First Do No Harm - The report of the Independent Medicines and Medical Devices Safety Review

Background

Jeremy Hunt, then the Secretary of State, commissioned the Review into Medicines and Medical Devices Safety in 2018. Baroness Cumberlege led the review. Evidence was taken from the entire breadth of stakeholders in the healthcare system.

Three medical interventions that harmed tens of thousands were the focus;

1. Sodium valproate, an effective medication for epilepsy that is still used, but causes harm to foetuses if taken by pregnant women.
2. Pelvic mesh, used to treat pelvic organ prolapse and urinary incontinence, and has resulted in terrible complications for many.
3. Primodos, a hormone pregnancy test taken by women between the 1950s and the late 1970s, associated with damage to children.

Key points for Industry

- It recommends that the **MHRA is reformed, underpinned by legislation**, so that the views of patients are systematically listened to and their experiences of medications and devices are used to inform licensing and regulatory decisions.
- It recommends that for both medicines and medical devices there is more robust, publicly accessible **post-marketing surveillance**. This includes a publicly searchable database including all adverse events for both medicines and devices.
- It acknowledges why medical devices are less rigorously examined before they are first marketed compared to medicines. However, it notes that MHRA has no involvement in the pre-market phase of medical device development, and suggests they **develop a proactive regulatory role for devices** that is more akin to the licensing of medicines.
- It suggests the **MHRA keeps a register of all devices approved for the UK market**, with manufacturers applying to the MHRA before marketing their device.
- It suggests **marketing approval for devices should be a staged process**, progressing to wider use and dissemination of the device as more information becomes available.
- Manufacturers are criticised for sometimes failing to acknowledge that their products are causing harm.
- The Review is concerned by doctors who have financial and other links with manufacturers. It recommends that the **register of the GMC is expanded to**

include a list of financial and non-pecuniary interests for all doctors.

- It also recommends **mandatory reporting for pharmaceutical and medical device industries of payments** made to teaching hospitals, research institutions and individual clinicians.
- A Redress Agency could be formed for those harmed by medicines and medical devices. It could be "*funded by a **mandatory levy paid by the medicine and device industries** in order to place a product on the UK market*".

Summary

The review is **highly critical of the healthcare system** – it is described as disjointed, siloed, unresponsive and defensive. It does not listen to patient concerns and forgets its purpose is to care for patients.

Baroness Cumberlege has described the **healthcare system as 'flying blind'** – there is a culture of denial, a resistance to no-blame learning, and an absence of accountability.

Recommendations

1. The Government should immediately issue a fulsome apology on behalf of the healthcare system to the families affected by Primodos, sodium valproate and pelvic mesh.
2. The **appointment of a Patient Safety Commissioner** who would be an independent public leader with a **statutory responsibility**. The Commissioner would champion the value of listening to patients and promoting users' perspectives in seeking improvements to patient safety around the use of medicines and medical devices.
3. A **new independent Redress Agency for those harmed by medicines and medical devices should be created** based on models operating effectively in other countries. The Redress Agency will administer decisions using a non-adversarial process with determinations based on avoidable harm looking at systemic failings, rather than blaming individuals.
4. Separate schemes should be set up for each intervention – HPTs, 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.
5. **Networks of specialist centres should be set up** to provide comprehensive treatment, care and advice for those affected by implanted mesh; and separately for those adversely affected by medications taken during pregnancy.
6. The **MHRA needs substantial revision**, particularly in relation to **adverse event reporting and medical device regulation**. It needs to ensure that it engages more with patients and their outcomes. It needs to raise awareness of its public

protection roles and to ensure that patients have an integral role in its work.

7. **A central patient-identifiable database should be created** by collecting key details of the implantation of all devices at the time of the operation. This can then be linked to specifically created registers to research and **audit the outcomes both in terms of the device safety and patient reported outcomes measures**.
8. Transparency of payments made to clinicians needs to improve. The register of the GMC should be expanded to include a **list of financial and non-pecuniary interests for all doctors**, as well as doctors' particular clinical interests and their recognised and accredited specialisms. In addition, there should be **mandatory reporting for pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions and individual clinicians**.
9. The Government should immediately set up a task force to implement this Review's recommendations. Its first task should be to set out a timeline for their implementation.

Further relevant information

The review heard evidence that:

- At times patients have been denied their fundamental right to have the information they need to make fully informed choices.
- The system does not identify promptly significant adverse outcomes arising from a medication or device because it lacks the means to do so. There is gross underreporting to the Yellow Card system.
- Crucial research evidence that should help shine a light on what are safe and effective interventions is neither prioritised nor funded. There is also research that is funded by manufacturers that never sees the light of day because it is negative or inconclusive for the product in question.

Conclusions on the 3 interventions:

- **Primodos** - continued to be given as a pregnancy test for years longer than it should. By 1967 a non-invasive alternative was available. The system failed as the regulator did not act on safety concerns.
- **Sodium valproate** - even today, hundreds of women who are taking valproate become pregnant without being aware of the risks to unborn children (results in one in two damaged babies). Health professionals do not inform them of the risks, regulators have not done enough to make them do so, and no one is tracing those affected.
- **Pelvic mesh** – mesh for the treatment of Stress Urinary Incontinence has been halted. There is still no consensus on how to treat complications and what type of procedures are best. However, women must be able to make a fully informed decision about a mesh implant in the full knowledge of all the risks.

The state and manufacturers have a moral responsibility to provide ex gratia payments to those who have experienced avoidable damage from the interventions the report reviewed.

Brexit is seen as an opportunity for MHRC to bring cultural and legislative reform. Implementation of the EU Medical Devices Regulation (MDR) has been delayed, as such the UK will not implement it during the transition period, and the MHRC will need to make its own strategic decisions.

Conclusion

The report is scathing of the culture and processes in the health system. It calls for some bold changes, particularly to regulatory processes.

It is unclear whether the Government, and all the bodies that comprise the healthcare system, will take heed of what has been recommended. The Government is considering the report and will officially respond in due course.

Baroness Cumberlege said in her press conference, "*if this Government and the Healthcare system ignores our Review, and another intervention damages people at such a scale, the Government and the Healthcare System will not and should not be forgiven*". Therefore, there is likely to be further political and reputational collateral damage to the institutions if the report is ignored.

ENDS

For further information on any of the detail covered in this note, please contact Decideum on 020 7368 1611 or info@decideum.com