



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Inspections, Human Medicines, Pharmacovigilance and Committees Division

Crisis simulation exercise coordinated by EMA in October 2017

The EU Regulatory Network Incident Management Plan for Human Medicines (EU-IMP) aims to ensure that concerned bodies in the European Union (EU) take appropriate action whenever incidents (new events or information) which could have a serious impact on public health arise concerning human medicines. It covers medicines authorised centrally, nationally and through the decentralised and mutual-recognition procedures.

The EU-IMP has been in operation within the EU regulatory network since September 2009. The plan's execution involves representatives from the European Medicines Agency (EMA), the European Commission (EC) and medicines regulatory authorities in the EU Member States (MSs). The current guidance regarding the EU-IMP is available publicly on the [EMA website](#).

The Pharmacovigilance and Epidemiology Department of the EMA coordinated a crisis simulation exercise in October 2017. The exercise aimed to test the EU-IMP in the case of a potential crisis situation. As per the EU-IMP, a crisis is defined as situation where, after assessment of the incident's associated risks, routine measures are not considered sufficient and therefore urgent and coordinated action within the EU Regulatory Network is required to manage and control the situation.

The exercise was based on a fictitious scenario, involving the suspension of use of a fictitious centrally authorised medicinal product (with a number of nationally authorised products marketed in various MSs containing the same active substance) in a MS following the receipt of a number of fatal case reports by the National Competent Authority of the respective MS. As part of this exercise, an Incident Review Network (IRN) teleconference was organised, and following the recommendation of the IRN, the EU-Executive Task Force (EU-ETF) was convened, with the overall aim to confirm whether the fictitious situation constituted a crisis, and to agree on the next steps. The exercise involved members of the IRN, EU-ETF, EC, EMA and MSs.

This was considered a very useful exercise which demonstrated that overall the EU-IMP works well. Apart from testing the system and raising awareness, this exercise will also enable EMA to further streamline relevant procedures and guidance. The lessons learned from the running of the crisis simulation exercise (which will also be carefully considered for the organization of any future similar exercises) cover areas such as: process streamlining, communications and interactions, membership and technical considerations. The existence of clear roles and responsibilities, good communication channels and a streamlined process were highlighted as prerequisites for ensuring timely coordinated actions in the case of potential incidents/crisis situations.

