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Medicines and Healthcare products Regulatory Agency

Board Meeting - public session 20 October 2017

Operation Pangea 2017 – tacking the illegal trade in medicines and medical devices – update

Issue/ Purpose: Provide the Board with an overview of the results of Operation Pangea X	
Summary: This paper sets out the background to Operation Pangea X and provides a breakdown of the results and activities from a UK and international perspective	
Resource implications:	None
EU Referendum implications:	None
<u>Timings:</u>	N/A
Action required by Board: To note the activity and comment as appropriate	
Links:	None
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Which of the five themes in the Corporate Plan 2013/2018 does the paper support?	
Theme 4 – safe medicines and devices and secure supply in globalised industries	
Theme 1 – role of regulation and the regulator	
If relevant, which Business Plan strategic activity does it support?	
CET Sponsors:	Gerald Heddell

Introduction

Operation Pangea is the name given to a coordinated week of action targeting the illicit sale of medical products via the internet. It was instigated in 2008 by the MHRA who were then joined by a small number of likeminded countries. Now coordinated by Interpol, it has grown to be their largest global operation. MHRA officials have been members of the organising committee since its inception and provide staff to support the operational week of action at the Interpol command centre in Lyon, France

Global Results

From a global perspective, the engagement of countries has exceeded all previous operations with 123 countries involved comprising of 197 police, customs and regulatory agencies. 1058 investigations took place and 400 suspects were placed under investigation. As well as raids at addresses linked to the illicit pharmaceutical websites, some 715,000 packages were inspected and 470,000 seized by customs and regulatory authorities. Through this activity, 25 million illicit and counterfeit medicines were seized amounting to a value of more than £38,000,000. In addition to medicines, Operation Pangea X also focused on the sale of illicit medical devices, such as dental devices, implants, condoms, syringes, medical testing strips and surgical equipment.

Of note, this year's operation saw the highest participation of African countries, many taking part for the first time, underscoring the global nature of the illicit online pharmaceutical trade. For example, in the country's first year participating in Operation Pangea, authorities in the Democratic Republic of Congo confiscated nearly 650 kg of illicit anti-malaria pills.

UK Results

Websites that allow the unlawful sale of medicines were targeted as part of the operation. Of the 3584 websites closed globally, the MHRA was responsible for investigating and closing 3413.

During the coordinated week of action, the UK inspected almost 1,500 packages and seized 1,333,597 units of medicines valued at £4 million. Of this total only 48 units (>0.004%) are suspected of being counterfeit, the vast majority of medicines seized were unlicensed. Medicines from a range of therapeutic categories were seized and included those used for treating erectile dysfunction, narcolepsy and breast cancer. Although there were 28 countries of origin, the primary sources were India, China, Hong Kong and Singapore. During the week of action twenty-three investigations were instigated and five search warrants executed.

At the conclusion of the Operation Pangea week of action, it is important to emphasise that investigations continue and are, consequently, not reported in the Interpol figures. For example, Operation Daniel which resulted in the conviction of 12 suspects at the Central Criminal Court originated from the activity during the week of action some years ago. Six suspects were together sentenced to over twenty-five years imprisonment and six defendants received suspended sentences totalling over four years for the sale of counterfeit and unlicensed drugs including Viagra.

The UK is one of the most progressive countries when it comes to Operation Pangea activity and in many respects, this type of enforcement activity is business as usual. Over and above the coordinated week of action, the MHRA carry out a range of activity throughout the year under the banner of 'Pangea'; two examples of this activity are as follows:

Operation Arca

This was the first joint National Crime Agency (NCA) / Border Force (BF) / MHRA operation targeting shipping containers and external temporary storage facilities at Felixstowe and London Gateway. The MHRA objective was to increase focus around medical devices. Various non-compliant medical devices were seized including ophthalmic equipment, dental compressors, wound dressings and surgical instruments. During the operation chemicals used in the production of antibiotics were identified which had been falsified by changing the expiry dates. Due to international trade laws (not entered the UK) cooperation with the Indian Authorities took place and the products were seized at Mumbai, investigations undertaken and arrests made.

Operation Lascar

Following concerns that the UK was being used by criminals as transit country to the USA a joint operation took place with Border Force, US FDA and MHRA targeting parcel facilities and cargo at London Heathrow Airport. A total of 349,079 doses of medicine and 7,200 medical devices were seized across the three days of activity. The value of these seizures is estimated at in excess of £1.3 million.

Conclusion

The operation Pangea brand is exceedingly strong; the challenge for Interpol and the organising committee is how to further develop this activity maintaining its relevance for all countries and maximising the opportunities to raise awareness that this type of global operation provides. The participating countries are at very different stages with some leveraging the week of action to raise awareness of medical product crime within their own jurisdictions to countries that have sophisticated and dedicated enforcement in this area and undertake activity throughout the year as a matter of course.

While the numbers of medical products seized are impressive and help to drive media interest and consequently raise awareness of the dangers of falsified medicines, this should not be a numbers game. There needs to be more sophisticated measurements of success and an aspiration to integrate 'Pangea' enforcement activity into business as usual.

It is understood that there is funding for another four operations and the MHRA will continue to play a lead role in the organising committee with a view to driving improvement.