EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Amsterdam, 11 December 2020

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COVID-19: Notice to wholesalers and parallel distributors

EMA and its partners in the European medicines regulatory network[1] are closely monitoring the potential impact of the outbreak of coronavirus disease (COVID-19) on the supply of medicines into and within the EU.

On 2nd December, INTERPOL issued an Orange Notice warning of the imminent threat of potential criminal activity in the Falsification, Theft and Illegal Advertising of COVID-19 and Influenza Vaccines (https://www.interpol.int/News-and-Events/News/2020/INTERPOL-warns-of-organized-crime-threat-to-COVID-19-vaccines), and EUROPOL has issued an Early Warning Notification on Vaccine-related crime during the COVID-19 pandemic.

We are therefore requesting wholesalers and parallel distributors to increase their vigilance to prevent the distribution of falsified or stolen medicinal products.

Both Interpol and Europol are warning that high demand for COVID-19 and influenza vaccines will likely attract organised crime groups seeking to capitalise on the pandemic situation and subsequent vaccination campaigns.

Medicines that also could be targeted include those for treating vulnerable patients and those for relieving symptoms of COVID-19.

EMA and its partners are reminding wholesalers and parallel distributors:

- To exercise extra caution when considering offers from new suppliers and report suspicious offers to their national competent authority.
- To qualify and approve any new suppliers before procuring medicines from them and only obtain supplies from holders of wholesale dealer authorisation (WDA) or manufacturing import authorisation (MIA) located in the EU. The authorisation of the WDA or the MIA holder should be checked on EudraGMP and there should be no GMDP non-compliance statement.
- To ensure customers are approved.

[1] The network includes national competent authorities and the European Commission.

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- To verify the authenticity of the safety features of packs in physical possession in accordance with Article 20 of Directive 2011/62/EU.
- To ensure adequate safeguards are in place to discourage theft from premises or during transit.
- Ensure that any returns are properly secured and disposed of in a secure method to prevent diversion of medicines.
- To pay extra attention to OTC products (such as paracetamol) bearing no safety features.

Wholesale distributors intending to import medicines into the EU from third countries must hold a manufacturing authorisation (MIA). Please refer to the EU's Good Manufacturing practice (GMP) and Good Distribution Practice (GDP) guidelines for further information.

If you do receive a medicine that you suspect may be falsified, contact the marketing authorisation holder, the relevant authority (EMA or the national competent authority).

EMA and its partners in the European medicines regulatory network would like to thank wholesalers and parallel distributors for their diligence and co-operation in protecting public health.