

Medicines and Healthcare products Regulatory Agency

24 April 2017

International Strategy

Issue/ Purpose: Update on the proposed Agency International Strategy

Summary:

The Agency's international work has become increasingly established over the past 5 years, focusing in particular on work to strengthen the security of supply chains from key global source countries and on work with other leading stringent regulators (in both pharmaceuticals and devices).

The UK's recent election to chair the International Coalition of Medicines Regulatory Authorities (ICMRA), and the work done under that banner on sharing of inspection information, together with active work on the global aspects of devices regulation, biological standards and use of real world information demonstrates that the Agency is seen as a leading global agency. There are, nevertheless, good reasons to take the international work of the Agency to the next level.

The attached paper pulls together the current and planned activities across the Agency. It demonstrates both the interest and commitment across the organisation to developing the Agency's global role, but also the value of ensuring that this is clearly joined, is ambitious, is progressed to clear purpose and objectives, and makes effective use of resources.

Following CET consideration at the March meeting it was agreed that the existing cross Agency group will periodically review the strategy and report back to CET.

Three key areas of focus for our international work include:

- i) Brexit, taken forward through the established Agency task force.
- ii) Security of the global supply chain
- iii) International opportunities to offer services and support other regulators using external financial support from for example, Gates or DFID.

To that end, the Board is invited to comment on:

- The direction of travel for this stage of the Agency's developing international work;
- The suggestions for managing the international work of the Agency strategically, ensuring effective use of resources.

Resource implications:

As the background analysis demonstrates, the Agency devotes considerable resource to its international work. Some resource will be needed to turn the material in the attached paper (which it is proposed should become a living document) into a programme of priority actions to develop and test these options further.

EU Referendum implications:

The outcome of the Brexit negotiations is likely to impact on the Agency's international strategy.

<p><u>Timings:</u></p> <p>Ongoing</p>
<p><u>Action required by Board:</u></p> <p>The Board are invited to consider the Strategy document, its status, proposed approach and provide feedback or comment on how it might be further enhanced.</p>
<p><u>Links:</u></p> <p>N/A</p>
<p><u>Author(s):</u></p> <p>Sam Atkinson, Deputy Director, IE&S Andy Gregory, Deputy Director, Policy Contributions also received from Divisional Representatives</p>
<p><u>Which of the five themes in the Corporate Plan 2013/2018 does the paper support?</u></p> <p>This is a cross-cutting issue.</p> <p><u>If relevant, which Business Plan strategic activity does it support?</u></p>
<p><u>CET Sponsor:</u></p> <p>Jonathan Mogford, Director, Policy Gerald Heddell, Director, IE&S</p>