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20 years of sampling & testing programme for medicines authorised for the EU

The European Directorate for the Quality of Medicines & Healthcare (EDQM) and the European Medicines Agency (EMA) have reviewed EMA's sampling and testing programme for centrally authorised medicines on the EU/EEA market, which has been organised yearly since 1998.

The number of centrally authorised medicines tested every year has steadily increased from nine in the 1997-1998 pilot project to 58 in 2017, totalling over 700 products. Most of the issues identified during the testing resulted in EMA requiring companies to amend the registered manufacturer's control methods for their medicines. In a small number of cases, the tested samples were not compliant with the authorised quality specifications for the medicine and required other regulatory actions such as re-testing, inspections, recalls or suspension of supply. These are some of the key findings in a report published today summarising the sampling and testing activities and main achievements over the past 20 years.

The programme is an important part of the supervision of the quality of centrally authorised products (CAPs) for human and veterinary use in all parts of the distribution chain. The tests are aimed at verifying the compliance of medicines with their authorised specifications and ensuring that the manufacturer's control methods are satisfactory.

EMA has overall responsibility for the programme and works together with EDQM, who is responsible for co-ordinating the sampling and testing operations. The programme is based on close collaboration with other key players, such as the national competent authorities in the EU/EEA member states and the European Network of Official Medicines Control Laboratories (OMCL), co-ordinated by the EDQM. This facilitates sharing of surveillance workload and has successfully reduced duplication of efforts by replacing individual national testing systems for CAPs with one harmonised surveillance procedure applicable to all EU/EEA member states under the responsibility of one co-ordinating body. The pooling of expertise gives access to novel technology and analytical methods and ensures best use of laboratory resources in the EU/EEA.

The selection of medicines for sampling and testing follows a risk-based approach and considers specific criteria such as products with a narrow therapeutic range, a complex manufacturing process, poor stability or a high exposure, as well as the pharmaceutical forms and patient profiles.

The programme will be expanded from 2019 to include testing of biosimilar medicines, and testing of CAPs from the parallel distribution chain to verify their authenticity. Additionally, the generics programme started in 2011 will be expanded to increase the coverage of market surveillance by creating synergies with national sampling and testing programmes for products authorised through the mutual recognition and decentralised procedures. Finally, a new ad hoc programme for active pharmaceutical ingredients (API) will allow the testing of APIs for CAPs sampled during good manufacturing practice (GMP) inspections.

Human vaccines, plasma-derived medicinal products and immunological veterinary medicinal products, which are subject to independent Official Control Authority Batch Release (OCABR) testing by an OMCL before release onto the market, are excluded from the programme.

Contact: Caroline Larsen Le Tarnec, Public Relations Division, EDQM, Council of Europe
Tel.: +33 (0) 3 88 41 28 15 - E-mail: caroline.letarnec@edqm.eu

Note for the Editor: Further information is available on the internet site **https://www.edqm.eu/**

The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark worldwide. The European Pharmacopoeia is legally binding in member states[1]. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

[1]There are thirty-nine members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, The Republic of North Macedonia, Turkey, Ukraine, United Kingdom and the European Union.*

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