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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Lines to take

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Coronavirus outbreak: EU medicines network is monitoring potential impact on medicines supply

- Chinese authorities have identified a cluster of novel coronavirus 2019-nCoV infections in Wuhan, Hubei, China. Cases have now been detected in several countries in Asia, but also in Australia, Europe and North America. Further global spread is likely. The 2019-nCoV is a new strain of coronavirus that has not been previously identified in humans. It is similar to the coronavirus responsible for the 2002-2003 SARS outbreak.
- Many active pharmaceutical ingredients are produced in China and the virus outbreak is affecting the manufacturing capacity and stability of the supply of these ingredients (due to shutdowns of factories and transportation networks). This could potentially lead to shortages of medicines worldwide.
- Marketing authorisation holders are responsible for continuity of supply of their medicines and should ensure that their supply chains are sufficiently resilient to withstand supply disruptions. Resilience measures may include holding additional inventory or having alternative sourcing of products and materials.
- Marketing authorisation holders and manufacturers are required by EU legislation to inform regulatory authorities well in advance in the event of supply disruptions leading to shortage or market cessations.
- EMA has so far not received any reports of supply disruptions due to the outbreak of novel coronavirus (2019-nCoV) affecting centrally authorised products.
- EMA is analysing and monitoring the situation in relation to the potential impact of the outbreak of 2019-nCoV on pharmaceutical supply chains in the EU.
- EMA is collaborating with EU competent authorities to obtain further information including information on nationally authorised products. EMA is also collaborating with international partners.

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- In addition, EMA is setting up, in consultation with the EC and the HMA Management Group, a coronavirus Steering Group on the availability of human and veterinary medicines to provide a strategic steer in case of shortages of medicines due to the coronavirus that require urgent and coordinated action within the Network to manage and control the situation.
- EMA will further communicate as necessary.

Addressing problems with medicines' supply in general: Role of the HMA-EMA Task Force on Availability of Authorised Medicines

- The HMA/EMA Task Force on Availability of Authorised Medicines was set up in 2016 to develop and coordinate actions to facilitate better prevention, identification, management and communication of shortages. Shortages or problems with availability of medicines in the wider sense have been a global problem for the past decade and are increasingly affecting the EU/EEA. They have been increasing in severity in recent years and are affecting many commonly used medicines including antibiotics, anaesthetics and oncology medicines. By bringing together experts from EU Member States, the work of the Task Force lays the foundations for an improved and harmonised EU approach in addressing the problems of medicines' availability issues. In the context of Brexit, the Task Force is facilitating the exchange of information between Member States, EMA and the EC on issues affecting the availability of medicines. More information on the Task Force can be found here: https://www.hma.eu/522.html
- The Task Force's workplan can be found on the following link: https://www.ema.europa.eu/en/documents/work-programme/work-programme-hma/ema-task-force-availability-authorised-medicines-human-veterinary-use_en.pdf