Meeting 3 – 29/04/21

Introduction and Welcome:

The co-chair gave apologies on behalf of absent members.

Due to Sophie leaving the group for personal reasons, Traverse also explained the process of selecting a new group member. This involved reviewing application scores again, with consideration given to finding someone who could represent similar interests and demographics to the original group member. Our new member, Branwen, then introduced herself, thinking about the same three introductory questions all other group members spoke to in our first meeting.

The MHRA team introduced themselves.

Traverse reminded the group of the ground rules and the access to the counselling service hosted by Victim Support should anyone need it.

Matters arising from Session 2 and DHSC update:

The department updated on the progress on Recommendation 8, part B (mandatory reporting of payments) stating that the relevant policy team are working closely with the part A team and are looking at options for this recommendation. The policy team have been given the summaries from previous meetings, and have been informed that the group feels strongly that mandatory reporting of payments should be essential. DHSC officials thanked group members for their clear messaging on this part of the recommendation.

Group members noted that they would welcome an update on how the policy team plan to take part B forward. The department agreed this would be useful and will look into scheduling, bearing in mind that there is a restriction on time.

Recommendation 6 Discussions:

The MHRA gave a short presentation on their work in relation to recommendation 6, *the MHRA needs substantial revision, particularly in relation to adverse event reporting and medical device regulation. It needs to ensure that it engages more with patients and their outcomes. It needs to raise awareness of its public protection roles and to ensure that patients have an integral role in its work.* This was followed by a short Q&A, and two group breakout room discussions. This followed the format of previous meetings.

The key points which arose from the group were:

Vigilance systems and adverse event reporting:

- A number of group members felt that reporting of adverse events for all devices and medicines should be mandatory, and that there should be a publicly searchable database of reports. Implantable devices and medicines taken during pregnancy were cited as priority areas.
- The visibility of vigilance systems such as the Yellow Card scheme could be improved. The onus should not be on the patient to know about these systems and disseminate information to others. Rather, the responsibility should be on the MHRA and other organisations to raise awareness. Examples given were the role that GPs and Pharmacists could play in raising awareness of vigilance systems.
- Vigilance systems should be more responsive. Some group members thought that systems should give an acknowledgement of receipt, as well as a timeframe on receiving a response to a report.
- Some group members thought that 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.

Patient engagement:

- Group members and the MHRA agreed that for the MHRA's culture change programme to be a success, enhanced patient engagement would be essential.
- Patient engagement must be meaningful. 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. 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.
- 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.
- There is a need to collaborate with other organisations such as NICE, CQC and PHE so as not to overload patients with requests was also noted

The MHRA team took away some questions that there was not time to answer on the day, and will provide a written response to the group.

Wrap up and close:

The co-chair thanked members for their contributions and asked for any further questions to be sent by email to be addressed by MHRA after the session.

Meeting 4 is on the 27th May and this meeting will cover recommendations 3, 4 and 7.
Traverse updated the group that an additional meeting be held from 11-1.30pm on June 15th for the Minister of State Nadine Dorries to attend and listen to the group.

The co-chair and Traverse will also be giving a progress update to the First Do No Harm APPG on 21st May.