Medicines and Healthcare products Regulatory Agency

Board Meeting - public session 24 April 2017

Update on Global Communications Programme to tackle SSFFC Medical Products in conjunction with WHO

Issue/ Purpose:

The MHRA is leading a World Health Organisation (WHO) initiated global communications programme against Substandard, Spurious, Falsely labelled, Falsified and Counterfeit (SSFFC) medical products over a 3-year period, (2016 – 2018).
The purpose of this paper is to provide the board with an update on the progress made during 2016 and outline our plans for 2017 and 2018

Summary:

At the November 2015 meeting of WHO Member State Mechanism (MSM) Steering Group held in Geneva the UK volunteered (and was endorsed), to lead one of eight workstreams prioritised by WHO to have a major impact on addressing, reducing and ultimately eliminating SSFFC medical products. The focus of the activity is to learn, share, and develop global communications thinking and campaign development amongst all 194 member countries of WHO, with particular emphasis on the prevention of the use of SSFFC medical products.

This paper provides an update on the work programme that has been undertaken in 2016, focussing on the programme set up, engagement with WHO Member State Mechanism, and key stakeholders, and providing information on the elements of the communications workstream that will be further developed during 2017 & 2018 to deliver this activity, together with the resources allocated.

Resource implications:

MHRA is supporting the programme through the provision of a dedicated Programme Manager on a 3-year fixed term contract to coincide with the planned programme duration.

EU Referendum implications:

There are no direct EU referendum implications, but it is recognised that the UK's leadership and expertise on this vital piece of work can enhance and reinforce the agency's international reputation for innovative and collaborative working in a pre and post-Brexit environment.

Timings:

This is a 3-year programme from mid-January 2016 to mid-January 2019

Action required by Board: The Board is asked to note the significant progress that has been made to date on the project, and the continued development of the programme.
Links: http://www.who.int/medicines/regulation/ssffc/en/
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Which of the five themes in the Corporate Plan 2013/2018 does the paper support? Theme 1: The role of regulation and the regulator Theme 4: Safe medicines and devices and secure supply in globalised industries **If relevant, which Business Plan strategic activity does it support?** Annex C to the Business Plan 2015-16 “IE&S/Communications to promote the safe purchase of medicines/devices”
CET Sponsors: Rachel Bosworth, Gerald Heddell

1. Introduction

The agency's Corporate Plan and Business Plan for 2015/16 highlights the need for continued effective communication with patients and the public, so they are better informed about the risks and dangers of sourcing medicines and medical devices from outside the assured supply chain, for example, by purchasing products from unregistered online sources.

Ahead of the annual WHO full Member State Mechanism (MSM) meeting in November 2015, CET approved a proposal for MHRA to lead on a specific Communications & Campaigns workstream aimed at equipping countries globally with the understanding and insight to improve the impact and effectiveness of their communications surrounding the risks of Sub-standard, Spurious, Falsely labelled, Falsified and Counterfeit (SSFFC) medical products.

MSM endorsed the UK (MHRA) as lead country for this activity, and a Programme Manager was recruited during January 2016 to lead the work.

As well as contributing to this important WHO workstream, the programme will be helpful to raise the agency's profile as a thought leader and communications innovator, and enable further international relationships and joint working opportunities to be identified with key partners, reinforcing our global public health reputation in a current and post-Brexit environment.

The overall approach of the programme dovetails well with the UK's current campaign to support the introduction of the Falsified Medicines Directive (FMD) across EU member states. Good consumer understanding allied to strong creative and innovative use of digital communication has produced encouraging attitudinal and behaviour change amongst target audience groups. It is envisaged that future development of the two workstreams will provide reciprocal insights and learnings that will be able to be adapted and adopted at a later stage by either programme.

2. 2016 Work Programme Progress Report

One of eight prioritised SSFFC activities, the communications workstream (Activity E) has been tasked with developing, sharing and evaluating the impact of a co-ordinated and cohesive global communications programme.

Phase 1 of the project during the first half of 2016 required a deep immersion in the subject content and the creation and building of a representative global communications community to contribute, advise and act as 'critical friends'.

As part of the programme, we established a Communications Working Group (CWG), comprising specialist communication experts from each of the six regions of WHO.

It was very important from the outset that the work developed and recommendations put forward be seen as the result of significant consultation and collaboration with member states and not be euro or indeed UK-centric. This approach was essential in order to engage member states and encourage diverse contributions to ensure that the insights generated and the outputs developed would be relevant to everyone.

During this early phase, we also established protocols and methodologies to help develop the work, including:

- Setting up the programme with WHO and putting in place consultation and collaboration mechanics utilising the WHO Mednet platform

- Establishing internal governance with a MHRA steering group, comprising senior managers from IE&S, Communications, and Devices to enable the work to dovetail with the agency's domestic campaign and policy work, and to allow reciprocal information sharing across our international stakeholder base

- Delivering a presentation of an initial Draft Communications Plan to the March 2106 steering committee of WHO MSM

- Preparing a first draft of a communications framework and timetable which was distributed to CWG members for critique and feedback

Phase 2 of the project through the remainder of 2016 helped to consolidate and progress the work with a continued focus on recruiting and engaging more subject matter experts to join the Communications Working Group, which now consists of:

WHO REGION	**CWG members**			
Europe	Sweden	Italy	Norway	UK
Africa	Senegal	Nigeria	Tanzania	
Americas	Argentina	Brazil	USA	
Eastern Mediterranean	Iran			
S.E Asia	Indonesia			
Western Pacific	Singapore	Republic of Korea		

In advance of a global piece of communications research planned for spring 2017, we undertook a pilot programme with CWG member countries to determine current user insight, market conditions and to establish baselines.

To ensure the outputs from the work are practical and usable we also used the research as a platform to understand which component parts of communications advice, (in essence a toolkit), would be most valued, as well as beginning to identify and assemble a collection of exemplar campaigns to be shared. The learnings from this research have helped to inform our work programme priorities and outputs for 2017/2018

As the programme developed, it became clearer that if we want to maintain relevance and pertinence over time we need to involve broader public stakeholder groups, including academics, healthcare policy makers and practitioners, as well as the wider communications industry --- all of whom can help us build a comprehensive and contemporary "Communications Knowledge Bank".

We were able to supplement this learning through participation at a wide range of relevant events, which largely focused on either best practice sharing or emerging communications thinking. Highlights included:

- European Heads of Medicines Agencies Working Group of Communication Professionals (chaired by the UK),
- Communications workshop with colleagues USFDA, Washington.

- Europol hosted EHFCN (European Healthcare Fraud & Corruption Network) workshop,
- MSM “Best Practice” workshop on Communication to the Public about the Common Logo and Falsified Medicines,
- Fakeshare Conference
- Global Quality of Medical Products Symposium & Networking Event, London School of Hygiene and Tropical Medicine.
- Global Human Behaviour Change Project: UCL, London.
- Global Social Marketing Conference, Helsinki.
- Hosting communications workshop at ICDRA (International Conference of Drug Regulatory Authorities) Capetown, South Africa

During this period and the early part of 2017 we also worked alongside WHO within their established protocols to undertake exploratory conversations with leading healthcare donors to determine their appetite to participate in the activity and provide resources/support. So far, we are in advanced discussions with one group and at a preliminary stage with another. Our planning for the second half of 2017 and first half of 2018 is dependent to an extent on the outcome of these discussions.

Our base scenario will be to undertake global research, -- aggregate, analyse and interpret the results, and then develop practical guidance in the form of workbooks/papers for member states irrespective of funding inputs. We are confident we will be able to achieve this with the resources we have within WHO/ MHRA, albeit that we will need to identify a small budget allocation for design, production and publishing.

In the event that we are successful with one or more of our bids, this will enable us to ramp up our activity plan and run communications pilot activity in one or more member states to test the real-world validity of any hypotheses we develop from our research work.

This in turn will lead to improved impact, efficiency and effectiveness of campaigning and thereby ultimately inform the quality and content of the long-term advice we are able to develop and share.

3. Looking Ahead to 2018 and beyond

Key components of our future, refined approach are likely to reflect a strategy that will enable us to improve, support and develop communications planning using best-practice behaviour change campaigning/activity and begin to develop global benchmarking standards or Key Performance Indicators (KPI’s) for campaign impact measurement.

As well as sharing exemplar activity to ensure coherence and consistency of thinking we hope to be able to generate original creative and communications channel planning guidance and work with CWG contributors to develop a legacy plan that will enable the work to continue organically post the conclusion of the 3-year programme.

This will be particularly important given the rapid change(s) in communications planning and delivery and the increasing impact of digital technology not only as a communications delivery channel but also increasingly as a product and advice interface for patients and public.

4. Recommendation

The Board is asked to:

1. Note the substantial progress made in establishing this programme of work over the last 12 months
2. Support MHRA's continued leadership of this work,

5. Conclusion

This programme has gained traction with WHO, member states and a number of interested, and potentially valuable stakeholders.

The board is thus asked to note progress that has been made on the project to date, support the plan for 2017, and share our ambition for 2018 and beyond.