Independent Medicines and Medical Devices Safety Review publishes its recommendations

Wide-ranging and radical recommendations call for widespread improvement across health system

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London, 8th July 2020: The Independent Medicines and Medical Devices Safety Review, chaired by Baroness Julia Cumberlege, has today published its report. Titled “First Do No Harm”, it comes after a two-year review of harrowing patient testimony and a large volume of other evidence concerning three medical interventions: Primodos, sodium valproate and pelvic mesh.

“First Do No Harm” sets out nine major recommendations to bring much-needed help and support to those who have suffered as a result of these interventions, and to reduce the risk of avoidable harm from medicines and medical devices in the future.

The Review team, led by Baroness Cumberlege, travelled across the UK to listen to hundreds of affected patients and their families, and received written evidence from many more over its two-year investigation. The team heard from people, mainly women, whose lives had been catastrophically affected and whose families had suffered terribly as a consequence.

The Review team also took evidence from the healthcare system, including the NHS, private healthcare providers, regulators and professional bodies, manufacturers, and policymakers.

Baroness Julia Cumberlege, Chair of the Independent Medicines and Medical Devices Safety Review, said:

“We have seen NHS staff rise to the enormous challenge posted by the Covid-19 pandemic and we applaud them for their amazing commitment. I’m afraid, however, that our report makes for uncomfortable reading, including for the hard-working, compassionate people who do excellent work in our health service.

“I have conducted many reviews and inquiries over the years, but I have never encountered anything like this; the intensity of suffering experienced by so many families, and the fact that they have endured it for decades. Much of this suffering was entirely avoidable, caused and compounded by failings in the health system itself.

“The first duty of any health system is to do no harm to those in its care; but I am sorry to say that in too many cases concerning Primodos, sodium valproate and pelvic mesh, our system has failed in its responsibilities. We met with people, more often than not women, whose worlds have been turned upside down, their whole lives, and often their children’s lives, shaped by the pain, anguish and guilt they feel as the result of Primodos, sodium valproate or pelvic mesh. It has been a shocking and truly heart-rending experience. We owe it to the victims of these failings, and to thousands of future patients, to do better.
“That is why, having spent two years listening to these stories of acute suffering, “First Do No Harm” is an appropriate title and a necessary reminder not just to doctors but to the whole healthcare system. We are urging the system to do what it should have done years ago, to help those who have suffered and put in place the processes that will enable it to learn from past mistakes so that we spare other families from such anguish.

“The system’s response – or lack of one – has added to the pain – both physical and mental - of those affected. The system and its leaders need to acknowledge what has gone so badly wrong. Our major recommendations, together with a number of actions for improvement we call for in our report, are wide ranging and radical. Given what we have witnessed, we are clear that is what is needed now.

I want to express my heartfelt thanks to my exceptional team. Their dedication, wisdom and sheer hard work has been absolutely invaluable. This has been a team effort.”

The Review’s major recommendations include:

- That the Government immediately issues a fulsome apology on behalf of the healthcare system to the families affected by Primodos, sodium valproate and pelvic mesh.

- That a Patient Safety Commissioner is appointed. This person would be the patients’ port of call, listener and advocate, who holds the system to account, monitors trends, and demands action.

- Separate schemes should be set up for Hormone Pregnancy Tests, valproate and pelvic mesh to meet the cost of providing additional care and support to those who have experienced avoidable harm and are eligible to claim.

- A Redress Agency for those harmed by medicines and medical devices in future should be established.

- The establishment of two types of specialist centres, located regionally – for mesh, and separately for those affected by medications taken during pregnancy.

- The regulator of medicines and medical devices, the MHRA, needs to put patients at the heart of its activity, and to overhaul adverse event reporting and medical device regulation.

- That a central database should be created by collecting key details including the patient, the implanted device, and the surgeon.

- That the register of the General Medical Council (GMC) should be expanded to include a list of financial and non-pecuniary interests for all doctors, as well as doctors’ clinical interests and specialisms.

- Finally, that the Government immediately sets up a task force to implement the Review’s recommendations.

ENDS
Notes to Editors

About the Independent Medicines and Medical Devices Safety Review

The Independent Medicines and Medical Devices Safety Review was commissioned in 2018 by the then Secretary of State for Health, Rt Hon Jeremy Hunt MP, to assess three medical interventions used historically across the NHS:

- **Primodos**, a hormone pregnancy test taken by women between the 1950s and 1978, associated with damage to children born after their mothers took it.

- **Sodium valproate**, an effective treatment for epilepsy known to cause harm to the unborn child if taken by a woman when pregnant. The risk of having a damaged baby is one in two.

- **Pelvic mesh**, used to treat stress urinary incontinence and pelvic organ prolapse in women. Many women have suffered terrible complications following their mesh surgery.

The Review was chaired by Baroness Julia Cumberlege CBE DL and is independent of the Government, NHS, regulatory and other public bodies, and the pharmaceutical and medical devices industries.

The three-person panel who led the Review were:

- Baroness Julia Cumberlege CBE DL, Chair
- Professor Sir Cyril Chantler, GBE, MD, FMedSci, FRCP, FRCPCH, Vice Chair
- Simon Whale, Member and Communications Lead

They were supported by a small secretariat led by Dr Valerie Brasse. The Review’s Lead Researcher was Dr Sonia Macleod.

The purpose of the Review was to make recommendations for improving the healthcare system’s ability to respond where concerns have been raised about the safety of particular clinical interventions, be they medicines or medical devices.

The Review has assessed the historic evidence relating to the science of what was known, (in the case of Primodos during its lifetime and now, and in respect of sodium valproate and pelvic mesh up to the current date) and the decision making and actions taken, based on that scientific knowledge, by the manufacturers, regulators, clinicians and policy makers.

The Review also considered the practice of obtaining patients’ consent to each of the three clinical interventions, historically in the case of Primodos, and up until the present day for sodium valproate and pelvic mesh, including appropriate practice (taking into account the historical context) in explaining to patients the potential benefits and the associated risks of any intervention.

The Review additionally focused on whether the processes pursued to date when safety concerns have been raised by patients, their families and others have been sufficient and satisfactory in relation to Primodos, sodium valproate and pelvic mesh.

More information: [www.immdsreview.org.uk](http://www.immdsreview.org.uk)
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