

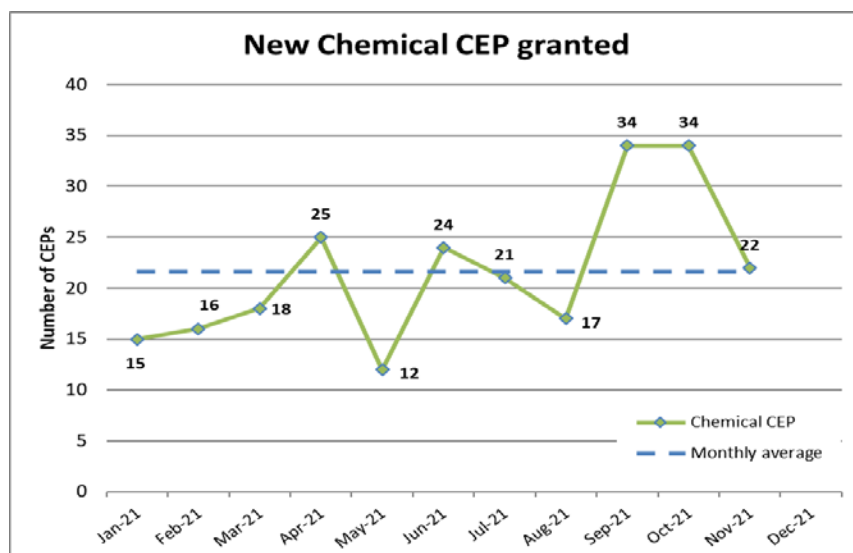
Certification of Substances Department

Strasbourg, December 2021

CERTIFICATION REPORT October & November 2021

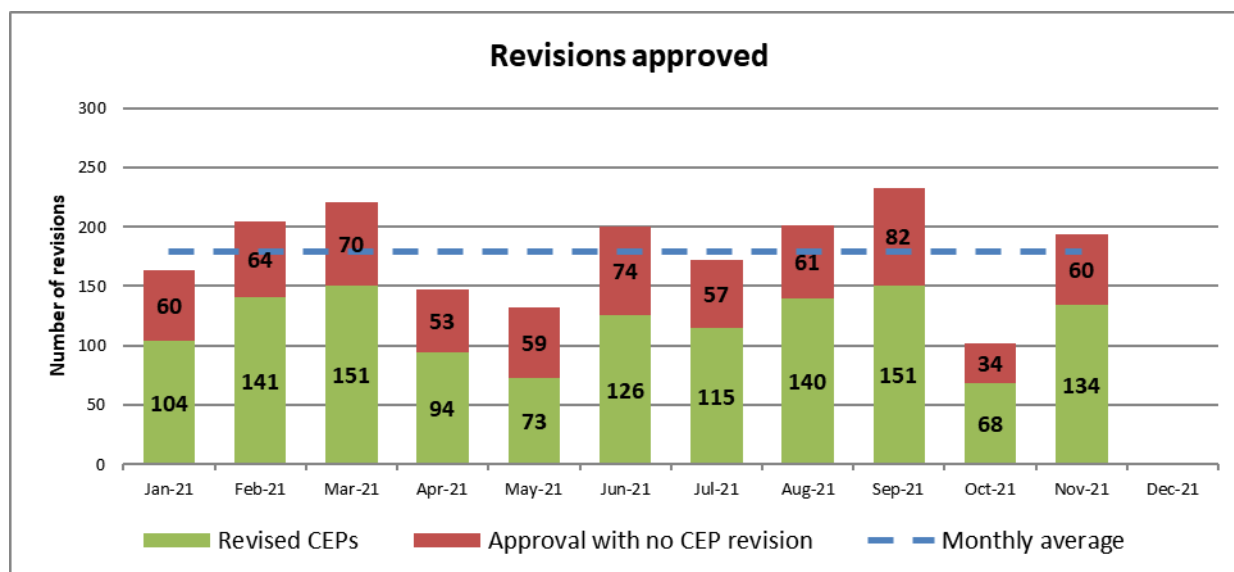
Since the beginning of October 2021, the CEP Department (DCEP) of the EDQM has been using a new IT application for the management of its activities. At the beginning of the implementation of this tool, issues were observed in the synchronisation of the web Certification Database which have been resolved. In addition, users of the CEP may note several non-significant changes to the presentation (layout) of the certificates of suitability.

New granted CEPs

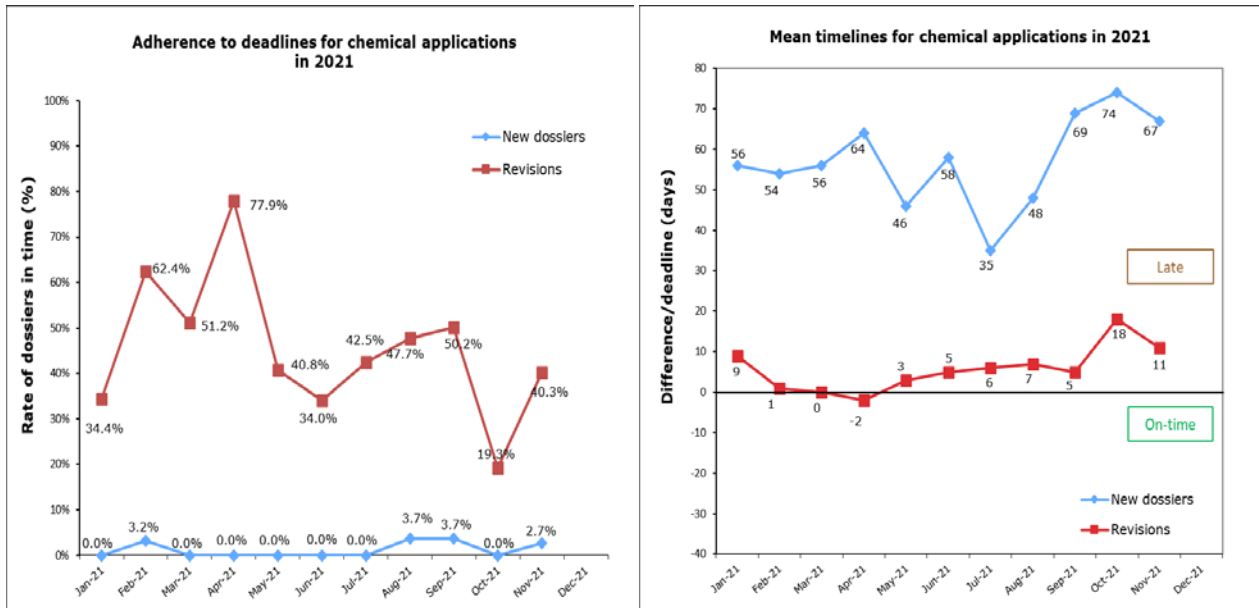


	New CEPs granted (total 2021)
TSE	9
Herbal	3

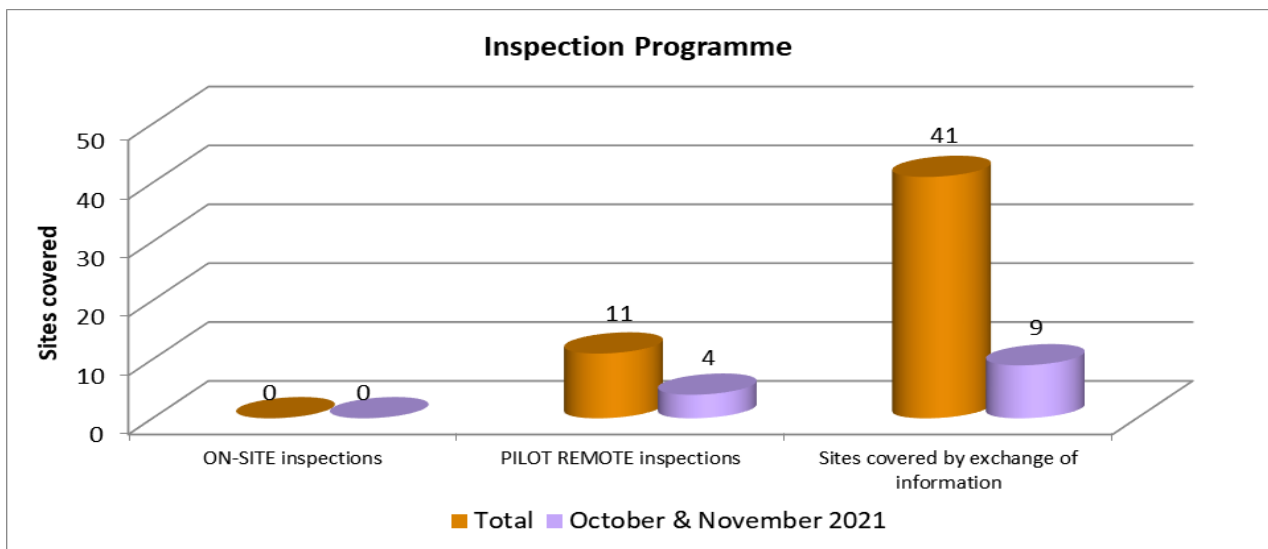
Revisions approved



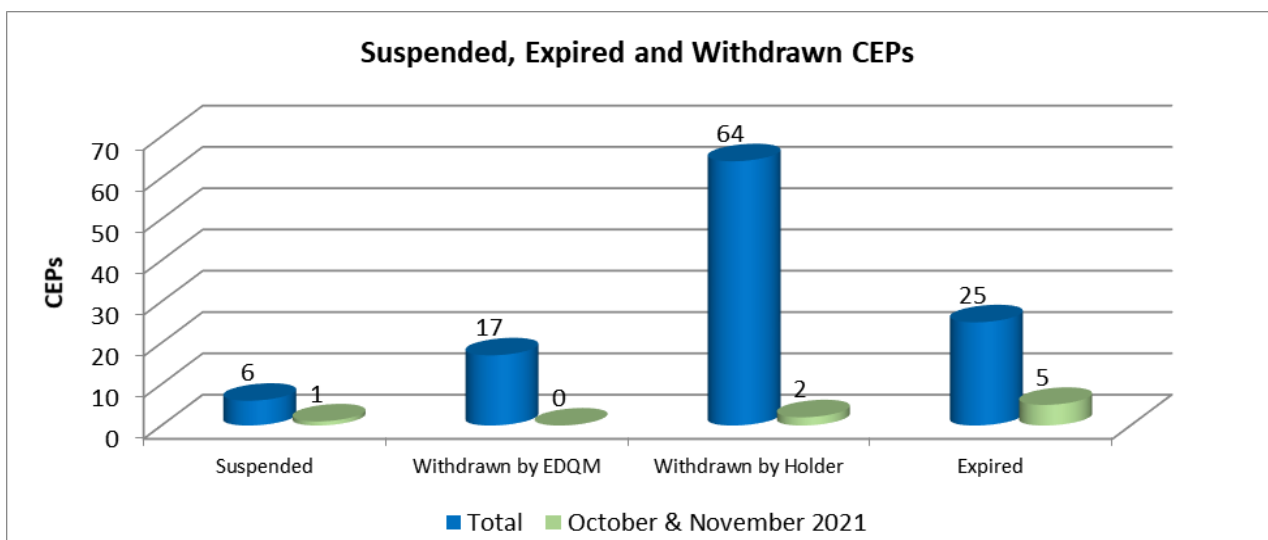
Time for treatment (rate of dossiers treated in time for chemical applications)



Inspections



Actions on CEPs



- Suspension of CEPs due to a failure to fulfill the requirements of the Certification procedure:
 - CEP 2010-381 Losartan Potassium

Information published on the EDQM Website (www.edqm.eu)

- 19/10/2021: Notification for CEP holders on the Implementation of the European Pharmacopoeia Supplement 10.7
 - 20/10/2021: Invitation to CEP holders to comment on draft monographs published in Pharmeuropa 33.4
 - 26/11/2021: Announcement on revision of EDQM document “management of CEP applications” and change in EDQM timelines
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