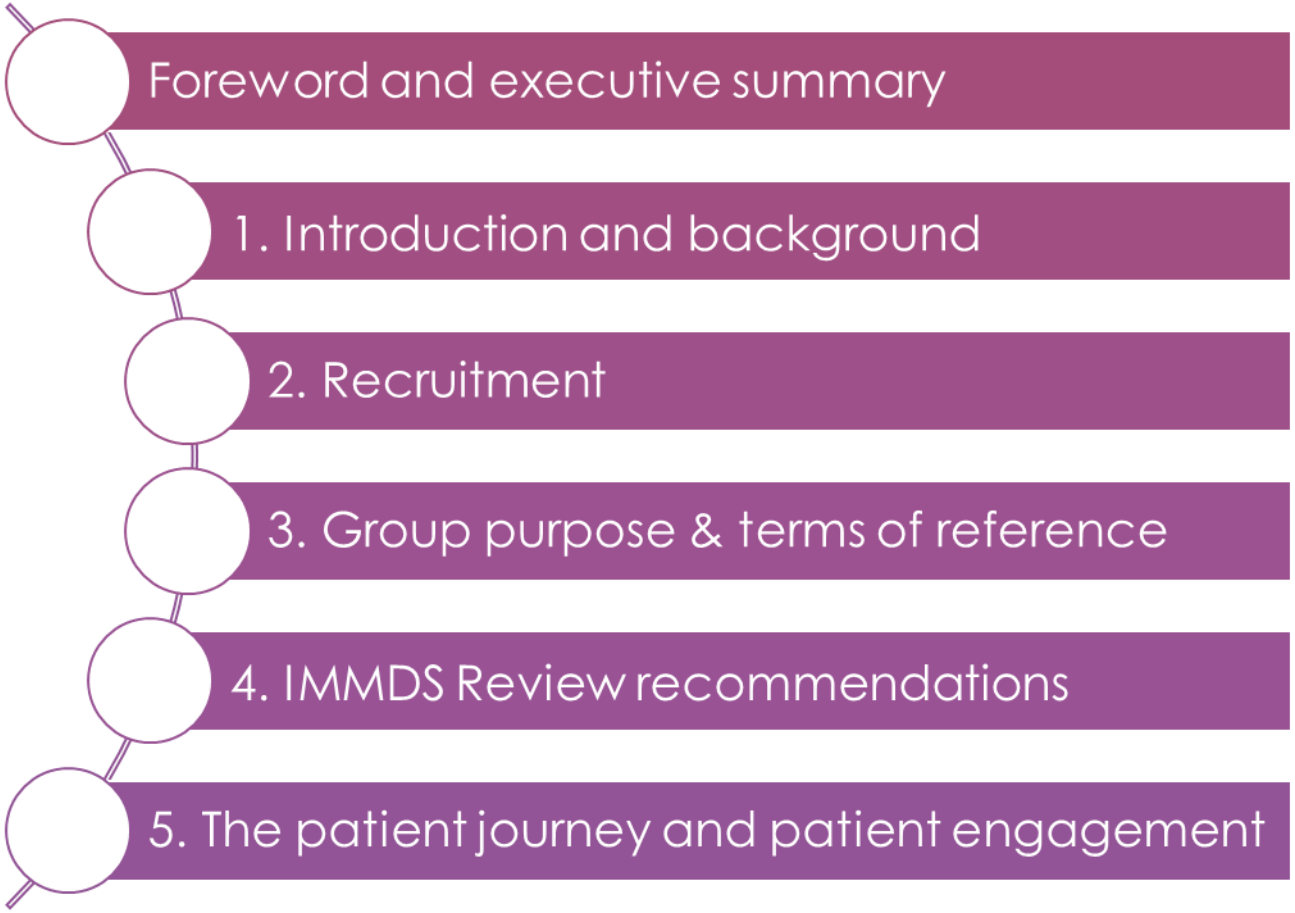
Independent Medicines and Medical Devices Safety (IMMDS) Review.

Independent Report of the Patient Reference Group

February – June 2021

TRAVERSE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Executive Summary

Marie Lyon – Patient Reference Group Co-Chair

I joined the group in response to the opportunity to influence and challenge proposed work on the recommendations contained in the Independent Medicines and Medical Devices Safety Review (IMMDSR) and to represent patients whose voices are still not heard.

The Minister of State is ultimately responsible to effect change, by seeking and responding to feedback from patients, still living with the medical mistakes made by the Department of Health and Social Care and in particular the MHRA.

Unfortunately, the culture of protect and deny continues to be the default response to patients, while stating lessons have been learned. These lessons will never equate to action and improved safety of drugs and devices, while Government Ministers mark their own performance as satisfactory when it is not. Many more women and children will be damaged unless this systemic culture of protect and deny undergoes a profound change.

Public consultations do not address the core problems within the health system as they do not ask how we were initially harmed by a medicine or device. The consultations are meaningless without the input of patients who have been harmed by medicines and devices and have first hand knowledge of how and why these harms occurred.

We need to stop the harm at source, which is the health system itself. The Government can make a difference to women's health by engaging face to face with groups similar to our own to receive honest answers about the improvements needed.

Do I regret joining the Patient Reference Group? No, I don't. I have been fortunate to meet members of the policy team who genuinely want to make a difference, but they are not the ultimate decision makers. Do I feel the group have made a difference? I reserve judgement until I see the final report on the recommendations produced by the DHSC.

I am grateful for the incredible support from the Traverse team who guided the Group throughout the process and without whose support my role as Co-Chair would not have been possible.

Finally, it has been a pleasure to work with members of the Patient Reference Group, who provided constructive, well informed and practical feedback from their personal experiences to assist the Policy Leads in understanding the issues, which provided the basis of the 9 recommendations.

Executive summary

The Patient Reference Group (PRG) was established by Traverse, an independent third-party organisation, who were commissioned by the Department of Health and Social Care in response to the Independent Medicines and Medical Devices Safety (IMMDS) Review. The PRG agreed its core purpose would be to provide challenge, advice and scrutiny to the Government's response to the review. The PRG considered each of the nine recommendations. This report sets out detailed responses from the group against each recommendation as well as providing some overarching themes. There is much to be taken from the detailed and considered feedback provided by group members but there are a number of key messages from the group that stand out.

- It's not enough to listen to patients. To honour all those who have been avoidably harmed and ensure the safety of all future patients the Government now needs to act on each of the recommendations set out in the IMMDS Review.
- Any registry of interests must be mandatory and must be regularly updated. The group will not support the response if it is not mandatory (recommendation 8 part a).
- Any reporting of adverse events for devices and medicines must be mandatory and responsibility to raise awareness of vigilance systems must be on the MHRA, and others such as GPs and pharmacist. The group want mandatory adverse event logging. (recommendation 6).
- Transparency of data is important – patients should be supported to understand how it is collected (recommendation 7).
- Without systematic data capture, patients cannot be informed of all the risks (recommendation 5).
- Not having a Redress Agency is a massive failing. Redress schemes must be actioned, with urgency, to support those who have been harmed. Until there is redress, there won't be change (recommendation 3 and 4).
- The Patient Safety Commissioner (PSC) needs to be truly independent and far removed from anyone with conflicting interests. The public must be involved in recruitment (recommendation 2).
- Mandatory reporting is the priority for the pharmaceutical and medical device industries of payments to teaching hospitals, research institutions and individual clinicians. The group will not support anything less than legislation. (recommendation 8 part b)
- There needs to be continued, ongoing patient engagement. Patients must truly be listened to and have their views taken on board or they will lose faith (recommendations 6, 7 and 8 part b).
- An overall end to end patient focused system must be a clear and defined goal within any Government response.

1. Introduction and background

Introduction and background

Background

On 21 February 2018, the then Secretary of State, Jeremy Hunt announced that he had asked Baroness Julia Cumberlege to conduct a review into how the health system had handled cases relating to two medicines and one medical device where serious concerns have been raised by patients and their families.

The Independent Medicines and Medical Devices Safety Review (IMMDS Review) published its report, *First Do No Harm*, on July 8, 2020.

The report made 9 recommendations directed at the Department of Health and Social Care (DHSC) and other organisations in the health and care system. A copy of the report can be found here.

As part of recommendation nine, the report recommended that there should be continued involvement of patient groups as the Government develops and implements its response – "*supporting the implementation process should be a reference group made up of a range of patient interests*" [pp.185]

Ministers asked policy officials to establish a patient reference group.

Why it matters

One of the central themes of Baroness Julia Cumberlege's report is that patients and families were not heard or listened to, and that there was a lack of transparency and trust in those in positions of authority, whether that be the medical profession or those responsible for delivering and regulating healthcare services.

The establishment of the Patient Reference Group goes some way towards addressing these concerns as part of the development of the Governments response. With the support of an independent facilitation team and a patient co-chair the group has together been able to consider each recommendation. By engaging directly with DHSC policy teams the group has aimed to influence and challenge decision making as the response to the report is formed and presented.

It should be noted that the Patient Reference Group is not intended to be representative of all interests or the only route for patients and families to influence decision making.

2. Recruitment

Recruiting Patient Reference Group members

The Traverse team created an advert to be circulated widely using patient networks, groups and social media, inviting people to express an interest in being involved in the Patient Reference Group.

The make up of the group aimed to include a range of different people from across England, with different experiences of medicines and medical devices, including, being a patient, carer, family member or a representative on behalf of a group of patients.

Expressions of interest were encouraged from all sections of the community, including those who have already been involved in the review and those who have an interest in patient safety generally. 90 expressions of interest were received via email.

The Traverse team responded to each of the expressions of interest individually and provided interested parties with an applicant pack, each applicant was asked to read the pack before applying with support available from the team if required. The applicant pack contained more detailed information about the purpose of the group, expectations of group members, the process for applying as well as a link to an applicant survey.

Applicants were able to submit their responses via email or via video. There were 53 applicants in total.

Once the set and advertised deadline for applications had passed, the Traverse team independently and separately reviewed all applications and scored them following a pre-agreed scoring system.

Recruiting Patient Reference Group members

The scoring system involved the Traverse team consideration of applicant responses against the following criteria that were included in the applicant pack. Scores were given between 1-5 for each applicant. (1=not acceptable, 5=great)

- Have a personal experience or understand the context of the IMMDS Review and the content of the report from the perspective of patients, carers, or families.
- Are committed to improving the experience of patients.
- Want to engage with others on the group and representatives of the Department of Health and Social Care to support the implementation of the IMMDS review.
- Can consider complex and emotive issues in a balanced and sensitive way.
- Have good communication skills, and want to build strong working relationships with the rest of the group.
- Respect the diversity of fellow group members, and not just represent your own experience and point of view.

Separate scores were moderated to achieve an agreed final score for each applicant. These were taken into account alongside achieving a balance of representation across different experiences of medicines and medical devices and those who had already been involved in the review and those with an interest on patient safety more generally. 14 people were offered and accepted a position on the group. Whilst many group members sit on other groups, and in other aspects of their lives represent specific areas of interest, each person was appointed in an individual capacity and took personal and individual responsibility for their role in the group.

All those who agreed to join the group received a ‘welcome call’ from Traverse.

Recruiting a Co-Chair

Applicants were also asked to express interest in being the Co-Chair of the group to work alongside the Traverse facilitator.

The Co-Chair role description set out the following:

- Has a personal experience or an understanding of the context of the IMMDS Review and the content of the report.
- Is committed to improving patient experience.
- Has excellent communication skills, and is able to build relationships with a wide range of people.
- Has facilitation skills to empower group members and support the group's mission.
- Knows the English healthcare system well.
- Is comfortable working on very sensitive issues, which may be emotional and distressing.

The group were ultimately responsible for choosing the co-chair and so all group members interested to take on the role were invited to express their interest to the rest of the group in advance of a vote as part of the second meeting.

The co-chair worked closely with the Traverse facilitator to design agendas and materials for the meetings. The Co-Chair supported group members to engage with the process and contribute to the group, making sure the group members' views were well listened to in meetings and in any other communications about the group.

3. Group purpose and terms of reference

Group purpose and terms of reference

Purpose of the Patient Reference Group as stated in the group's Terms of Reference:

The purpose of this group is to assist in the development and implementation of the Government's response to the IMMDS Review.

This group will provide challenge, advice and scrutiny to the Government's response to the Review. Through this process, the group will:

- Share their passion for everyone's voices to be heard, including those from different communities
- Use their powerful desire for change to elicit positivity from the negative experiences discussed
- Seek more transparency at a system level, particularly around:
  - the role of regulators and conflicts of interest,
  - better understanding of risks associated with medicines and medical devices,
  - a clearer complaints process that is easier for everyone to navigate and;
  - help to promote change so that this doesn't happen again, with patient voices at the heart of the change process.

Personal purposes as stated by group members:

- "Advocating for change."
- "Passion to use voice to improve services."
- "Want to prevent harm in the first place, and support those who have been harmed and offer redress."
- "Lessen impacts on people wherever we can"
- "Make patients feel their concerns are listened to and addressed"
- "To ensure the safeguarding of others now and in the future."
- "Set out clear and credible processes that benefit everybody"
- "Build a system which listens in a timely manner"

Group purpose and terms of reference

Terms of reference

The terms of reference was drafted by Traverse and sent to group members to read and consider in advance of the first meeting. When attending the first meeting it was then discussed and group members had the opportunity to raise any questions, ask for clarifications, or suggest amendments.

The final version was then re-circulated to the group via email and each member signed and agreed to them individually.

An official Terms of Reference document was then published to the Traverse website so that it could be viewed both by group members as well as interested members of the public following the progress of the Patient Reference Group.

The purpose of the Patient Reference Group:

- To assist in the development and implementation of the Government's response to the IMMDS Review." Further detail from the previous slide was also included.

How the Patient Reference Group will work:

- At regular meetings, members of the group will share ideas, recommendations and challenge the government's plan to develop and deliver the IMMDS Review. The group will be chaired by a member of the group who will be chosen by the group once the group is in place. An experienced facilitator and team from Traverse will support the Chair and facilitate each meeting."

Timetable:

- The first 4 meeting dates were included in the Terms of Reference, as well as the acknowledgement that timings will be agreed based on the preference of the majority of group members. Meetings were held virtually with full support available to help with this.

Support:

- An emotional support phone line was also made available to group members. The purpose of the phone line is to provide emotional support, utilising a caseworker model. The support line has been available throughout the life of the working group. The service is independent, confidential and non-judgemental.

Group purpose and terms of reference

Thank you payments:

- All members of the group were reimbursed reasonable expenses and recognized for their time with a thank you payment of £75 for each meeting attended.

Code of conduct:

- Group members were asked to treat each other with respect and without discrimination. All members should feel comfortable sharing their views without judgement. Any behavior not meeting this standard may result in a member being asked to leave the group. A more comprehensive set of ground rules was shared at the start of each meeting.

Confidentiality and your data:

- Group members were not expected to sign a confidentiality agreement. However, it was acknowledged that there may be discussions, especially related to the development of policy that group members will be asked to treat as confidential and not share outside the group, this will be made clear prior to the discussion. Group members were also asked not to speak on behalf of the Department of Health and Social Care, and the Department of Health and Social Care expected any formal enquiries (such as from the press or formal stakeholder bodies) to be directed to them.
- Personal details are held on file in order to invite group members to events and to administer thank you payments, but this is separate from any data on the views people express in the group events. We will report all feedback you give to us anonymously. These anonymous reports will be shared with colleagues in the Department of Health and Social Care, and a high-level summary will be made available to those who have expressed interest in the work of the group. This high-level summary is posted on the Traverse website.

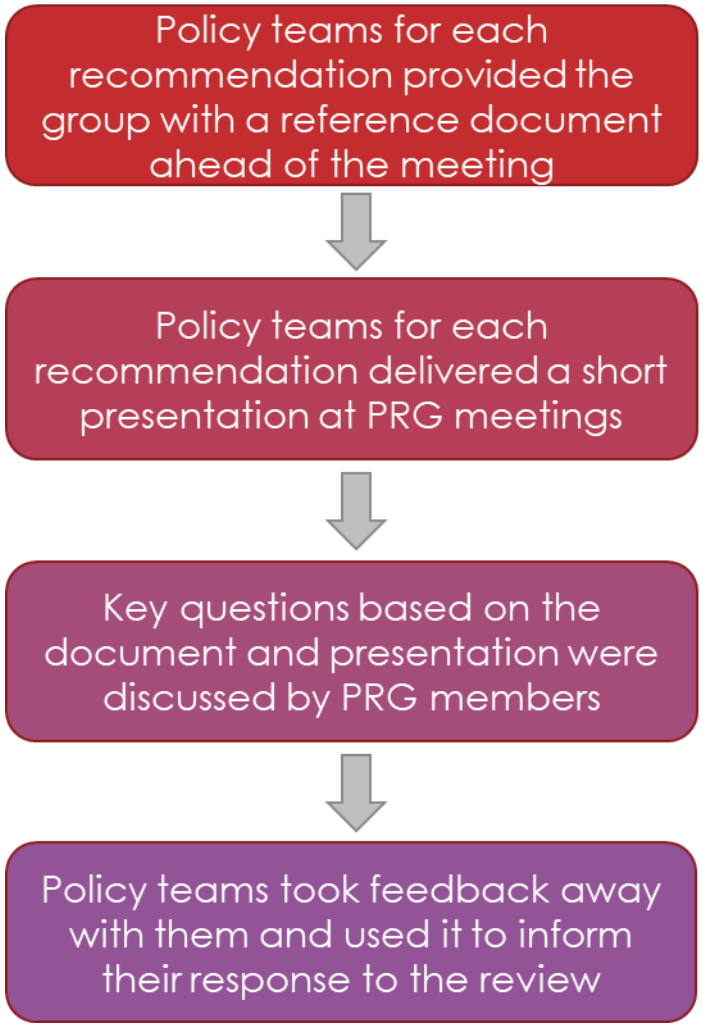
Signatures:

- All group members signed to show that they agreed to the terms of membership of the IMMDS Patient Reference Group.

4. IMMDS Review Recommendations

How the group addressed each of the IMMDS Review recommendations

- The Patient Reference Group (PRG) met 7 times from February to June 2021.
- The first meeting focused on the group getting to know each other and establishing the terms of reference for the group. The second meeting was a 'development session' where the group learnt about the Government and DHSC decision making process and key points of influence. This ensured everyone had the same base level of understanding of how their feedback would be used throughout the life of the group.
- The following 5 meetings focused on the IMMDS Review recommendations. The time spent on each recommendation and the order in which they were addressed were informed by a prioritisation exercise the group completed in the development session. The recommendations are presented in this report in the order they were addressed by the PRG.
- For each recommendation discussed, there was a dedicated policy team from DHSC and/or its arms-length bodies including NHS England and Improvement, the MHRA, and NHS Digital. Ahead of each meeting, the policy team provided the PRG with a reference document outlining the current status of the recommendation. Policy leads then delivered a short presentation (c. 10 minutes) on progress made so far, timelines for decision making and what decisions were in and out of scope.
- PRG members then went into breakout rooms (with policy teams in attendance) to share their views and to discuss the key questions in relation to the recommendation. Group feedback was shared with policy teams who used it to differing extents to inform their response to the review.



Recommendation 8, part a

First Do No Harm Report recommendation ***- "Transparency of payments made to clinicians needs to improve. 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' particular clinical interests and their recognised and accredited specialisms."***

Key questions discussed

- What do you think are the strengths and weaknesses of our proposal?
- What is your definition of clinical decision-making staff?
- In your opinion, out of all regulated healthcare professionals, who do you think it is most important declares their interests and why?
- What professions do you consider to be high-risk to patients?
- How do you think we should monitor this approach to ensure it is effective?

Key feedback from the group

Any registry of interests must be mandatory and must be regularly updated. The group will not support the response if the registry is not mandatory.

Any registry must be widely publicised and easy for patients to understand and access.

The monitoring of any registry needs to be independent.

The group were concerned that the second part of recommendation 8 was not being discussed. There should be mandatory reporting for the pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions and individual clinicians.

Recommendation 8, part a

Feedback from the group

The group felt that any registry of interests must be mandatory and must be regularly updated. It must apply to all clinical decision-making staff and capture non-permanent staff members. The current voluntary reporting systems that are in place do not work. The group wanted assurance that *"where people do not adhere to those standards, it needs to be clear that action will be taken."* There must be defined consequences for non-compliance. Various group members indicated that they would not support the response if the registry of interests was not mandatory.

Any registry must be widely publicised, and easy for patients to understand and access. They discussed whether there should be a centralised reporting system rather than clinicians reporting to their employing organisation. Members felt patients should be supported to *"understand the importance of transparency"*, including how payments are made to clinical staff and how this may affect the decision-making process.

The monitoring of any registry needs to be independent – and independent from the influence of the MHRA. Additionally, any approach must have a clear and consistent message shared across the NHS and independent sectors.

Significantly, group members raised concerns about the second part of recommendation 8. There must be mandatory reporting for the pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions and individual clinicians. They wanted to know why this was not being discussed with the first part of the recommendation. The department accepted this feedback and agreed to arrange for the team for recommendation 8b to attend a separate meeting to discuss the second part of the recommendation. This was a direct result of feedback from the PRG.

Other work that is being undertaken in response to similar recommendations, for example in the Paterson report and any other systems being implemented or set up should be aligned. Further, the Sunshine Payments Act in the United States and the Centres for Medicare and Medicaid Services open payments were suggested as models to explore for the recommendation.

Recommendation 6

First Do No Harm Report recommendation ***"The Medicines and Healthcare products Regulatory Agency (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."***

Key questions discussed

- In moving to a more responsive reporting system, what are the priorities we should be looking for?
- In planning for increased patient involvement, where do you think this can have most impact for the Agency?
- How can access to better evidence for robust and rapid decisions on the safety of healthcare products be supported?

Key feedback from the group

Reporting of adverse events for all devices and medicines must be mandatory.

Responsibility to raise awareness of vigilance systems must be on the MHRA, GPs and pharmacists.

Patient engagement must be meaningful. Currently, engagement with the MHRA feels "hollow" and a "tick box exercise".

MHRA must be much more proactive in reaching out to different communities.

Rigid legislation with financial penalties for non-compliance is needed to prevent issues and ensure manufacturers are acting in patients' interests.

Recommendation 6

Key feedback from the group

A number of group members felt that reporting of adverse events for all devices and medicines should be mandatory, and that there must be a publicly searchable database of reports. Many of the group felt that the "overhaul" of Yellow Card reporting mentioned by policy leads was *"PR and marketing"* talk. The plans currently in place are *"not good enough"* and feel like *"cherry picking"* which products and medicines to report on. Implantable devices and medicines taken during pregnancy were cited as priority areas to report on. There should be rigid timescales on taking action and the database should be easily searchable (as per the MAUDE system in America). For the MHRA to show *"a change in attitude, mandatory reporting is essential as you need to have vast data collection and put power back into the consumers of these drugs. At the moment it is a one-way system."*

The visibility of vigilance systems such as the Yellow Card scheme must be improved. Many members of the group had not heard of the Yellow Card scheme despite their experiences of the healthcare system. *"I think it is shocking that people dealing with these groups do not have a toolkit to do so."* Members felt that the onus to report and disseminate information to others is currently on patients. Rather, raising awareness of vigilance systems must be the collective responsibility of the MHRA and other organisations such as GPs and Pharmacists.

Additionally, vigilance systems should be more responsive. Some group members thought that systems should acknowledge receipt and provide a timeframe on receiving a response. *"I'd want an acknowledgement and then a timeframe on when I'm going to receive a response. It needs to be something that has a resolution."* Transparency of systems could also be improved, for example, by being able to see if other people have also reported the same problem or concern. Reflecting on how information moves much quicker following Covid-19 and reported side effects, some members felt the MHRA could give quick general updates, *"We've moved into a different space for how ambitious the MHRA has the ability to be."*

There is a need to collaborate with other organisations such as National Institute of Care Excellence, Care Quality Commission and Public Health England so as not to overload patients with requests. *"Patients are already under many stresses and they shouldn't have that burden on them. I want real engagement."*

Recommendation 6

Key feedback from the group

Group members and the MHRA agreed that for the MHRA's culture change programme to be a success, enhanced patient engagement would be essential and must be meaningful. It currently feels *"hollow"* and like a *"tick box exercise"*. Patients need to be involved at all stages of the MHRA's work, for example in both pre and post market approval of new medicines and devices. The MHRA must be proactive in reaching out to communities and building relationships, especially minority and vulnerable communities who may have lower awareness of the MHRA. *"How are you engaging with them if our group have not heard from you?"* Moreover, patients must be able to see how their feedback has influenced decision making. The aim of patient engagement should be to avoid potential harm and ensure manufacturers always act in the best interest of patients.

The group wanted the MHRA to understand the human cost of harm caused by medicines and medical devices, not just statistics. They want to see more empathy from the MHRA. *"People poured their hearts out to you and it was not received with empathy or emotions."* There is also a fear that people won't be truly listened to or believed.

There should be *"a larger measure of honesty recognising that the quick evidence is low quality evidence."* It is upsetting that Covid-19 hesitancy webinars are going on when there isn't strong evidence around vaccines, for example. *"We're shown reports that haven't been verified, peer reviewed or are authentic."* Data must be verified. Sometimes swift action is needed, but we need to trust the reports on medicine. Independent scrutiny can be used for quick decisions.

There should be mandatory legislation when it comes to manufacturers so that if information is not found to be 100% right there is action that can be taken. Manufacturers are not always acting in the interest of the patient, so we need to trust the data to prevent issues. *"That can only happen through rigid legislation."* The quality and source of the evidence needs to be transparent to be trusted. The experts providing the evidence should be independent and without conflicts of interest.

The MHRA team took away questions there was not time to answer on the day, and agreed to provide a written response to the group. The MHRA also agreed to arrange a further meeting with the group, to enable discussion of issues not addressed in this initial meeting. This meeting is scheduled to take place on July 29th.

Recommendation 6

Feedback on the Delivery Plan 2021 - 2023

Since the original meeting, the MHRA have shared with the group their Delivery Plan for 2021 – 2023. Some group members have provided feedback by email. General themes from the email responses are included below. Full responses have been passed to the MHRA ahead of the follow up meeting at the end of July.

The Delivery Plan talks about a strong patient focus but uses lots of jargon and doesn't speak strongly enough to patients, patient safety and the elimination of avoidable harm. To maintain trust, the MHRA first need to have trust from their most important stakeholders, the public. The plan in general and the concept of 'one agency' feels vague with insufficient clarity about what constitutes a meaningful impact for patients and patient safety. The new plan should not be a refresh of an existing plan, instead the plan should set out a complete change.

There is concern that collaborative partnerships with the pharmaceutical industry linked to financial sustainability of the MHRA raises conflicts of interest. Benefits and risks must be transparent and communicated quickly and easily to patients. The MHRA should monitor the evidence of safety and ensure any evidence where safety has been compromised is available and accessible. Membership of the Expert Advisory Committee should be transparent, including how they are appointed and any declaration of conflicts of interest. It is encouraging to see devolved nations included in the drive towards better outcomes, however more information on who will be involved from the wider stakeholder groups would be welcomed.

Regarding patient safety it is important to know how an adverse event reporting system will be achieved. "Driving compliance is not the same as mandatory reporting". It should be made clear that the purpose is to learn quickly, respond and take action.

Feedback from group members provided a cautionary note for the MHRA to directly address the criticisms of the MHRA culture as set out in the Independent Medicines and Medical Devices Safety review and to concentrate on their own transformation before focusing on becoming world-leading.

Monitoring of progress should be truly independent. The unitary Board and Executive Committee are employed by the MHRA and would be, "like marking your own homework". What role will patients and the public play?

Recommendation 7

First Do No Harm Report recommendation ***"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 recorded outcomes measures."***

Key questions discussed

- If you were developing the Medical Devices Information System (MDIS) what would be the key element or elements it must have, to give you confidence it will work?
- What would you want to see in a consultation process, to ensure patients' voices are heard in the development of MDIS?
- Is there any example / model for patient engagement which you have seen work well elsewhere? Do you have examples of what hasn't worked and how to avoid this happening again?

Key feedback from the group

There must be a commitment to long-term data capture. Devices need to be tracked for life.

Transparency of data is important – patients should be supported to understand how it is collected, including clarity surrounding data input from the Consultants implanting devices.

Numerous sectors and patient groups should be consulted throughout the process to create genuine co-production.

Do not have tokenistic engagement. It is okay to not act on what you hear as long as you explain why with good evidence.

Recommendation 7

Feedback from the group

In order for the group to have confidence that the Medical Devices Information System (MDIS) would work, they raised a number of essential elements concerning how to use the system, data capture and analysis.

There should be a variety of means for patients to give feedback, including a feedback form that can accurately capture what has gone wrong. The MDIS should capture conditions that might not have been initially recognised. It was suggested that a free text box option should be incorporated, with artificial intelligence mechanisms to spot trends and track data. This should pick up unexpected complications and deal with emerging trends, and send an alert to someone.

The MDIS should be committed to long term data capture. Devices need to be tracked for life, particularly higher risk ones. This is also essential to pick up on unexpected and delayed complications. Transparency of data was strongly emphasised. Patients should understand how it is collected, including clarity surrounding data input from the Consultants implanting devices. It must address the fact that *"the current input by health professionals is not fit for purpose, due to their own opinion on these issues."*

The data should be analysed and used efficiently and kept safely now and in the future. It must be publicly searchable and patients supported to access this data. The DHSC should heavily advertise the MDIS so that new and existing patients know this resource is available to them, inform them on all changes and updates to their current understanding and gather a range of feedback from people with differing circumstances. The MDIS should always aim to improve the life of the patient.

Information captured should be fed back to the device manufacturers to implement improvements. There must be *"punishments for medical errors from manufacturers"* and these must be made public. *"In some places there are legal moves in place that force companies to share their data or suffer a monetary penalty."*

Some group members felt that the MDIS could expand on existing systems, rather than starting from scratch. Regulatory mechanisms should interact with existing Registries here and abroad. For example, use existing data from and learn from others such as the National Joints Registry, which would contribute to a global network of learning. Many of the group were in favour of this approach.

Recommendation 7

Feedback from the group

The group agreed that patient engagement and ensuring patients' voices are heard in the development of the MDIS were essential to trust in it working.

The DHSC and MDIS developers must consult numerous sectors and patient groups throughout the development process to create genuine co-production. The group also placed a repeated emphasis on advertisement. It is important to have a transparent timeline and not rush the process. Ensure the feedback loop is closed and include timely responses that are retrospective around device removal.

During the engagement process, careful consideration must be given to how patients are selected and how to hear from them in the most appropriate way. For example, arranging to meet with people in various locations as it is sometimes easier for people to share their views in person. There needs to be a wider net collection of correct specialisms. Simplify language and explanations to cater to those from varied backgrounds and enable all to report accurately. Some systems offer patients support through a buddy system, using people who are more of an expert with patient experience to help and encourage involvement by people from across communities.

Patients must truly be listened to and have their views taken on board or they will lose faith. Lots of people get swept under the carpet because organisations would rather not know that there's anything wrong with their devices or medicine. But this provides *"an opportunity to catch these problems quickly from patients."*

The group stressed *"Do not have tokenistic engagement."* It is okay to not act on what you hear as long as you explain why with good evidence. This can be done by clearly evidencing reasons for decisions and policy-making through documentation and process.

One group member noted that it would be useful to state how much work is being done with other arm's length bodies as people would be more comfortable if they were aware efforts were being made.

The Co-chair stated that this session had been *"one of the best engagements we have had with the policy teams [because the team] wanted to listen and wanted to learn"*. The Co-chair also noted that the policy team gave immediate and positive feedback for almost all of the group's questions.

Recommendation 3

First Do No Harm Report recommendation ***"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."***

Key questions discussed

- This recommendation was covered in the same meeting as recommendation 4. Prior to the meeting, the Government's position on this recommendation was that a new independent Redress Agency would not be created.
- The government's position on this recommendation was communicated to the group in advance of the meeting.
- Traverse informed the group that more time was held to discuss recommendation 4 than 3 as that was where there was more opportunity for members to influence decisions. However, the group were welcome to use the chat and follow up emails to make comments or ask questions about recommendation 3.

Key feedback from the group

Not having a Redress Agency is a massive failing.

If recommendation 3 is not taken forward, those harmed will never get justice.

Litigation is not a viable substitution for a Redress Agency.

As the Redress Agency would not be created, the group felt this engagement was a waste of their time.

Recommendation 3

Feedback from the group

The group agreed that if recommendation 3 is not taken forward, those harmed by medicines and medical devices in the future will never get justice. A member wrote *"recommendation 3 is so important as there are many people harmed by things other than the 3 IMMDS interventions"*.

Group members strongly resented the notion that litigation was a viable substitution for a redress agency and as an acknowledgement that patients had suffered harm. Their reasons included that *"many people don't know where to go when seeking redress from harm, and many cannot access legal services. For example, women in Northern Ireland do not have the benefit of no win no fee schemes to be able to take legal action."* The group wanted the government to understand that redress would be a positive investment and essentially a different cost to the litigation cases they have to defend against.

One member wrote that *"stats from the Society of Clinical Injury Lawyers say that only 3% of cases are actionable and so litigation is not a viable means of securing redress in 97% of cases in which harm has been caused by medicines or medical devices"*. In addition to this, the group wished to highlight the low success rates of cases that are initially actionable, and that many are dropped unreasonably.

The group also felt strongly about the high emotional strain of the few successful cases, expressing anger at the trauma individuals and their families are forced to go through to obtain sufficient finances to survive, especially when their daily lives have already been made difficult through no fault of their own. The group wanted the policy team to understand that having to go through a traumatic experience (litigation) whilst having difficult day-to-day lives is too big of an ask.

The group felt the government should not leave causation to the courts because looking at redress, for historic cases, through a causation lens is impractical because the evidence does not exist. Furthermore, *"Causation is a barrier to any legal action, particularly when the damage is historic."*

Recommendation 3

Feedback from the group

Many members of the group felt that the Government's position on previously established schemes providing redress was *"wholly erroneous"*. Group members provided some evidence of the inaccuracy of this assertion and what patients need. The group want a clear definition of what is meant by 'redress schemes' when discussed by the policy team going forward.

Many expressed anger and insult as a result of *"public money"* being repeatedly mentioned as a barrier to redress and used the term *"guilt trip"* in response to this. Members also felt patronised by the response explanation. Members clarified that redress provide a place for harmed individuals to recoup the costs caused by medical failings. One member highlighted *"Evidence from schemes run outside the UK demonstrate that a dedicated medicines and medical devices redress agency does make products safer as it provides a central data collection point that can be monitored and responded to in a timely fashion. A no-fault redress agency also promotes an open, transparent and just culture across the NHS which further supports patient safety."*

One member responded *"We need a full and meaningful discussion about the urgent need for a levy on industry - this money then goes into a money pot which is used for financial redress - and will stop this appalling guilt trip of saying redress is using public money. I am actually appalled."* This strongly reflected the feelings of many of the group.

Although a select number of members understood the logistical difficulties of the recommendation, the group strongly felt that not having a Redress Agency is *"a massive failing"*. The Government needs to change the initial structure and ultimately that will reduce pay-out because they will catch mistakes earlier. If they don't do this, it will never change.

Recommendation 3

Feedback from the group

Some members of the group highlighted the benefits associated with a dedicated redress agency:

- Significant reduction in costs to government that are associated with litigation
- Economies of scale through central administration
- Timely data collection and the ability to identify and rectify systemic and other failings in a timely fashion
- Supporting an open and transparent NHS that has a 'just' no-blame workplace culture. Litigation as the only means of redress undermines this aspiration

The group were informed before the meeting that the government had already decided not to accept the recommendation for a redress agency. Many members expressed frustration and that *"to have scrapped the redress entirely made this session feel like a tick box and lip service exercise."* To some members, it felt like the government had *"failed to take this critical issue seriously."*

Recommendation 4

First Do No Harm Report recommendation ***"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."***

Key questions discussed

- Are there other considerations that we should be bringing into our advice?
- Are there any additional sources of information we could consider?
- We understand redress means different things to different people. We would like to understand the range of different views from the people in this group

Key feedback from the group

The policy team needed to provide more detail on how they were planning to respond to the recommendation.

Until there is redress, there won't be change. Penalties must be enforced otherwise behaviours and practices will not change.

Redress is more than financial compensation, it shows regret and willingness to accept responsibility.

Expecting patients to go through the trauma of litigation whilst living difficult day-to-day lives (as a result of avoidable harm) is too much to ask.

Recommendation 4

Feedback from the group

Group members felt the policy team needed to give more detail on how they were planning to respond to the recommendation. The group felt the policy team did not provide enough clear evidence. For example, *"there are no specific tests for some devices, very few autistic children are correctly diagnosed and there is not enough knowledge surrounding Foetal Valproate Syndrome."* The group wondered if a potential source could be the national archives as some of the sodium valproate campaign groups found a document on the risk of harm of sodium valproate in utero in the archives at Kew Gardens.

The group wanted the team to understand that redress is more than financial compensation, it shows regret and willingness to accept responsibility. Litigation is only a financial lens, *"…it doesn't encourage learning, it doesn't encourage safety, it creates adversaries when the medical system should work for patients… It is a false dichotomy that with redress you can't improve patient safety."*

The group stressed the point that these things are not binary; you can improve patient safety and redress, whilst still having litigation. The group agreed that until there's redress, there won't be change. Penalties must be enforced otherwise behaviours and practices will not change. Many of the group felt that a levy on industry must be mandated to fund compensation redress. *"It is wholly unacceptable to expect injured patients to seek redress through the courts as many fall out of the timeframe allowed, especially with implanted devices such as mesh."*

There are systems set up in other countries with specific agencies that put patients first. Group members cited schemes in Scandinavia, New Zealand, and America. A group member wrote that 'MacLeod says: *"Evidence from other nations and other sectors within the UK indicates that these outcomes can be achieved by replacing clinical negligence litigation with redress delivered via an administrative scheme."'*

With redress, there also needs to be an acknowledgement that the children affected need a care plan and disabled carers are a further layer of complexity. It was also noted that the impact on mothers and family members is emotional as well as financial. *"'Care and support' should include mothers as well in terms of financial redress. So yes, redress is more than financial compensation but it must include financial compensation."* Group members agreed there will be great anger from patient groups if there is no redress scheme or ex gratia payments.

The group wanted to know what the policy team envisioned learning from this experience would look like to them. Some group members expressed their concerns that *"nothing will come out of this."*

Recommendation 2

First Do No Harm Report recommendation ***"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."***

Key questions discussed

- Do you agree or disagree with these proposals?
- What do you think are the strengths and weaknesses of these proposals?
- Are there any other reasons you agree or disagree?
- Do you have any additional thoughts on the appointment and operation of the Patient Safety Commissioner?

Key feedback from the group

The Patient Safety Commissioner (PSC) needs to be truly independent and far removed from anyone with conflicting interests.

Transparency is key for the PSC to work and for patients to have faith in it. The public must be involved in recruitment.

The PSC must not merely be a sounding board but have the power to make changes. They must have the power to ensure the mandatory following of recommendations.

There should be an advisory board, but not one the PSC has to answer to. If this was the case, the chair of the board would hold power and confuse independence.

Recommendation 2

Key feedback from the group

There was group consensus that having a Patient Safety Commissioner (PSC) is important to ensure patients are treated fairly and with respect. However, the PSC needs to be truly independent and far removed from anyone with conflicting interests. The group stressed that an opportunity for public comment on the candidate is important as there may be people nominated that are not seen as independent. Transparency is key for the PSC role to work and for patients having faith in it. The public needs to have input throughout the entire development of the role, including in the recruitment process.

The PSC must not merely be a sounding board but must have the power to make changes. The group questioned the PSC's power to make organisations follow the recommendations rather than only responding to them. The PSC must have the power to ensure the mandatory following of recommendations. *"It's important to get the right appointment - not just skills and experiences but behaviours and values. Someone that patients can trust. Important to get the right person - someone highly credible, visionary and can secure the trust of patients, communities and campaigners."*

The PSC advisory board must include a broad range of experience. The voices of those who have been affected by medicines and medical devices are important and must be part of the advisory board. There must be a consultation on which experts should be included in the advisory board.

The group stressed that there is a difference between an advisory board and a board which the PSC would answer to. If it was the latter, the chair of that board would hold power and confuse independence. *"If commissioner is accountable to the board, they are accountable to the chair who is then more important than the commissioner..."* The group were in favour of an advisory board with the PSC ultimately accountable.

Recommendation 2

Key feedback from the group

Patients do not want to have to wait a whole year for issues to be reported up the ranks, the system needs to be more reactive to ensure people aren't harmed in the meantime. The first commissioner would need to set out a long-term strategic plan spanning perhaps 3-5 years that would outline their vision and the legal frame they'll be working within. There needs to be more regular quarterly reporting, perhaps some form of dashboard, as there were fears a year-by-year plan could become task orientated.

The group expressed optimism regarding the PSC role with the caveat that *"there is a lot on your [the policy team's] shoulders."* They stated their appreciation at being involved in the process rather than being expected to give their approval once all decisions had already been made.

Recommendation 8, part b

First Do No Harm Report recommendation ***"…In addition, there should be mandatory reporting for the pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions and individual clinicians."***

Key questions discussed

- For medicines, what are the most important ways to expand the Disclosure UK scheme? Do its current definitions and delivery work, or is more fundamental change needed?
- For medical devices, there is currently a gap in reporting. Are there particular areas where this information would be helpful? What kind of action is highest priority?
- How can we ensure continued engagement with you on these issues?

Key feedback from the group

Mandatory reporting is the priority – voluntary reporting is not good enough and doesn't work.

There needs to be accountability through penalties in order to create change. The Government must commit to this.

Transparency is essential for patient safety and ensures a long-term positive impact on quality of care.

The patient voice is essential, these people are experts in their own care. There needs to be continued, ongoing patient engagement.

The only way to enforce this is legislation – through a Sunshine style payment Act. This is in place in America and similar schemes in Denmark, Italy, France and Portugal.

Recommendation 8, part b

Key feedback from the group

Mandatory reporting is the priority. *"Voluntary reporting is not good enough, it doesn't work."* This must be added in section 60 in the health and social care bill. It needs guidance right from the top, as a requirement for only voluntary reporting infers the government are *"not interested in what's going on".* The group acknowledged that it's difficult to force the pharmaceutical industry to report anything, so institutions must also be forced to report. The group stressed that anyone involved in decision making processes must report financial incentives, including perks such as pharmaceutical weekends for example. This relates to transparency at all levels, there must be no way to conceal interests or opt out of reporting or the recommendation will not work as intended.

There must be accountability through penalties in order to create change. Board members of pharmaceutical companies, teaching hospitals and research institutions must be accountable. The group noted that in the USA, drug companies who do not report payments properly are being penalised. Patients need to know there is intent to make this recommendation mandatory and enforce penalties. The Government needs to commit to this.

Transparency is essential for patient safety. Patients need to know about their options and all devices and medicines available to them through education and support. Transparency also ensures a long-term positive impact on the quality of care by involving teaching hospitals and contributing to training better scientists and clinicians coming through those institutions. *"It's not good enough to only ensure safety from the manufacturer if it is then put into the hands of inattentive or inexperienced staff."* This is necessary to prevent flaws/bias in the scientific evidence and practice.

The triangulation of transparency is also crucial. Clinicians must be forced to report, as well as hospitals, institutions, pharmaceutical and medical device industries. The CMS Open Data System in the USA was cited as a system that was easy for patients to use and see conflicts of interest. The alternative UK system is incomplete as many names are not included and only includes medicines, not medical devices. *"It's tokenistic and doesn't build trust."*

Recommendation 8, part b

Key feedback from the group

The patient voice is essential, these people are experts in their own care. To support this, there needs to be continued, ongoing patient engagement. The group suggested *"an oversight group for accountability and testing ideas as the implementation of recommendations will be a lengthy process."* The group expressed hope that there will be a way for the policy team to continue to talk to groups of people who have experience.

Recommendation 5

First Do No Harm Report recommendation ***"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."***

Key questions discussed

- What clarifications do you have on mesh centres?
- Medicines taken during pregnancy – what is currently working well and what is not working well?
- Medicines taken during pregnancy – what does good look like?

Key feedback from the group

There needs to be regional, local access with the same pattern of care, treatment and advice no matter where people live.

Appalling that the Patient Reported Outcome Measures (PROMs) for mesh centres which are already open and operating have not been developed and validated.

Without systematic data capture, patients cannot be informed of all the risks.

Systematic patient feedback mechanisms are required as soon as possible.

Support for those adversely affected by medications taken during pregnancy must start before conception and be available to those already affected.

Recommendation 5

Key feedback from the group – specialist mesh centres

One member of the group raised that despite the mesh centres opening on 1st April, the NHS has not committed to funding the validated Patient Reported Outcome Measure (PROM) for mesh. "*Women are getting supposedly full, partial removal and we won't know how these are going if we haven't been gathering information. How are you going to share information if you're not gathering it in a uniform fashion?*" The group felt that without the PROM and the current lack of data capture women accessing mesh centres are *"at the forefront of experimentation."*

The group felt that patients accessing these centres were not fully informed of all risks associated with the treatment, care and advice provided. Although specialist centres have the potential to coordinate provision, the group felt that currently this was an aspiration, rather than reality. The group stressed the importance of systematic data capture and patient feedback to ensure specialist centres are effective. *"Without the data, we're flying blind."*

Although the group acknowledged that Patient and Public Voice (PPV) representatives are important, what is needed in the development of specialist centres is patient feedback. It was stressed by some members that systematic patient feedback mechanisms are required as soon as possible. This involves setting up reporting systems, surveys, listening to feedback and campaigning groups to design how the specialist centres operate. Those responsible for setting up and running the centres must listen and respond with action.

Group members questioned why work that has taken place to create mesh centres cannot also be done for valproate patients as much of what would be needed is already in existence (i.e. local and regional services for children with neurodevelopmental disabilities) and just requires better coordination. It was acknowledged that there is a lack of communication between organisations and professions which needs to be addressed to tackle this. The group were advised of aspirations to develop a single commissioning plan as a focused strategy to bring different specialisms and organisations together. The group agreed that the voice of paediatricians is influential in education and so those pathways need to be utilised. Group members stated that this information was helpful as it explains barriers whilst giving positive suggestions for direct action.

Recommendation 5

Key feedback from the group – specialist centres for those adversely affected by medications taken during pregnancy

There needs to be local or at the very least regional access, with the same pattern of care, treatment and advice no matter where people live. Some group members shared their experiences of *"having to travel for hundreds of miles and staying overnight, spending a lot of money and time gaining opinions from consultants… it's not practical for people to do."* Specialist centres could be places to coordinate care and treatment, but access and quality needs to be the same across regions.

The group were informed that there are centres already in place which can be adapted for valproate families, but co-operation is needed to make this happen and that there were concerns that specialist centres encourage competition where equity of access is hampered rather than facilitated. Networks of responsibility on the other hand encourage collaboration and education. The group were in favour of this approach, and wanted to know more about how they could contact and engage with The Royal College of Paediatrics and Child Health to push for collaboration.

Some group members felt that strengthening the services for treatment and care of those adversely affected by medications taken during pregnancy was *"picking up the pieces after the event."* Treatment, care and advice needs to *"start with pre-conception counselling and complete honesty about the risks in easy to understand terms."* For children affected by sodium valproate, research needs to be prioritised to understand the likelihood of inheriting / passing on their difficulties to their children should they have any. *"I feel that in order to break the cycle of valproate harm, the government must prioritise this for valproate and act more quickly."* Questions were also raised about whether the focus of the specialist centres would include children already affected by medicines and who have experienced avoidable harm.

Recommendations 1 and 9

Recommendation 1

First Do No Harm Report recommendation ***"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."***

- The group did not discuss this recommendation as Nadine Dorries, Minister of State (Minister for Patient Safety, Suicide Prevention and Mental Health) made an unreserved apology on behalf of the health and care system in July 2020.

Recommendation 9

First Do No Harm Report recommendation ***"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."***

- The group did not discuss this recommendation as the work of the Patient Reference Group itself is part of the recommendation.

Roundtable with Nadine Dorries, Minister of State (Minister for Patient Safety, Suicide Prevention and Mental Health)

The Patient Reference Group were joined at their last meeting by Nadine Dorries, Minister for Patient Safety, Suicide Prevention and Mental Health for her to hear what's important to the group and the DHSC response to the review. Each group member (and the Minister) had 2 minutes to say what they wanted.

Five key themes emerged from what the group said:

1. **There is huge disappointment and anger at lack of redress offered to date.** The group are accepting of the apology from the government, but it is nothing without redress or action to follow it up. There is a desperate need because of sacrifices and harms caused in people's lives.

2. **There is a real opportunity for action.** This will only happen if the group is listened to. The issues discussed have been raised before and there needs to be acknowledgement and action to prevent this happening again.

3. **Patients shouldn't have to wait years to access redress or receive responses.** The time between apologies and actions isn't good enough. It's taken too long to receive an apology; it shouldn't be the same amount of time to see action. There should not be future occurrences of this happening.

4. **The system is broken and doesn't listen to and learn from patients or failures.** Patients have time again been dismissed despite their experience and knowledge. The MHRA and other areas should be listening, practicing humility and developing. There are inequalities in health because the voices that should be heard are not, including those from minority communities. Affected patients must be involved in consultations.

5. **Many people are proud to be part of the group and to be making a difference.** There is a general agreement that there is pride in how strong and honest the group is. However, members will assess if differences have been made based on the publication of the final report.

Roundtable with Nadine Dorries, Minister of State (Minister for Patient Safety, Suicide Prevention and Mental Health)

The group also provided key examples of actions needed including: a database with patient capture, medical devices to be introduced in small numbers, adverse events to be reported to MHRA on a compulsory basis, for financial and non-financial gifts to be publicly logged, an American style sunshine payments act, amongst others.

The Minister of State for Patient Safety, Suicide Prevention and Mental Health, Nadine Dorries MP, introduced herself and her departmental responsibilities, which include being the lead Minister for the government response to the IMMDS Review. The Minister noted that the report made the pain and suffering of patients very clear, and that it highlighted that women were not being listened to or taken seriously. The Minister said that IMMDS Review has provided the momentum to launch new work on women's health, such as the Women's Health Strategy.

The group had mixed views about their interactions with the Minister, as exemplified by the following quotes:

"My personal view of the meeting with Ms. Dorries is that it was another exercise in being seen to do something without providing any substance or real intent. The Minister said she was there to listen, but although she may have listened she did not hear. I felt patronised and marginalized, but also angry that such an important opportunity to learn from patients who have been harmed, was treated as no more than a tick box exercise in her very busy schedule. The raw emotion from our Group was palpable, yet the Minister was completely unmoved and offered platitudes where there should have been empathy and understanding. We didn't want to know about planned public consultations, WE are the public!!"

"Just a reflection that healthcare is incredibly complex. If it was possible for Nadine to press a button I'm sure you would."

5.
The patient journey and patient engagement

The patient journey

Whilst the group considered and focused on each recommendation in order to inform the Government's response it should be noted that group members were keen not to lose sight of the system **as a whole** from the patient's perspective. This was a goal that was articulated at the first meeting when group members considered their core purpose.

It would be useful for the Governments response to reflect how the whole structure will fit together differently from the current one. Setting out **both** recommendation detail **and** whole-system overview and reform **with a response to the patient at the centre**. This will guard against a risk that individual pieces of the jigsaw might not fit very well at the end and avoid a sense of tinkering with existing structures rather than really enhancing the patient experience.

It may be useful for DHSC teams to prepare a flow diagram with stages and timescales of how a patient will go through the process under any 'revised' system, highlighting all interactions in a systematic way. A form of response to the diagram that the Review Team included on p29 (Theme 5) of the 'First Do No Harm' report.

A useful future test may be that patients and families will know to whom they should express a concern and be confident that the progress of any concerns will be easy to navigate and track and that good quality responses with fair answers will be provided in a proportionate amount of time will be the norm. An overall end to end patient focused system must be a clear and defined goal within any Government response.

Patient engagement

Patient engagement has been a consistent theme throughout the work of the Patient Reference Group and was articulated strongly at the first meeting through individual introductions about why people wanted to be involved in the group. **In short, the group agreed their core purpose was to share their passion for everyone's voices to be heard, including those from different communities.**

But it goes further than this, and there are wider considerations for the Governments response to each of the recommendations and the overall patient journey about the importance of engaging patients and families.

The establishment of the Patient Reference Group, in its own right, is part of the Governments response, however, it is important to remember that the Patient Reference Group is only one part of a much bigger picture of patient engagement. Each recommendation should have its own detailed plan for patient engagement and this should go beyond simple consultation on pre-determined questions. People should be engaged as early as possible and throughout any changes. There is no simple single way to do patient engagement. A range of individuals, groups and organisations should be involved throughout, using a range of methods, techniques and approaches.

Any engagement should be underpinned by the principles of co-production, recognising people as assets, building on people's capabilities, developing two-way reciprocal relationships, encouraging peer support, blurring boundaries between professionals working in the delivery of services and people who use services; and facilitation rather than delivering.

Patient engagement should be meaningful, inclusive and proactive. It should not be tokenistic. It should be done in an open and honest way being clear about what can and can't be changed and why.

Further, the impact on people who are asked to draw on their personal and lived experience should not be underestimated and there should be recognition of how hard this is with support in place.

Group members

The following people were recruited to the Patient Reference Group:

- Marie Lyon – Co-Chair
- Charlotte Fensome
- Helen Hughes
- Jennifer Pearl
- Julia Hobbs
- Juliet Tylor
- Kath Sansom
- Miriam Knight
- Neelam Heera
- Paula Goss
- Rachel Power
- Richard Ballerand
- Branwen Mann
- Daniel Mason
- Sophie Arcedeckne-Butler

The Traverse team would specifically like to thank each and every group member for committing their time, energy and lived experience to help inform the Governments response to the Independent Medicines and Medical Devices Safety Review. We have been humbled by the generosity of spirit shown by group members and we are privileged to have been able to work with them.

For further information please contact
jessie.cunnett@traverse.ltd or
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Anonymous individual questions/comments from notes, chats & emails

The following slides include the anonymous content from questions and comments made by the group. Given the limitations of time available to discuss each recommendation within group meetings and the complexity of some of the topics, in addition to questions and comments captured in the notes of each meeting, PRG members were invited to share questions and comments in the online chat function during meetings and to follow up with additional questions or comments by email if they had anything further they wanted to say.

PRG members requested that the questions and comments be made available alongside the report.

Questions and comments are included as they relate to each meeting and consideration of each recommendation.

Anonymous individual questions/comments from notes, chats & emails

Meeting 1

From meeting notes:

- Is it okay to speak about being a member of the group?
- Is it okay to share the meeting notes that are on the website with others?
- Is there any scope to make findings published on the website accessible via multiple languages?
- If a member shares their name publicly, but has a common name, how will they be identified?

From meeting chat:

- Can we discuss whether group members are happy to engage with each other outside of the meeting?

Development Session

From meeting notes:

- Are there any formal arrangements?
- Were the review recommendations for the UK or England?

From meeting chat:

- Does the DHSC cover the UK or just England? How does this relate to the devolved administrations in Wales, Scotland, NI?
- With the working group – is there any representative from the patient reference group? Or is this delivered on our behalf?

Anonymous individual questions/comments from notes, chats & emails

- Is the working group the decision maker? If not, who/where is that?
- Can you circulate the presentations.
- Does the M&MD Act have particular sections on any of the recommendations or is the Act a 'skeleton'/enabling piece of legislation?
- The levy – has this been looked at and rejected or not even considered?

Meeting 2 – Recommendation 8a

From meeting notes:

- Why is 8b not being discussed with this first part of the recommendation?
- Can we make the documents easy read?
- The majority of patients are not aware of the payments made to prescribers in the decision-making process. How can you make sure the patients are aware of this?
- How are you going to draw to the existence of the website in the first place?
- Will adverse events be captured separately from this process?
- Do they have a role in decision making that will influence along with NICE?
- Do you see the CQC role as an auditor if it's mandatory?
- How are you actually going to police it?

Anonymous individual questions/comments from notes, chats & emails

- What about monitoring?
- How are you going to guard against the risk of perception of bias when that may not be correct?

From meeting chat:

- The proposal seems to be saying that individual advice must be given to each patient about COI – but how would that happen in practice?
- If the independent health care sector are going to have a central register (if they are), then why not the NHS?

From email submissions:

- Would doctors go to report to every employer they go to, or do they leave an old list with the 1st & never update it but see that as compliance?
- They should also list the trials they're involved in too, as it may influence the choices they offer to patients & the going rates seem to be around £90k per investigator + if they get money for each participant recruited & commissions off each product.
- They should list their associated charities & medical societies they belong to or consult to.

Meeting 3 – Recommendation 6

From meeting notes:

- How will you deal with reporting sample bias, and how will you engage with a wider sample?
- What is the innovative licensing pathway?

Anonymous individual questions/comments from notes, chats & emails

- Will there be links to international safety alerts on medicines in pregnancy?
- What are the MHRA doing to turn patients/public into either reporting patients or engaged patients?
- Whether pharmacovigilance is going through citizenship studies? – MHRA said they would find out for the group.
- If MHRA had evidence to show mandatory reporting doesn't work and if so to show the PRG.

From meeting chat:

- What is the selection process for Patient Workshop sessions?
- But what work will be happening to have a wider awareness of the reporting scheme and how to gather insights from social media, clinician reporting etc and link with other organisational and reporting systems?
- Can you tell us what the role of the MHRA has been in this registry?
- Will all MHRA licensing decision be made public?
- How will you have full assessment when approval of most medical devices is done on the basis of Equivalence (510K in America)?
- Who is the new chief safety officer? have they come from industry?
- The patient safety board - does it have actual patients on the board?
- What's the link with SI reporting for clinicians in NHS organisations?
- Will the MHRA consider its revolving door culture with a 2yr time gap between a job in industry and a senior role at the MHRA?

Anonymous individual questions/comments from notes, chats & emails

- Will MHRA link its reporting system to international recalls so that if a product is deemed unsafe in one country a trigger warning alert is set for this country also?
- In moving to a more responsive reporting system, what are the priorities we should be looking for?
- Will whistle blowers be able to report into the system as well?
- The culture change needed at MHRA; what's your baseline assessment, how are you developing this as a programme? Monitoring its effectiveness?
- Will the culture change include breathing space so that seniors cannot jump straight from industry to senior MHRA roles?
- Some healthcare organisations are appointing Chief Patient Directors. Are the MHRA considering this?

<u>From email submissions:</u>

- The MHRA need a more powerful and ambitious vision that they then break down into actions; for example 'every person in the UK must know about the role of the MHRA and in particular the Yellow Card Scheme and about Medicines in Pregnancy'. They need to be thinking about regular TV campaigns, not just social media and printed documents although they are very important.
- The CEO's comment around, 'we want to (make change?) but we need help' is absolutely right and I think that the current leadership perhaps aren't the right people to lead that change. At the very least they need a transformation leader with a transformation team – they need someone who doesn't 'need help' but instinctively knows what must be done openly, transparently and publicly.
- The culture needs to move towards one of continuous improvement – of people and processes and outcomes. A transformation leader should embed this but it cannot be a one off, they must continually improve and be held to account.

Anonymous individual questions/comments from notes, chats & emails

- The culture must become one of customer focus for patients first and foremost but also for health professionals/other external stakeholders. In addition, they should assess where they are in terms of customer focus internally for their own people – this could help to spot barriers to achieving the vision, team and personal objectives and encourage high performance and accountability.
- They would benefit from regularly benchmarking themselves externally against other bodies internationally carrying out similar roles and use best practice. The vision here could be to become the leader of bodies such as theirs, a key player.
- In relation to their Patient Consultative Forum – what are the demographics of this Forum and are they representative of the population by age, gender identity, ethnicity, geography, occupation. How many people are there, how often and how do they engage with them?

The following thoughts were sent to us in one email and therefore should be read together in response to recommendation 6:

Part 1:

I asked about Yellow Card updates (an integral part of 'listening to the patient voice) and got a long spiel back blaming their software as an excuse for why it's been impossible to update a report (necessary in long-term cases) for over four years. I was asked if he'd answered my question and, although I was thinking NO, I actually said yes thanks. I felt very aware that time was marching and we hadn't started on what we were meant to be discussing.

Part 2:

Was that uncomfortable session of listening to MHRA bosses telling us how they will change in future our discussion of the (for me) most important recommendation? Baroness Cumberlege used the word "Overhaul"

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in her speech and this is what must be done. Promising to be "committed to delivering a step-change in how we engage and involve patients and the public in our work." is simply not enough. I know we now have an extra session planned but I feel this last one was a complete waste of time. Yes, we listened to them – but was I the only one thinking their attitude was one of patiently waiting for us all to be patted down and sent home? I feel the function of the PRG should be to thrash out the realities of the recommendations and not to waste time listening to disingenuous waffle (which, to be honest, we have all heard before).

Part 3:

"Fluoroquinolones affect the mitochondria and affect the whole body and how it creates its energy. This was stated in our public hearing and first reported in the 90s. The MHRA said it has nothing to do with them so they don't tell the doctors. I need the MHRA to answer that fully. I don't see how they have the right to pick and choose what they tell us about drugs?"

I don't want to keep banging on as there are so many other groups with similar experiences but I think this is very telling. I have no doubt at all that I and my colleagues were "used" in order to show how great the MHRA were at 'engaging' prior to the Cumberlege report being published. We had a meeting with them around the time (unknown to us) the IMMDS report was commissioned and, just as we were wrapping up, the Head of Engagement suddenly asked if we'd be interested in helping with a video to help promote the YC system. We said yes, thinking awareness of YC reports is important, plus we were keen to 'keep in' with them. A few weeks later we were asked to comment on an animated video – which, for me, was a 2 minute watch and a quick email to point out some timing was wrong (and absolutely nothing to do with fluoroquinolones); I'm not actually sure if my colleague commented or not. Imagine my surprise when I saw this in the MHRA Annual Report July 2019:

"In addition, QTSUK representatives commented on draft instructional videos aimed at explaining to the public how to complete an adverse drug reaction or adverse medical device event using the Agency's online Yellow Card reporting form. The QTSUK feedback, together with comments received from other patient representatives, has informed further development of these videos."

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Every time an MP has asked the DHSC a question about fluoroquinolones this wretched video is mentioned in the standard reply, along with other exaggerated claims about our "successful engagement". The MHRA make it sound like they nursed us throughout the whole review and hearing process although we'd have been absolutely fine without them. We copied them into everything thinking they were 'on our side' while they used every contact as an example of their engagement prowess.

(N.B. The engagement with sodium valproate representatives was also mentioned in this Annual Report.)

Part 4:

I have been reading a H of C select committee debate titled "The Influence of the Pharmaceutical Industry" from 2004 (brought to the attention of the PRG by a colleague) which reads as if the debate happened today. This is just one quote:

"The organisation (MHRA) has been too close to the industry, a closeness underpinned by common policy objectives, agreed processes, frequent contact, consultation and interchange of staff."

The committee recommended that the MHRA be the subject of an independent review – yet here we are in 2021 (SEVENTEEN years later!) expected to believe that now the MHRA will finally make adequate changes to the way they operate.

Reading the transcript of the Select Committee of Health's Examination of Witnesses prior to the above 2004 debate, I notice comments such as:

- "The MHRA threatened me with prosecution…I am still somewhat fearful of the MHRA's approach to me."
- "Let us be clear what happens…They take this data, they take out the good bits of the data, the bits that suit them, and market that back to us and call it science, when clearly it is not."

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- "The whole... issue of commercial confidentiality, meant that anything submitted by a company to the regulators could not be disclosed under penalty of fines and prison, etc, and that meant that many things could be discussed in the regulatory agency, which were absolutely private. That led... over the 40 or more years, to a closeness between the regulators and companies... the culture became confirmed that the industry is the client and the client must be looked after."

- "every time we made difficult decisions there was always this issue of: "We (MHRA) have got to be very careful because the pharmaceutical companies will sue us if we get this wrong;"

- "The issue I think that we have... is have we got a regulator that is robust and trustworthy, because at the end of the day both GPs and patients are relying on the information that comes out of the regulator? I do not think we can expect an industry making huge amounts of profit necessarily to be effective at self-regulation in these areas."

More very familiar reading was the reminder of the 2013 Early Day Motion which also raised concerns that the MHRA was too reliant on industry funding. The motion was not carried so the MHRA continued with business as usual. What really grieves me is that all of our arguments have been more than adequately made before yet this time the MHRA are saying they are really going to change as if it hadn't occurred to them in 2004 or 2013? I simply don't believe it.

<u>Part 5:</u>

I have nothing extra to say to the MHRA although you are welcome to send these thoughts to them on my behalf. I have asked them many questions over the last three years and have had many unsatisfactory replies from someone skilled at not answering anything in as many words as possible. I sent them 30 examples of "the patient's voice" in December 2018 and had no reply until last week (what a coincidence) when I was told by their new Head of Engagement that they possibly may be considered in November this year (after publication of a relevant study). I asked the CEO at the March open board meeting if she meant it when she said listening to the patient voice is "vital" and she said "it is integral to what we do now" and asked patients to "kick the tyres, tell us what you think".

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At last October's Open board meeting, when side effects to opiates were being discussed, Dr Raine said "if we over-emphasise risks, that may impede someone having all the benefits". I believe this line could be used in respect of many medicines as I know the serious side effects to not only fluoroquinolones but also isotretinoin, montelukast etc. are played down so much that doctors barely mention them. I'm fairly sure most people would prefer to have the benefit of full information before choosing whether or not to gamble with their lives yet the MHRA policy is to deliberately conceal or under-emphasise the risks.

Part 6:

"kick the tyres, tell us what you think"? (MHRA CEO March 2020):

What I think is that MHRA have no intention to change anything, in fact, they do not have the ability to change as they are completely shackled to the pharmaceutical industry.

What I think is that the DHSC has to completely separate the regulator from the industry and the funding. Until this is achieved the MHRA will only be able to serve its one master while the public and patients, far from being at the heart of everything, will remain firmly at the other end.

Meeting 4 – Recommendation 7

From meeting notes:

- The Rec 7 team noted that they would be interested to hear more about what the group knows in terms of patient partnership.
- What are your thoughts so far on recruiting a wide range of participants in an appropriate way with a span of specialisms?

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- Rec 7 team noted that if group members are keen to keep informing the process, they can get in touch to continue their involvement in some way.
- One group member noted that it would be useful to say how much work is being done with other arm's length bodies, people would be more comfortable if they were aware that efforts were being made elsewhere too.

From meeting chat:

- How long would this database follow up patients for?
- Will it have the free text box where information can be assessed and analysed using AI?
- Is there a system built in to spot trends and issue patient safety alerts?
- Will the database be open and transparent for the pubic to search?
- If safety alerts are issued on a particular medical device, will there be a time frame in which this concern must be investigated with sanctions if this does not happen within agreed time frames?
- How will be reaching all sections of communities to take part?
- Can you guarantee there will be no data breaches of patient information?
- And also groups that struggle and need additional support filling these out - is there support to help them get their voice heard
- How long does it take to tailor an individual PROM for each medical device? Ish?
- Will this design process involve independent clinical researchers? I am concerned that so far it has not involved independent researchers and thus far has only involved mesh patients and pro mesh surgeons

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- Are you looking at 'safety in use?' So not just the product safety, but how the decision has been made for product section, (and how informed consent was made), the surgery and its safety and whether there were any errors made (eg surgical site infections and proper positioning etc), post surgical care, efficacy of the device (and any problems, how manged, how resolved etc)?
- How will you engage patients to trust that their personal information is secure and safe?
- Will you access data from hospital incident reporting systems and NRLS/and its replacement?
- Would it be possible to have an All-Trials style Device PROM to capture new onset of complications to avoid delay in waiting for a new PROM for every single implantable?
- Will the database only be for Class IIB and above / high risk?
- GIRFT obtains information from litigation. What can be done to obtain information from potential claims that are not actionable. This is important as the majority of cases are not actionable.
- Can we ensure data is confidential?
- Are you going to collect data on secondary complications such as mesh removal operations?
- What about devises that have been in for years? How will they be put on the system?
- And how will you find out about historic implants to include them on the register?
- Where do regulatory mechanisms interact with existing Registries? Who will be undertaking analysis of the data compiled? NHS bodies alone or wider research groups etc
- The data input by the health professional is not at the moment fit for purpose, due to their own opinion of issues, how can this be addressed?
- Who will be undertaking analysis of the data compiled? NHS bodies alone or wider research groups etc?

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From email submissions:

- *Rec 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."*
- I have no comments to make on this recommendation except to say that I was shocked to discover that there is not a 'one size fits all' database already in use to collect data about who has had what device inserted into their bodies. Given the recent silicone implants (PIP) scandal (https://www.imarcresearch.com/blog/pip-breast-implant-scandal) was first known about in 2010, and a pause was placed on mesh implants in 2014, why hasn't such a register been put in place already?

Meeting 4 – Recommendations 3 & 4

From meeting notes:

- Members want a clear definition of what is meant by 'redress schemes' when discussed by the policy team.
- Have you looked to the Welsh model for litigation at all? Where there's qualifying liability for up to £25,000.

From meeting chat:

How can Primodos be left out when thalidomide patients have had redress without causation?

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From email submissions:

The following detailed text is from one group member

Rec 3: "A new independent Redress Agency for those harmed by medicines and medical devices should be created."

Another member asked the question 'what are these other redress schemes?' which I also planned to ask as my own search only led me to a property scheme, letting agent redress scheme, a Scottish redress scheme for survivors of abuse in care and the former British child migrants financial redress scheme.

I did start to look at the **2006 NHS Redress Act** and found a paper published **January 2018** called:

Making amends or making things worse? Clinical negligence reform and patient redress in England **which states their *"analysis shows that the government has missed a golden opportunity to establish a scheme which truly 'makes amends' to patients who have suffered harm through medical treatment in the NHS."***

(Published online by Cambridge University Press: https://www.cambridge.org/core/journals/legal-studies/article/abs/making-amends-or-making-things-worse-clinical-negligence-reform-and-patient-redress-in-england/88DDB895F8BA6C97EFD7438AA7E6C477)

After last week's meeting I can only think that this Government is going to miss yet another golden opportunity. I would like to ask now if the DHSC will please give us examples of existing redress schemes that ARE relevant plus also fully explain why Ministers think that the existing schemes mean it is not necessary to establish an independent redress agency as set out in recommendation 3?

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As I said at the meeting, this recommendation is the main reason I applied to join the panel. I took the wording to mean that every single person suffering from iatrogenic harm, whether by medicines or devices, should be entitled to compensation.

There is a huge list of drugs* that can cause long term harm but the current thinking at the MHRA seems to be to "not over-emphasise the risks" (as stated by the [MHRA CEO] re opioids at the October 2020 board meeting - but could equally apply to many other drugs). The attitude of down playing risk and keeping doctors at all levels not fully informed about the dangers means all manner of possibly life changing drugs and devices are regularly issued without proper warnings to the innocent public – the very people the MHRA are supposed to protect.

To have your life ruined because a trusted doctor gave you a trusted drug or device is bad enough but to then have to painfully claw your way through weeks, months and years of disbelief and denial from these same doctors is criminal. To try to fight for some kind of recognition and compensation is beyond many people suffering needlessly from ruined or failing health (both physical and mental) and a compassionate redress scheme as suggested by the First Do No Harm Report would be the one saving grace in all this mess. We're told the UK will be a world leader in tackling climate change, financial services, famine relief, vaccines etc. (from my Internet search today) yet we're seriously lagging behind other countries with established redress schemes. Shame on the Ministers.

*** List of drugs that can cause long term harm:**
An actual list would be so long that this email would be unreadable however the ones named here are of particular interest to me.
When contributing to the PRG meetings I always mention the fluoroquinolones as I have 8 years experience of dealing with people seriously affected by this class of antibiotic including founding and managing an on-line support group. I also mention Isotretinoin, an acne drug often given to teenagers (and children) which has been found to cause depression, chemical castration and suicidal thoughts and/or completion (sometimes spontaneous); also Montelukast, an asthma drug which is often given to children and which can also have similar unfortunate adverse reactions. Then we have the antidepressants and antipsychotics which are known

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to be addictive and which also carry a very real risk of suicide ideation and/or completion. These life-changing (sometimes life-ending) drugs can be prescribed by GPs with minimal, if any, training about the severity of what can and does happen. This has to change.

Recommendation 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."

I know I am not alone in feeling anger towards the DHSC representatives who took the time to meet with us but then let us – and themselves – down by saying that all redress has to be paid from the public purse. Are we supposed to feel guilty for discussing redress?

The pre-meeting notes spoke of "seeking to understand" and "causation" but nowhere did it discuss the fact that real people leading normal lives have had these lives stolen from them. N.B. I'm using "stolen" in the context of criminal theft here.

My husband has MS, he was diagnosed in 1990 and we knew then that his life would not be the normal one he expected – but these things happen and he's comparatively lucky because there are other debilitating illnesses that work a lot faster. "Normal" lives are changed and lost through nobody's fault and there's nothing that can be done about it.

By comparison, iatrogenic harm (or the criminal theft of lives) can be stopped, quite easily, by the same Ministers who are now shrugging and expecting the whole First Do No Harm thing to just go away with minimal change required.

Presumably, looking back at similar reports and studies, the DHSC are assuming that this 2020 report will also soon be forgotten. Perhaps Ministers should look back at the 2010 report "Equality and excellence: liberating the NHS which outlines the government's vision of putting the public and patients first (which, incidentally, sounds very much like the MHRA's new 2020 motto) through shared decision-making. Or the 2011 White

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paper Making shared decision-making a reality: no decision about me, without me or Good practice in prescribing and managing medicines and devices published by the General Medical Council in 2013 (now revised: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices).

Instead of seeking causations of harm and trying to avoid redress schemes because the funds have to come from the public purse, the DHSC and its Ministers should first take a good look at the actual cause of most iatrogenic harm and rediscover the fact that the cause is buried deep within the MHRA. Almost twenty years ago the House of Commons Health Committee published a report called **"The Influence of the Pharmaceutical Industry"** which commented that *"The Department of Health has for too long optimistically assumed that the interests of health and of the industry are as one"* and observed *"The consequences of lax oversight is that the industry's influence has expanded and a number of practices have developed which act against the public interest."*

https://publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf

If I may, I humbly suggest that all DHSC staff and Ministers read this paper and then, rather than let both it and the First Do No Harm Report go to waste, take some real action to stop the malpractices that have been happening in the name of protecting the public health.

Just as Baroness Cumberlege said in her press speech that the MHRA needs to be **overhauled**, this 2005 report said:
*"In view of the failings of the MHRA, we recommend a **fundamental review** of the organisation in order to ensure that safe and effective medicines, with necessary prescribing constraints, are licensed".* (My bold)

I made it clear after the PRG's discussion of recommendation 6 (" **The MHRA needs substantial revision**") that nothing will change unless the way the MHRA is (mostly) funded by the pharmaceutical industry changes. The 2005 report stated *"The Secretary of State for Health cannot serve two masters. The Department seems unable to prioritise the interests of patients and public health over the interests of the pharmaceutical industry"* yet this is still the case now.

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The DHSC has to take control of the funding. The MHRA must then be paid to fulfil its role of regulating drugs and ensuring they are safe, including regular reviews, for the public to use. Any drug or device licenced by the MHRA which causes long term or life changing harm to a patient has to be the responsibility of the MHRA alone and they alone must pick up the tab. At present they are knowingly (and I use this term advisedly) downplaying or concealing the seriousness of adverse reactions to many drugs. They have always done much as they like regarding medicines and medical devices while the Government pays for their "mishaps". They, along with the pharmaceutical industry, are taking the Government and the medical professionals (along with the public they are supposed to be protecting) for fools.

I'm sure many of the Ministers are actually fully aware of this and that they also know our PRG is simply a nod to "the patient's voice" or yet another tedious box-ticking exercise. I'm also sure that nothing will be done, nothing will change and the MHRA will be allowed to continue making money for itself and its masters while we, the patients, are merely collateral damage. I think I already know that, if I'm still around in 15 years time, I will see yet another report which will say exactly the same as First Do No Harm and the 2005 one quoted above.

As I said, these are merely my thoughts on last week's meeting with the DHSC. I heard early last week that a young man from one of my groups committed suicide because he could no longer stand the constant agony caused by fluoroquinolone ADRs. I then had a message yesterday to say that an elderly lady had just died after struggling for 3 years to survive with the problems caused by being given a fluoroquinolone (despite warnings not to give them to the over 60s). If I sound angry it's because I truly am, as well as being upset. Full information and disclosure from the MHRA (and the EMA whose review formed the latest fluoroquinolone guidelines) could have saved these two from being just another couple of digits on a stats form. They were both loved people with families – so who do the MHRA think they are? Who do the DHSC Ministers think they are? And how dare the DHSC staff try to patronise us and send us on guilt trips? We spend huge amounts of time trying to support many thousands of suffering and grieving people (real people!) while the MHRA happily poison thousands of others and the DHSC sit on their hands.

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The following detailed text is from a second group member

Recommendation 3: Creation of a new Independent Redress Agency for those harmed by medicines and medical devices

Note: Despite having been invited to advise the Government on their response to the recommendations made in the IMMDSR Report, the Patient Reference Group were advised that Recommendation 3 and the creation of a dedicated Redress Agency would not be discussed as their response had been decided, as stated above. As a patient stakeholder, this decision has undermined any perceived commitment that the Government may have, not only to patient stakeholder engagement generally, but also to future patient safety and the provision of effective remedies when things do go wrong.

The following written submission was completed prior to the advice given at the meeting of 29th May 2021. A dedicated Redress Agency is considered to be central to both patient safety and the availability of effective remedies in the future and it is for this reason that my thoughts on recommendation 3 are included, despite the Government's final response.

The Government has indeed previously established redress schemes without the need for an additional agency. Thalidomide and Infected Blood Products are examples of this.

However, these schemes have proved to be an ineffective means of ensuring that adequate, timely, and accessible redress is provided to those harmed. For example, it took more than ten years for compensation to be provided to only 62 families, a small percentage of those harmed by the drug Thalidomide. Ongoing campaigning has been necessary in order that all those harmed have access to the scheme and that

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compensation is adequate. The initial compensation provided by Distillers represented a mere 40% of assessed damages. It was not until 2010 that the Government provided a 'health-grant' to those harmed. However, healthcare needs are, in many cases, still unmet and campaigning for adequate redress continues to this day.

Throughout the 1970's and 1980's, an estimated 30,000 individuals were harmed by contaminated blood products. Approximately 3,000 haemophiliacs have died to date. Although ex-gratia payments were made from 1989, these were minimal and fell significantly short of any assessed damages. Initially, the payments were also limited to those infected with HIV, leaving many without access to any form of redress. It took the Government until 2016 to partially rectify this shortfall. A full inquiry commenced in 2018, and it is expected that a full report will be published in 2022-23. The Government has now stated that it could pay compensation in full, but that this will depend on the reports findings. If compensation is forthcoming in the future, those harmed will have waited decades.

In the case of those harmed by Valproate, it took over two decades of campaigning for this to be recognised. No form of redress, pecuniary or non-pecuniary, has therefore been received to date, despite the significant additional costs associated with Foetal Valproate Spectrum Disorders. A significant percentage of those affected are now adults and have not had access to support when most needed. This is particularly the case where neurodevelopmental issues present, given the well-established principle of early intervention being the key to success. For many families, at least one parent has been unable to access employment opportunities for a period of many years as a consequence of their child's significant care needs. This has had a devastating impact economically.

It is understood that those affected by Primodos and their families share a similar experience to the Valproate group, as do those harmed by mesh.

All of the above cases clearly demonstrate that the current system of individual redress schemes, created after prolonged periods of patient-driven campaigns and failed attempts at litigation, are unable to provide any remedy for the harm caused by medicines or medical devices within a reasonable period of time. A statutory Medicines and Medical Devices scheme which includes a general scheme for those suffering an Adverse Drug/Device Reaction requiring hospitalisation (as with the Japanese Pharmaceutical Compensation Scheme, there would be certain exclusions), would overcome this currently unacceptable delay.

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The administrative costs of creating separate redress schemes that are administered by different organisations will inevitably be significantly higher than where different injuries caused by medicines and medical devices are processed under a single administrative structure (such as a Medicines and Medical Devices Redress Agency), by virtue of economies of scale. Discrete funds for different harms may still be maintained under a single administrator meanwhile.

In addition to a reduction in the administrative costs associated with redress schemes, a single Medicines and Medical Devices Redress Agency would also allow for information sharing, learning, and collaboration between the various schemes, thereby supporting the ongoing development of effective and sustainable policies, procedures, and practices.

The Society for Clinical Injury Lawyers reports that only 3% of potential cases screened are actionable.

The barriers to claims made under negligence include funding, time limitations, and difficulties in establishing causation.

In terms of product liability and claims made under the Consumer Protection Act 1987, very few claims made against pharmaceutical companies have been successful for a similar set of reasons.

Historically, litigation has been a highly ineffective means of securing redress for harms caused by medicines and medical devices, despite the strict liability provisions of the Consumer Protection Act 1987. The ten year long-stop rule presents a further difficulty for those harmed in utero.

However, these well recognised barriers to actionability do not change the fact that historical harms caused by medicines and medical devices represent ‘arguable claims’ and that as such they demand that an effective remedy be made available under Article 13 ECHR.

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Most patient claims made under the Consumer Protection Act 1987 rely on public funding. Legal Aid reforms have further limited the availability of this funding source for claimants, making litigation an unrealistic option for most.

In cases that involve the principle of informed consent and a prescriber's failure "to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments", the costs of adversarial litigation to the Government far exceed those that would be associated with an inquisitorial redress scheme.

The difficulties that patients have historically faced in seeking redress for harm caused by medicines and medical devices has undoubtedly been a significant contributing factor in undermining public confidence in the industry. This has had a negative impact on vaccine uptake during the COVID pandemic and, whilst there has yet to be an assessment of the costs related to this, likely they will not be insignificant. A dedicated redress agency would support efforts to regain this trust, which is key to the wellbeing not only of the individual but also of society generally.

Given the well recognised practical problems that are associated with litigation as a means of accessing redress in this context, arguably there is a social responsibility to provide those harmed by medicines or medical devices with an alternative means of accessing an effective remedy via a non-adversarial process when things do go wrong.

Last updated in 2015, the **NHS Constitution** places the patient at the heart of everything the NHS does. Recognising the difficulties patients experience with litigation when things go wrong should be viewed as a critical component of this principle.

The NHS Patient Safety Strategy 2019 recognises that whilst mistakes will inevitably made in the context of a healthcare setting, by adopting a patient safety culture and systems, the potential for future error can be reduced through learning and acting. However, any patient safety culture demands openness, transparency and a 'psychologically safe' working environment for staff. The strategy states that:

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"Culture change cannot be mandated by strategy, but its role in determining safety cannot be ignored. 'Just cultures' in the NHS are too often thwarted by fear and blame. A consistent message in the consultation responses was. That fear is too prevalent across NHS staff, particularly in relation to involvement in patient safety incidents……..

Blame is a natural and easy response to error. It allows the cause of mistakes to be boiled down to individual incompetence, carelessness or recklessness and asserts that the problem is the individual. Blame relies on two myths. First, the perfection myth: that if we try hard, we will not make errors. Second, the punishment myth: if we punish people when they make errors, they will not make them again……

….this individual approach does not prevent errors.

The Government's proposals for the Health and Care Bill reiterates the approach taken in the Patient Safety Strategy. The White paper states that:

"High-performing teams and organisations have vibrant cultures that create the conditions for people to perform at their very best. They are collaborative and open organisations, people focussed with processes that support rather than suffocate the efforts of individuals to do good work."

Whilst the above proposals are commendable, it is far from clear exactly how the Government intends to align patient's ongoing reliance on adversarial litigation as a means of obtaining redress with the creation of a 'just culture', openness, transparency, and learning in healthcare settings. **Adversarial litigation is diametrically opposed to the culture the Government seeks to obtain across the NHS** and it is reasonable to assume that the ongoing threat of litigation when things do go wrong will present a significant barrier to achieving the Government's patient safety-related objectives, as outlined above.

In contrast to the adversarial model, an inquisitorial, 'no-fault' approach to redress fully supports the cultural changes the Government seeks to achieve across the NHS, as is outlined above. A dedicated medicines and medical devices redress agency offers a means of providing a 'no-fault' scheme that fully supports learning, openness, transparency, collaboration, and accountability across the NHS.

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As part of their patient safety strategy 2019, the Government has stated that* "'Insight' work aims to improve understanding of safety across the whole system by drawing intelligence from multiple sources of patient safety information". *Information drawn from litigation is identified as a key source of patient safety information, to be supported by the Getting it Right First Time (GIRFT) litigation workstream.

However, the fact that only 3% of potential claims are found to be actionable places a significant restriction on the availability of relevant patient safety information.

Furthermore, the very nature of adversarial proceedings will place restrictions on the depth of any insights gained, and, given the length of time that proceedings tend to take from the time the harm was suffered until the claim is decided, such insights cannot be provided in a timely manner. So whilst the Government fully acknowledges that an "*organisation that identifies, contains and recovers from errors as quickly as possible will be alert to the possibilities of learning and continuous improvement*", it needs to recognise that information drawn from litigation does not provide an effective means of supporting this.

Redress schemes administered by a dedicated redress agency has the potential to provide a flexible approach that overcomes: the barriers to litigation (causation, funding, time limitations for example) that restrict the availability of relevant information; the delay in providing relevant safety information; and the quality and depth of the information provided.

RECOMMENDATION 4: REDRESS SCHEMES FOR EACH OF THE PATIENT GROUPS

It is undeniably the case that each of the patient groups addressed in the IMMDSR report experienced significant avoidable harm. As a patient representative, my own experiences relate to Valproate.

I was initially prescribed Valproate in 1995 at the age of 23 for the treatment of epilepsy, having been unmedicated for a period of several years. No other treatment options were discussed at that time.

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In terms of pregnancy, my prescriber advised only that there was an additional 2% risk of spina bifida in comparison to the general population, but that this risk would be mitigated by my taking folic acid on a daily basis for a period of at least two months prior to pregnancy.

My son was diagnosed with autism and related difficulties in 2001, at the age of 2 ½. The early age of diagnosis provides a good indication of the extent of the challenges faced. There is no history of autism or of any other neurodevelopmental difficulties on either side of his family.

At the time of my son's diagnosis, I had access to a university library. Within a short space of time I was able to identify a number of peer reviewed research papers that identified Valproate as highly teratogenic and the cause of autism-like symptoms. With this knowledge I made a firm decision not to have any more children. My son is therefore my only child.

To add insult to injury, it has been a constant battle to access healthcare, special educational needs provision, welfare benefits and, more recently, support from adult services, despite the complexity and extent of my son's challenges. Over a period of approximately 14 years, we have been forced to undertake two SEN tribunal appeals, an appeal to tribunal against a decision regarding PIP, and a formal complaint against our Local Authority's Adult Services. These experiences are known to be fairly typical and can therefore be safely said to represent those of others.

The extent of the demands that my son's challenges combined with the adversarial processes involved in securing support meant that I was forced to withdraw from my PhD studies at the LSE in 2005. I was unable to resume my studies until around 2016. Although I did some part-time work as a cleaning lady, I was unable to access meaningful employment. The impact of this on my economic wellbeing has been devastating and an additional source of stress. Lack of employment and reliance on Carer's Allowance also affected my son and my ability to provide for his needs.

As a consequence of his disabilities my son: has missed out on a significant part of his education; has experienced extreme social isolation; has experienced severe mental health difficulties causing him to self-harm and engage in suicidal ideation since the age of seven; has been denied access to the educational

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and extra-curricular activities that were available to his peers; has experienced both direct and indirect discrimination, exclusion and stigmatisation on an almost daily basis; has not yet been able to secure employment (he is now 22 and requiring a large amount of support to enable him to move forward on this); requires a large amount of support in order to live independently (currently assessed by adult services as requiring 12 hours one to one support a week).

It remains unclear if my son will ever be employable or able to live without support, despite his being of at least average intelligence.

Submissions made to the IMMDSR by parents have almost entirely focused on the harm caused to their children. However, it is clear that parents have themselves also experienced significant harm, particularly in terms of both their physical and mental health, as well as their economic wellbeing. Furthermore, the extent of the impact of having a child with multiple complex challenges on a mother with epilepsy's health was, without question, reasonably foreseeable.

It is understood that a group action was made against Sanofi in 2010. However, Sanofi advised that they had informed the Government about the teratogenic risks associated with Valproate. As such, Sanofi could not be held liable for any of the harm caused, the case was deemed 'unwinnable', and the claim was withdrawn.

It is also understood that following the group action against Sanofi, the Government placed a blanket ban on Legal Aid funding for this and any future claims made.

This makes funding claims against Sanofi, a multinational pharmaceutical company with unlimited legal resources, impossible.

Insight into when patients should have been informed about the teratogenic risks associated with Valproate has been provided by a cumulative meta-analysis of available research. From this it has been established that **patients should have been informed of the risks by 1990**, when a doubling of risk was established.

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Legally, a doubling of risk is the point at which there is sufficient certainty to establish causation.

Although the evidence against Valproate was, by 2005, "overwhelming", it was not until 2014 that the European Medicines Agency recommended restricting the use of Valproate in women of childbearing age. In March 2018, a strengthened regulatory regime was finally established by the MHRA.

It is understood that those claims which have been successful involved harm that was caused after 2014.

The Government has accepted that the risks associated with Valproate were known and that it had always been the case that Valproate should not be prescribed to women of childbearing age unless absolutely necessary. However, the IMMDSR report was unable to provide any answers as to why this was not the case and why patients were not informed, despite the GMC's guidance around informed consent, which the case law has established as relevant to claims where the harm occurred at least as far back as 1998.

In my own case, I alerted [my neurologist] to both my son's diagnosis and the peer reviewed literature on the teratogenic risks associated with Valproate in 2005. His response was that he 'was unaware of any such research'. A clinical letter stating this is in my patient file and having known [my neurologist] for many years I have no reason to doubt him.

It remains the case that parents have campaigned against Valproate over a period of around two decades. Yet their concerns were actively dismissed with no further investigation being undertaken.

Given that Sanofi alerted the Government to the risks associated with Valproate in 1974 when the drug was first licensed, why did the Government fail to review their policy of not informing women because they may become 'distressed', and why were prescribers unaware of the risks?

Given the extent and severity of the harm suffered as consequence of Thalidomide, it is hard to reconcile the level of complacency and lack of action taken in relation to Valproate with the fulfilment of duties and responsibilities prescribed by the Medicines Act 1968.

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The failure of the yellow record reporting system has been repeatedly reported to be inadequate since its inception, yet no effective action was taken to address this. Had the issues raised been adequately addressed in a timely fashion, many of our children would have been spared the lifelong irreparable damage that they have suffered and continue to suffer.

Due to the current lack of relevant research and knowledge relating to foetal Valproate syndrome, a number of children are unable, at this point in time, to receive a formal diagnosis. Many parents are being told that no definitive conclusion can be reached one way or the other. It is expected that as further research is completed, a greater understanding of Foetal Valproate Syndrome will be gained and that children who are currently in this situation will, in the future, be able to gain a formal diagnosis.

It is also the case that as a consequence of the lack of suitably qualified and experienced experts, many families are struggling to access diagnostic services. Provision should be made to ensure that all children exposed to Valproate have access to such services. Given the numbers involved, funding to support relevant training and expertise relating to FVS is requested.

The above two issues represent an additional barrier to establishing causation and therefore the actionability of any potential claim.

The potential claims in Valproate essentially boil down to a lack of informed consent and therefore fall under the tort of negligence. It is assumed that if redress is to be sought via litigation, each mother would have to make a claim against their prescriber, who should have both known and informed mothers of the risks associated with Valproate in pregnancy. Given the numbers involved, arguably this is not a cost-effective means of providing a resolution to families, least of all for the Government.

To summarise: a doubling of risk was established by 1990, at which point women should have been informed of Valproate's associated risks; there is no claim against the manufacturer under product liability law as Sanofi informed the Government of the risks when Valproate was first licensed; the Regulator is exempt from liability; an estimated 20,000 plus claims for clinical negligence will need to be made against prescribers by those families who have been affected. This is not a good use of the Court's already overstretched resources.

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Litigation on this scale is also not a good use of the taxpayers money; a large percentage of those affected are currently unable to secure a diagnosis for those reasons outlined above.

Given the 40% risk of neurodevelopmental abnormalities that is associated with Valproate, any child born to a woman who was prescribed Valproate during pregnancy should be assumed to have been harmed where developmental delay is diagnosed.

The Redress scheme for Valproate should include both pecuniary and non-pecuniary support.

The Redress scheme for Valproate should provide flexibility so that the variable needs and preferences of families can be accommodated. Both lump-sum and periodic payments should be made available, for example.

In addition to the harm caused to children, the Redress scheme for Valproate must provide an effective remedy for the recognised breach of the mother's right to informed consent under Article 8 ECHR and consequent harm suffered.

Given the nature of the harm caused to children, the Redress scheme for Valproate must include access to suitably qualified and experienced healthcare and educational professionals with relevant expertise.

Whilst Nordic-type schemes have been proposed elsewhere, these are 'top-up' schemes made available in addition to an extensive welfare system of the type which is not available in the UK. A Nordic-type scheme is not, therefore, considered to be an appropriate model upon which to base any of the Redress schemes for each of the three patient groups.

Each of the three Redress schemes should provide for damages assessed at the same level as they would be had the claims been actionable.

Each of the schemes should be administered by an independent body who bears no responsibility for funding the schemes.

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For each of the schemes, the burden of proof should not be placed upon the patient. Rather it should be assumed that any harm was caused by the medicine or medical device, unless the scheme's administrator can prove otherwise.

In designing the schemes, the Government must work closely with each of the patient campaign groups – advice from this Patient Reference Group alone will not be adequate. Effective measures must also be taken to reach out to minority groups and others who may not have aligned themselves with the various campaign groups.

Meeting 5 – Recommendation 2

From meeting notes and chat:

- Who will the PSC report to - who is their boss / line manager/ where will their office be cited? who will they sit among?
- Who will sit on the advisory panel?
- How will this work across the devolved nations?
- Is there an opportunity for public comment and for patients/members of the public to influence the appointment of the PSC?
- What kind of board do the team intent to implement -advisory or one to which the PSC must answer to? It should be advisory in the group's opinion.
- How will the team ensure adequate resources and support will be provided when it won't be clear what the tole will entail and what will come out of the yearly report?

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- How do we ensure independence and financial independence?
- Group members wanted further details on the time frames regarding this recommendation.
- What resources are behind the commissioner? Will they have a team working for them? How will everything fit together and feed in?
- Who will the PSC report to - who is their boss / line manager/ where will their office be cited? who will they sit among

Meeting 5 – Recommendation 8b

From meeting notes:

- In the USA they have already started to penalise drug companies who are not doing it properly, why can't we do the same?

From email submissions:

- Sunshine style payment act
- There is plenty of evidence to show that receiving money from industry can bias prescribing options or scientific research, therefore in post pandemic Britain in particular it is vital that patients/the public can see who is funding our doctors voices.
- There needs to be a transparent payment register based on the American CMS Open Payment model so industry is mandated to report money to Drs, teaching hospitals, research institutions, charities and APPGs. E.g. look at the industry money taken from a pro mesh surgeon since 2014 https://openpaymentsdata.cms.gov/physician/30143
- There are similar models in France, Italy, Portugal, Denmark. This is vital for the UK.
- There needs to be financial sanctions for non compliance.

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Meeting 6 – Recommendation 5

From meeting notes:

- How, in response to the report, will implementation within healthcare happen?
- How can you ensure that the commitment to listen to patients is happening?
- It sounds more about identifying things earlier on or during pregnancy, will you be looking at current cases?
- The group asked why the NHS has not committed to funding for the validated proms for mesh? How will this be done? Will they all be in agreement?
- In terms of patients being informed on all risks, is that happening, how is that happening, are these centres working?
- Regarding patient informing, what is the mechanism for getting that feedback from patients?
- The changes discussed are not happening soon so what do we do in the meantime?
- The group asked how the policy team will increase the pool of experts who are able to find a diagnosis and increase the pool of knowledge.

From meeting chat:

- Can you explain some more about what is the Pelvic Floor Info System?
- Can you say whose decision it is within the NHS to fund the PROM?

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- Can you possibly capture the points you are making and provide more information on why and how to contact the College of Obstetrics?
- Is there a way of incorporating an automatic referral for assessment for any child born to a mother who was taken a known teratogen during pregnancy into the NICE Guidelines?
- You mentioned many areas where you think the patient voice will help drive change. Would be good to get a note of all that.
- Will new proposals ensure patients are better engaged in their care?

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The following detailed text is from one group member in response to Meeting 6 and Recommendation 5

1. When I introduced myself to Ms Dorries I referred to a Parliamentary Question (PQ) that she'd recently answered and I said the figures provided by the MHRA for her answer were "meaningless". For the sake of clarity and to inform my colleagues on the PRG I would like to explain further what I meant by this (I have also promised to write to the Minister to explain to her).

The PQ, asked by the MP of a member of my fluoroquinolone (FQ) support group, enquired how many Yellow Card reports of people suffering from FQ-related mitochondrial damage and oxidative stress had been received by the MHRA. Ms Dorries replied (2 days later) that there had been one report of mitochondrial damage and two of oxidative stress (adding there was a note to say these were duplicates). I said these figures are meaningless because, while it has been proven, and the MHRA accept, that FQs cause mitochondrial damage and oxidative stress, they have not issued this information to the Healthcare Professionals (they say it wouldn't be helpful). The result is, when someone has an adverse reaction to a FQ antibiotic, every doctor knows to look for well known symptoms such as tendon and muscle pain but is at a loss as to why a myriad of other, increasingly worsening, symptoms are also present. None of their information tells them that mitochondrial damage is occurring (which creates oxidative stress) so this isn't included in any YC reports.

I want to make absolutely clear that it is this withholding of information that is not "helpful" to HCPs. Mitochondrial damage, if not halted and reversed, leads to all manner of debilitating illnesses associated with secondary mitochondrial dysfunction such as MS, RA, Parkinsons etc. Imagine a doctor prescribing a course of antibiotics knowing that there was a slim chance that they could cause an illness of this kind. Unthinkable; yet it happens every day as the YC figures show. My records show that the MHRA receive an average of 25 reports of serious adverse reactions to FQs a month. The MHRA acknowledge that under reporting is about 10% so I can perhaps estimate that there may be 250 people a month seriously affected. If they are elderly (over 60) or their health is compromised in any way there is a very strong possibility that the damage caused will never be fully resolved.

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I said the figures were meaningless because every person who takes FQs suffers from some damage somewhere, whether they are aware of it or not. Every one of us has billions of mitochondria and the FQ's unique mechanism of action of interfering with bacterial DNA also happens to attack our mitochondrial DNA. They were originally used as chemotherapy drugs which should be a huge clue that they can damage mammalian cells (e.g. tumours). The reply to the PQ should have been an honest "we have no idea as we haven't told the doctors about it". Instead they provided these ridiculous figures presumably intended to demonstrate that the whole idea of mitochondrial damage itself is ridiculous. Why? What is their reason for hiding it?

N.B. I have written about FQ's here but (CEO of MHRA) can be seen on video* saying 'There's no need to over-emphasise the risks' when discussing opioid side effects (which are known for causing addiction, overdose or suicide). Similar statements showing a reluctance to make certain that HCPs are warned of the suicide and chemical castration risk associated with the acne drug Roaccutane can also be found on Youtube.

*MHRA Open Board Meeting October 2020.

https://www.youtube.com/watch?v=XEzIwOQiZP8

Video recordings of monthly Open Board Meetings are on Youtube.

2. Ms Dorries, when introducing herself to the PRG, said that Cumberlege "kicked the door open" and commented that she wouldn't be surprised if there were similar findings from other reviews and reports.

She must be unaware of the 2010 report "Equality and excellence: liberating the NHS which outlined the government's vision of putting the public and patients first through shared decision-making (which, incidentally, sounds very much like the MHRA's new motto, TEN years later).

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She has probably not read either the 2011 White paper Making shared decision-making a reality: no decision about me, without me or Good practice in prescribing and managing medicines and devices published by the General Medical Council in 2013 (now revised: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices).

She might not know that almost twenty years ago the House of Commons Health Committee published a report called **"The Influence of the Pharmaceutical Industry"** which commented that *"The Department of Health has for too long optimistically assumed that the interests of health and of the industry are as one"* and observed *"The consequences of lax oversight is that the industry's influence has expanded and a number of practices have developed which act against the public interest."*

https://publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf

The report, from **2005**, also said that:
*"In view of the failings of the MHRA, we recommend a **fundamental review** of the organisation in order to ensure that safe and effective medicines, with necessary prescribing constraints, are licensed".*

There should be no need to compare this with Baroness Cumberlege's words from 2020:

"We are recommending that the regulator of medicines and medical devices, the MHRA, is overhauled."

It is certainly no coincidence that the MHRA are overtly more interested in preserving the levels of prescriptions of drugs that are known to cause long term harm than in restricting them or increasing levels of warnings to prescribers. The 2005 report stated:

"The Secretary of State for Health cannot serve two masters. The Department seems unable to prioritise the interests of patients and public health over the interests of the pharmaceutical industry",

although I believe the problem is not so much with the DHSC as with the MHRA. Their relationship with the pharmaceutical industry began way back even before the MHRA was formed from its two predecessors.

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They are fully funded by the industry (re medicines) and, rather than answering to the DHSC, are simply left to look after their affairs themselves. They are run by executives who are incestuously involved with the industry (via the well known "revolving-door") and successive governments have been happy to let them get on with it. It is the MHRA who are unable to prioritise the interests of patients as this may well have an adverse effect on the interests of their one master, the pharmaceutical industry.

A House of Commons select committee debate took place in 2004 as part of the above report. One quote from this debate is:
"The organisation (MHRA) has been too close to the industry, a closeness underpinned by common policy objectives, agreed processes, frequent contact, consultation and interchange of staff."

We are now, 17 years later, expected to believe that the MHRA are at last changing their spots and 'will be putting patients and the public health at the heart of everything they do' from now on. I sincerely hope the DHSC isn't taking this promise seriously.

Ms Dorries may be interested to be reminded of the 2013 Early Day Motion by Paul Flynn MP, which begins by stating *"That this House calls for reform of the weak Medicines and Healthcare Products Regulatory Agency (MHRA) that is funded by the pharmaceutical industry and repeatedly fails the public interest"*.
https://edm.parliament.uk/early-day-motion/45355

I repeat what I said after meeting 4:
The DHSC has to take control of the funding, i.e. all the fees and other payments made by the pharmaceutical industry. The MHRA must then be paid by DHSC to fulfil its role of regulating drugs and ensuring they are safe, including regular reviews, for the public to use. Any drug or device licenced by the MHRA which causes long term or life changing harm to a patient has to be the responsibility of the MHRA alone and they alone must pick up the tab. At present they are knowingly (and I use this term advisedly) downplaying or concealing the seriousness of adverse reactions to many drugs. They have always done much as they like regarding medicines and medical devices while the Government pays out for their "mishaps". The MHRA have to take financial responsibility for their actions. They, along with the pharmaceutical industry, have for too long taken the Government and the medical professionals (along with the public they are supposed to be protecting) for fools.

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The paper published **January 2018** called:

Making amends or making things worse? Clinical negligence reform and patient redress in England **which looks what has happened since the** 2006 NHS Redress Act **. It states their *"analysis shows that the government has missed a golden opportunity to establish a scheme which truly 'makes amends' to patients who have suffered harm through medical treatment in the NHS."***

(Published online by Cambridge University Press: https://www.cambridge.org/core/journals/legal-studies/article/abs/making-amends-or-making-things-worse-clinical-negligence-reform-and-patient-redress-in-england/88DDB895F8BA6C97EFD7438AA7E6C477)

The following detailed text is from another group member

Recommendation 5: part b

Although the IMMDSR report states that 'some' children and families have faced difficulties accessing services and support, the reality is that all families who submitted evidence to the team reported such difficulties.

The difficulties faced by those affected by Valproate reflect those of families with children with additional needs generally.

It is recognised, as the policy advisors state, that services for all children with neurodevelopmental conditions are managed by multidisciplinary teams commissioned at local level, and that regional clinical networks working with specialist neuroscience centres support these services. Similarly, both education and social care services are commissioned at the local level.

It is also recognised that in an ideal world, services and support would be best provided at local level to those harmed by Valproate and/or other teratogens.

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However, the reality is that healthcare provision, special educational needs provision, and social care provision are all inadequately resourced and are therefore exceedingly difficult to access.

For example, in 2019 the BMA reported that only 10% of children had a diagnostic assessment for autism within the three-month target time-frame. Autism is particularly relevant to Foetal Valproate Syndrome. Delays in diagnosis further impact upon:

I. Access to special educational needs resources (including Speech and Language Therapy, Occupational Therapy, specialist teaching provision, for example), delivered via Individual Education Plans and statutory Education and Healthcare Plans;

II. Severity and number of symptoms – children with SEN will experience an increase in both without adequate provision and support;

III. Long-term prognosis. It is well recognised that 'early intervention is the key to success' where neurodevelopmental conditions are concerned. A delay in diagnosis will inevitably impact upon the level of functionality achieved in the long-term therefore. This represents additional costs both to the individual harmed and to the taxpayer in the long term.

IV. Access to social care and support.

V. Access to welfare benefits, in particular Carer's Allowance and Personal Independence Payments.

My own experiences with my son provide a clear illustration of the inadequacy of relevant sources of provision and support. Over the course of the last 16 years we have been forced to:

I. Engage in two special educational needs tribunals, one in primary school and the other upon transition to secondary school, both of which were successful. A third set of tribunal proceedings were avoided through the intervention of my local MP and his communicating directly with the Local Authority's Head of Children's Services;

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II. Engage in welfare tribunal proceedings following the withdrawal of my son's Personal Independence Payments. The outcome was again successful.

III. Engage in a formal complaint procedure regarding Adult Services after they failed to produce a support plan after assessment for almost a year, with all attempts at communication prior to the complaint being made having been unsuccessful.

It should be noted that where my son's special educational needs were concerned, reports undertaken by independent Speech and Language Therapists, Occupational Therapists, Educational Psychologists, and Child Psychiatrists were necessitated as a consequence of the inadequacy of those undertaken by the Local Authority and the fact that they failed to provide an accurate account of my son's multiple and complex needs. Thankfully our family had access to resources to pay for these assessments. Many, if not most, do not.

Every family affected by Valproate will tell you that the battle to secure adequate provision and support for their child is 'unrelenting'. Certainly this was my own experience.

Many describe the work required to secure and maintain adequate provision and support as equivalent to a 'full-time job' which is a significant contributing factor to their being unable to access employment opportunities. This was also my own experience, with devastating economic consequences.

In order for the government's response to the IMMDSR report's recommendation 5 to be viable in this particular context (avoidable harm suffered by both mothers and their children as a consequence of multiple systemic failings);

I. All those exposed to Valproate in utero must have accelerated access to relevant healthcare and educational needs assessment, monitoring, and treatment provision for both congenital abnormalities and neurodevelopmental difficulties on an ongoing basis. Wait times should not exceed those that would be experienced in a private healthcare setting. Patients of all ages must be catered for.

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II. The government must commit adequate funding to research into the impact of Valproate exposure in utero. This research should be aimed at increasing understanding of Valproate exposure in utero generally, as well as improving both diagnosis and long-term outcomes through medical and educational interventions.

III. In addition to ii above, research funding should also be provided to the pharmacogenomics (safe mum safe baby), and other relevant research projects. This research will increase the likelihood of prescribers being able to identify the least risky treatment plan for women of childbearing age, as well as our understanding of the teratogenic properties of all seizure medications generally.

IV. Similar provision should be made for teratogens generally.

V. Funding for healthcare and educational needs assessment, monitoring, and treatment and educational provision should be treated as part of the package of non-pecuniary redress measures and must be ringfenced so as to ensure its adequacy on an ongoing basis. Adequacy of funding cannot be dependent upon the budget made available to local Clinical Commissioning Groups and Local Education Authorities generally. This also applies to other known teratogens, as well as those that may come to light in the future.

VI. The adequacy of funding and of healthcare and educational assessment, monitoring, treatment, provision and research should be monitored by an independent redress administrative body responsible for Valproate.

VII. No family affected by Valproate (or any other teratogen), should have to repeatedly subject their child (or children), to assessments done for the purpose of securing adequate healthcare, educational, and/or welfare provision and support, although regular reviews will be necessary in order to monitor progress and both the adequacy and appropriateness of provision and support. Children and young adults affected by Valproate report that they find the constant need to "prove themselves worthy of provision and support" through formal assessments undertaken by numerous professionals to be "dehumanising, humiliating, degrading and stigmatising".

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- The government has not yet provided adequate assurance that they fully take on board the extent of the teratogenic risk that exists in relation to pharmaceuticals. Nor have they demonstrated any real acknowledgment of the potential costs to the taxpayer that this represents, both in the short term and in the long term.
- The ongoing pharma complacency that continues to be observed raises a number of concerns in terms of the ability of local healthcare, education, and social care providers to adequately support and develop this specific area of expert knowledge, or to support and provide for the needs of those harmed.
- The government has not yet detailed how they intend to *guarantee* that specialist research, knowledge sharing/professional development, monitoring, assessment, and provision in relation to Valproate and other teratogens will be adequately funded.
- The government has not yet detailed how they intend to ensure that each and every local provider, together with their relevant employees, has full knowledge of foetal valproate spectrum disorder (or any other teratogen), how this presents, and what the range of healthcare, educational and support needs might be.
- The government is also yet to detail the measures that they will put in place to ensure that those affected by Valproate (or any other teratogen), are not constantly forced to battle for support and provision.
- The process for accessing an Education, Health and Care Plan (EHCP) can be lengthy, particularly when parents have a need to appeal a local authority's decision, as is often the case. This often means that children with special needs experience significant delays in accessing adequate support and provision, to their detriment. It is not appropriate that those harmed by Valproate or other teratogens should be subject to such delays and they must have access to a 'fast-track' type process therefore.
- At this point in time, the government's current response to recommendation 5b is wholly inadequate. Further detail regarding funding, access, and the delivery of support and provision is required.

https://www.bma.org.uk/media/2056/autism-briefing.pdf

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Further general feedback

On the one year anniversary since the publication of the IMMDS Report, **ten of our members have died**, still suffering the guilt that they were responsible for the damage to their babies. How can the Government allow this to continue before acknowledging we have a right to have our evidence heard. We have been fighting this battle since 1978 and it is only with the support of 135 MP's who are members of the All Party Parliamentary Group, for oral hormone pregnancy tests, that the Government agreed to initiate the IMMDS Review. Now they need to ensure the recommendations of the Review are implemented in full.

The Expert Working Group (EWG) Report, published in 2017, commissioned by former Prime Minister, Ms. Theresa May, was managed by the MHRA. As Secretariat to the EWG, the MHRA were responsible for selecting evidence to present to the Group as well as the selection of the EWG members. The evidence presented to the EWG by the MHRA was cherry picked, inadequate and incomplete. Members of the EWG had clear conflicts of interest and unsurprisingly the Report concluded there was no *causal* association, even though the Terms of Reference was to determine if there was a possible association. The TOR were altered without discussion and without advising the Association for Children damaged by HPT's/Primodos. The EWG Report was not independently peer reviewed and the changes to the TOR and conclusions were fully supported by the MHRA. An independent Group of Scientists reviewed the total documentation and concluded the Report was seriously and possibly deliberately flawed. The MHRA have refused to accept the conclusions of the independent and PEER REVIEWED Report on the EWG conclusions and continue to protect the UK Regulator and deny any link to adverse effects and oral HPT's. There is a culture within the MHRA to select representatives with ties to the Organisation and even the Pharma Industry, even if this causes conflicts of interest. The same selection of people are used to enable the MHRA to control the results of inquiries, which are usually in line with their requirements.

The meeting with the MHRA to discuss recommendation 6 was contentious and emotional and failed to provide the reassurance the PR Group needed. It did not help that [the CEO] was included in the representatives from the MHRA as her involvement did not inspire any confidence that the MHRA really want to change their culture of protect and deny. Other representatives from the MHRA who attended the meeting genuinely listened and wanted to know how they could help to improve patient engagement and safety. However, the final decision will not be theirs, despite their desire to effect the necessary changes. We did have some success with the MHRA Policy Leads who did listen and provided feedback to the MHRA, which

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resulted in a written response from [the CEO], which offered a further meeting to discuss the unresolved issues. The meeting is scheduled for late July. Although I live in hope, I also manage my expectations. Recommendation 6 was one of the most important recommendations for discussion, yet was one of the most disappointing and frustrating for every member of the Group.

I was invited by the DHSC, together with another member of this group to contribute to the design of a Condition Insight Report for Primodos, which would assist our families in the event they needed to claim PIP support. The same request was received by the Mesh and Valproate Campaign Groups. After liaising for months, the CIS was finally approved and our families informed. Our families felt such a relief that their condition had finally been recognised and they would not have to continually explain about how they had been affected by an oral HPT each time they were interviewed by the PIP representatives. This quickly turned to utter horror when the CIS was withdrawn, without explanation, just 24 hours before it was due to be published on the DHSC website. The CIS Reports for Valproate and Mesh were implemented in full and remain in use today. The distress caused to our families can not be overstated, yet the lack of Patient engagement meant the DHSC could not recognise the dreadful impact this had on our families. Without patient feedback on how their actions impact on the lives of our families, nothing will change.

Having the opportunity to work with members of the DHSC during the PRG review has enabled the Policy Team within the DHSC to understand the human cost of failing to engage with and listen to Patients. Feedback from members of the DHSC has been positive about the value of Patient Engagement and acknowledged as a way to better understand real life effects of the harms caused by medicines and devices, which is not captured by using statistical information. I feel real progress was made with members of the DHSC, however they will not be responsible for implementing the recommendations, only advising the Ministers who WILL be responsible for implementation of the recommendations.

The Government's failure to engage with families damaged by Medicines and Devices, to listen and understand how they were damaged and accept responsibility, is why The Association for children damaged by oral hormone pregnancy tests have been forced into legal action against both the Government and the Manufacturers.

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Our HPT families have always been disadvantaged, as successive Governments have refused to acknowledge and accept responsibility for the damage caused by oral HPT's, unless we can prove a causal association and it is time this position changed. The Government recently acknowledged and accepted responsibility for the damage caused by Thalidomide, despite the lack of evidence of a causal association and awarded £40 million and a lifetime care package for Thalidomide survivors, which is absolutely the right thing to do. Recommendation 4 advises that separate schemes should be set up for each medical intervention, Mesh, Valproate and Primodos, which would provide redress to acknowledge the damage caused to our families. This could be similar to the package provided to the Thalidomide survivors, however progress is slow and information scarce which does not inspire confidence that this recommendation will be implemented any time soon, or even at all. We were not impressed with the presentation on recommendation 4 and felt there was a distinct unwillingness to engage with the group, together with a total lack of empathy. The recommendation 3 team, were at least honest in their presentation and admitted there had been no progress made on consideration of implementing a separate redress agency. It was apparent the Policy team for recommendation 4 were more interested in the financial impact of redress than in the moral obligation owed to the Patients damaged by medicines and devices. Very disappointing meeting which achieved absolutely nothing.

The Government refuses to accept responsibility for our HPT/ Primodos families, WITHOUT a proven causal association and instead references the results of the 2017 EWG Review, which stated there was no conclusive association, but admitted later in a Sky TV interview and to the IMMDS review team, they did find a possible association. A leading Scientist who has worked for 20 years on research to find the causal link to Thalidomide, stated in May this year *we may never find the causal link* although a possible link for Thalidomide is accepted. The causal association for both Mesh and Valproate has been accepted and therefore there can be no barrier to implementing redress for both these groups. The Government have a moral duty to Patients to ensure their safety and if they fail in this duty then they must provide redress to acknowledge the harm and compensate for the life changing effects suffered by our families. This would include our HPT families.

Baroness Cumberlege stated, both in the Report and on Sky TV, that Primodos should have been withdrawn from use in 1967 after the first substantial Report was published. The response from the Government

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was *the IMMDS Review did not revisit the existing science*. However, although the IMMDS team did not revisit the science, they reviewed all the existing documents, including the scientific evidence available at the time and this evidence formed the solid basis of their conclusions. Another example of the protect and deny culture from the Government.

There was a moral duty for Government representatives of the Committee on Safety of Medicines to protect Patients, but they failed in their duty of care, by suppressing the evidence of harm caused by the drugs. The Government continues to deny and suppress the evidence even today, while supporting the flawed conclusions of the 2017 Expert Working Group Report.

The IMMDS review was funded separately and was therefore completely independent from Government Departments who would be unable to apply pressure on the Group or influence the results of the Report. The recommendations contained in the Report are a true and documented account of the evidence provided to the IMMDS team, all of which was verified by IMMDS as a true reflection of events.

The recommendations are as a direct result of evidence viewed by the IMMDS Team and not on manipulated data which was the basis of the 2017 EWG Report. A Freedom of Information request revealed multiple additions and redactions to the Provisional EWG Report, which had been presented to Government officials, one month earlier. A prime example of protect and deny, still endemic in our Health Service and embedded within our Government Departments. There must be accountability, transparency and acceptance of responsibility when mistakes have been made. How else can the Health Services learn and change.

The manipulation of the data in the 2017 Report has never been acknowledged by the Government and instead forms the basis of their legal defence against our families. We have been forced to take legal action to ensure our evidence is presented and publicly available, which the Government are aware they will be unable to refute. The Government Barrister has accused us of an Abuse of Privilege for bringing the action and are attempting to have the case *struck out* which will ensure our evidence never sees the light of day. How can this be right. How can we be advised that *litigation* is the right way to gain redress. We constantly have to provide more and more evidence, including

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genetic testing by our families, to prove there is no genetic fault to explain the damage to their babies. How will this help our members who lost their babies through stillbirths and miscarriages. What proof will they need to provide. Litigation is brutal, stressful, time consuming and most of all a de-humanising process. We become numbers and statistics, measured only by nuisance value. This needs to change and implementing recommendations 3 and 4 will prove there is a willingness to change the existing culture, acknowledge harms and improve patient safety for the future.

Apologies by the former Health Secretary Matt Hancock and Minister Nadine Dorries were a worthless and pointless exercise used purely as a public relations exercise. Without a firm intent to provide some form of redress, to acknowledge and accept the avoidable harm caused by our own Health Regulators, I consider the apology an insult to our families. At present it appears redress or a care package will not be provided by the Government for HPT's/Primodos families, as the criteria to include a demand for proof of a causal association is a deliberate barrier to prevent acknowledgement and accountability for the harm caused by historic and current Regulatory failures.

My personal view of the meeting with Ms. Dorries is that it was another exercise in being seen to do something without providing any substance or real intent. The Minister said she was there to listen, but although she may have listened she did not hear. I felt patronised and marginalized, but also angry that such an important opportunity to learn from patients who have been harmed, was treated as no more than a tick box exercise in her very busy schedule. The raw emotion from our Group was palpable, yet the Minister was completely unmoved and offered platitudes where there should have been empathy and understanding. We didn't want to know about planned public consultations, WE are the public!!

The incredible work by the IMMDS team and Baroness Cumberlege will be a waste of time and public money, if all the recommendations in the Report are not implemented. Each campaign group deserves to be recognised for the suffering they have endured and only by implementing the recommendations will this ensure our Health Service is fit for purpose, which is to protect Patients from harm now and in the future.

Our families owe a huge debt of gratitude to Baroness Cumberlege and her team for the dedicated, thorough and impartial way they conducted the review. Please don't let the recommendations in this incredible Report end up in a box in Westminster.