that the healthcare service in Wales is determined to learn from its mistakes and there is a commitment to improve. In addition, the review team’s recommendations, in particular to establish a patient identifiable database and registry, should allow the tracking of the effects of medicines, hormone tests, medical devices and surgical techniques on patient outcomes, to ensure patients are not harmed. In terms of regulation there is likely to be a greater emphasis on patient safety, rather than commercial considerations such as the impetus to rapidly move treatments to market.

I will be responding to the review team’s recommendations in a further written statement in the coming weeks.