Medicines and Healthcare products Regulatory Agency

12 September 2016

Working with the Devolved Administrations

Issue/ Purpose:
This paper provides information on the Agency's activity to engage and collaborate with the Devolved Administrations (DAs) of Scotland, Wales and Northern Ireland and considers what the coming months and years may mean for our relationship. It seeks the views of the Board on how to enhance further collaboration.

Summary:
The relationship with the Devolved Administrations has been much improved over the past year, primarily through the quarterly Cross-UK group which was set up in order to improve communications and engagement. Prior to this the DAs had not always felt sufficiently included and consulted on Agency activity that affected them.

Following the success of the Cross UK group it might now be an appropriate review point to consider if the relationship could be further enhanced including the case for a Partnership Agreement between the Agency and the DAs.

Suitable for team briefing?
Yes

EU Referendum implications
Devolved Administrations will be keen to ensure ongoing good communication and engagement with the Agency, and a regulatory landscape that continues to meet their needs.

Action required by the Board:
The Board is asked to consider key points highlighted in preliminary action note.

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Are there any sensitivity issues that would prevent this item being discussed by CET in the presence of staff observers?
NO

Which of the five themes in the Corporate Plan 2013/2018 does the paper support?
Vision, Scope and Partnerships

If relevant, which Business Plan strategic activity does it support?
Build closer and stronger collaboration with other partners in the health and care system

CET Sponsor: Jonathan Mogford, Director of Policy

ANNEX A

WORKING WITH THE DEVOLVED ADMINISTRATIONS

Purpose

1. This paper provides information on the Agency's activity to engage and collaborate with the Devolved Administrations (DAs) of Scotland, Wales and Northern Ireland and considers what the coming months and years may mean for our relationship. It seeks the views of the Board on whether there are ways in which the relationship might be enhanced further.

Background

2. Over the past year, our strategic relationship with the DAs has been much improved, principally through regular quarterly meetings in the form of the Cross-UK Forum, which provides a constructive and clear channel to enhance working relationships and ensure engagement on key issues. Prior to this the DAs did not always feel sufficiently included and consulted on Agency activity that affected them. Many of these issues have now been resolved through discussion and agreement at the operational level and regular, focused consideration of the DAs' concerns.

3. The Cross-UK group does not supersede day to day business, which is still conducted directly between relevant divisions of the Agency and their counterparts in the Scottish, Welsh and Northern Irish Health and Social Care systems. For example, Vigilance and Risk Management of Medicines Division hosts monthly teleconferences on medicines safety issues with the DAs, and Devices Division is establishing a similar process; Policy Division held a specific teleconference recently to seek detailed views and ideas from the DAs on the Agency's burden reduction programme, and there have been a recent series of visits to the DAs by Policy Division officials to work on the implementation of the Falsified Medicines Directive.

4. Cross-UK group meetings are used to:

    - brief the DAs on, and provide an opportunity to discuss, MHRA strategic priorities;
    - discuss key documents sent to the DAs for consultation (e.g. the Corporate Plan update 2016, Business Plan 2016/17and Innovation Plan); and
    - update on issues of particular interest in different parts of the UK (for example TVT mesh, which remains a hot topic in Scotland).

Issues of Current Interest to the DAs

5. In the light of the EU Referendum result, the DAs are likely to want to ensure consistency of service from MHRA and to be consulted on changes that may take

place to ensure that the regulatory services of MHRA continue to meet their needs. Matters that affect the DAs will be the subject of significant consultation work, most probably via a set of bespoke meetings as well as being on the agenda for quarterly meetings for the foreseeable future.

6. Issues of particular operational interest to the DAs and covered at recent meetings have included:

Medicines Safety

- VRMM has been holding monthly teleconferences with representatives from the DAs to update on ongoing safety issues since April 2015. An issues register is circulated every month prior to the teleconference and includes an update on important ongoing medicines safety issues. The agenda for the teleconference also includes advance notice of articles which are due to be published in that month's Drug Safety Update.

- The initial plan had been to replace the teleconferences with written monthly communication if attendees felt they were no longer necessary; however the teleconferences continue to be well attended. The routine interaction has led to increased understanding among the DAs of the regulatory processes and has provided them with advanced notice of regulatory communications. The benefits for MHRA have included useful intelligence on local issues relevant to the regulatory position and feedback on the impact of regulatory communications.

Medical Devices

- Devices Division have been updating the DAs on progress with the high profile safety issues of common interest including metal on metal hip implants, vaginal tapes and meshes, and breast implants. There has also been briefing provided on the more strategic safety and surveillance work including the Agency Patient Safety and Surveillance Strategy, integrated the Local Risk Management System reporting project being undertaken with the National reporting and learning system staff and NHS Improvement.

- Devices Division has also begun to hold separate regular operational teleconferences on reporting developments which have covered such topics as:
  - standardising on the Global Medical Devices Nomenclature;
  - impact of encouraging healthcare professionals to report incidents to MHRA on the DA's reporting systems, sharing information, and parallel investigations
  - updates on IMDRF terminology development
  - update on WEB RADAR and future mobile reporting applications for medical devices.

Patient Relations

- Information about the Agency's Patient Group Consultative Forum (PGCF) was circulated to the DAs in early 2016. This was followed by a

presentation, delivered to the 20 April Cross-UK meeting, to provide more details about the operation of the PGCF and its involvement in the work of the Agency's regulatory divisions to date. The PGCF team will be following up with Scotland and Northern Ireland on areas of shared interest and opportunities for future collaboration in relation to the activities of the PGCF.

- Each DA has a place on the Agency's UK Medicines Reclassification Platform, which also includes representation from patient groups and relevant healthcare professional bodies.

- The Agency's approach to engaging on specific issues affecting patients seeks to include the DAs where relevant. For example, Wales has been represented at multi-stakeholder meetings about Sodium Valproate and Scotland has been involved in work on TVT.

Enforcement

- Enforcement powers under medicines legislation are, in the main, the responsibility of the Secretary of State for Health. The enforcement role is undertaken by MHRA for Scotland and Wales; in Northern Ireland it is undertaken by the Department for Health, Social Services and Public Safety Northern Ireland.
- The Scottish and Welsh governments are content that operational activity and strategies concerning medical product crime are covered by the MHRA and engage specifically when there is Ministerial and / or media interest. Operational activity in Scotland is often supported by Police Scotland and the MHRA participates in a working group dealing with illicit trade under a Police Scotland chair.
- Links to DAs are also established through the Controlled Drugs National and Cross Border Groups, organised by the Care Quality Commission. All DAs are represented.
- The Inspectorate also undertakes inspections in NI, Scotland and Wales.
- The British Pharmacopoeia (BP) works closely with the DAs, for example, to gain their agreement for BP Commission member appointments/reappointments and to gain agreement to publish the BP each year.

Progressing relationships

7. There are indications – not least from the positive engagement at quarterly meetings – that the strategic engagement and focused communication which the group provides has made a positive impact on relationships. It is clear that at the operational level the meetings are being seen as a useful way of sharing information and progressing business.

8. Relationships between the Agency and DAs have been further enhanced by bilateral meetings between the Agency Chair and Chief Executive and senior partners in the Devolved Administrations, as well as invitations to the DAs to attend Board meetings as observers.

9. There is, though, a continuing concern that the quarterly group meetings may not be seen as sufficiently high priority at senior (Chief Pharmaceutical Officer) level in the DAs. The Secretariat is considering what more can be done to ensure that the meetings deliver sufficient value to encourage that senior level engagement, and will continue to seek the DAs' views. This will form a substantive item for discussion at the next quarterly group meeting in October.

10. The Board is invited to suggest ways in which the relationship and collaboration between the Agency and the DAs can be further strengthened. One option which has been mooted is whether the time is now right to move to a more formal partnership agreement between the Agency and DAs.

11. The Agency's Framework Agreement with the Department of Health (DH) sets out that:

    'As the Agency exercises its functions on behalf of the UK, it consults the DAs on, and keeps them informed of, proposed changes to legislation, policy and practice that affects them as well as giving advance notice of (and the opportunity to observe) and investigations or inspections of manufacturers based in their country'.

12. The question is whether a separate agreement with the DAs would add anything beyond this existing commitment. On the other hand, MHRA is seeking partnership agreements with other bodies in the Health and Social Care system and there may be a benefit of having a partnership agreement with the DAs in setting out a similar commitment to key areas of collaboration..

Next Steps

13. The next quarterly meeting will take place on Wednesday 26 October and the agenda will include: the implications of Brexit for the Agency's work and relationships with the DAs; Regulatory Excellence and Burden Reduction; Hot Topics; updates on other medicines safety issues; and options to enhance the work of the group and further improve relationships.

14. It is anticipated that the group will continue for the foreseeable future, along with the more detailed day to day work between the Agency and DAs. For logistical reasons meetings are generally held by teleconference, though there is an open invitation to DA colleagues to join in person at Buckingham Palace Road, and the Agency has committed to travel once a year to one of the DAs for the meeting . Last year this took place in Edinburgh and DAs have been invited to consider whether one of them would like to host one of the coming meetings.

Conclusion

15. The Board is invited to note the contents of this paper and make suggestions for further enhancing collaboration and building on the progress already made to improve relationships..

Policy Division