

Certification of Substances Department

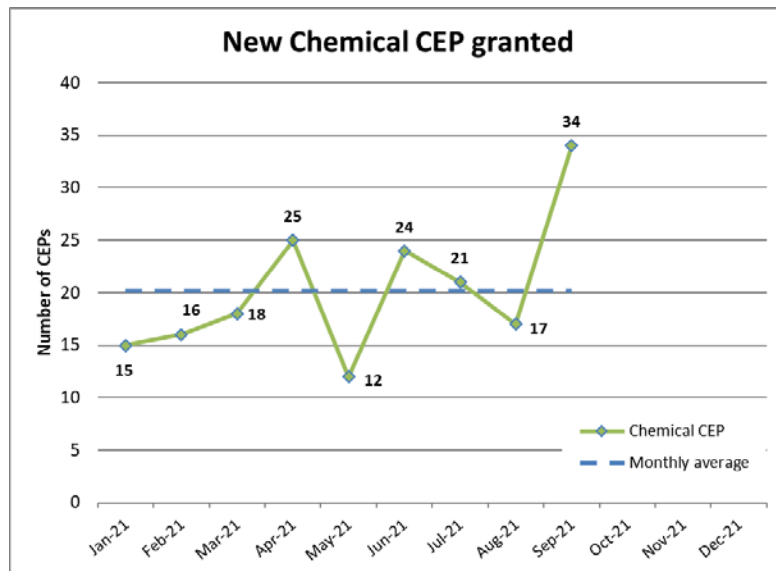
Strasbourg, October 2021

CERTIFICATION MONTHLY REPORT

End of September 2021

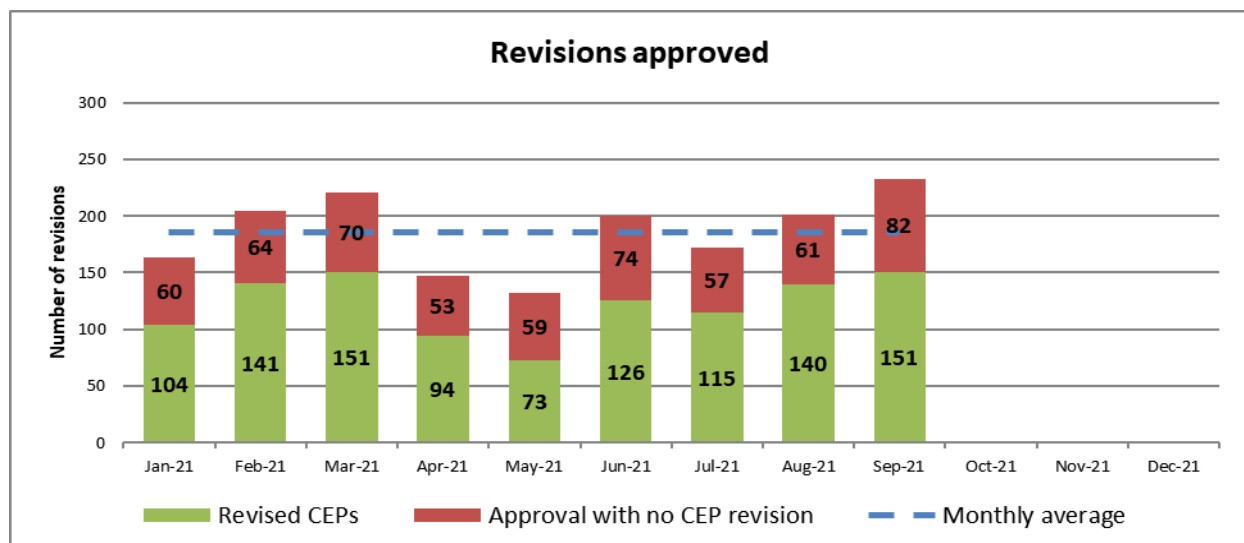
From the beginning of October 2021, the CEP Department (DCEP) of the EDQM will use a new IT application for the management of its activities. The implementation of this new IT tool will change the way the EDQM communicates with applicants/CEP holders, and may slow down CEP activities during the initial introductory phase.

New granted CEPs

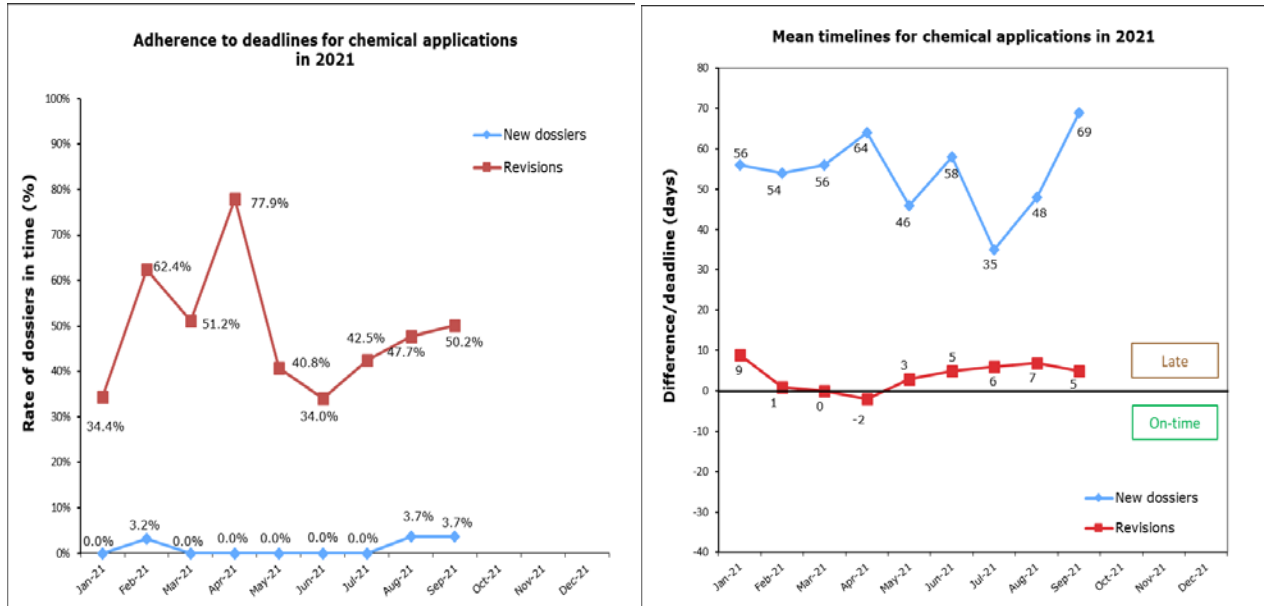


	New CEPs granted (total 2021)
TSE	7
Herbal	2

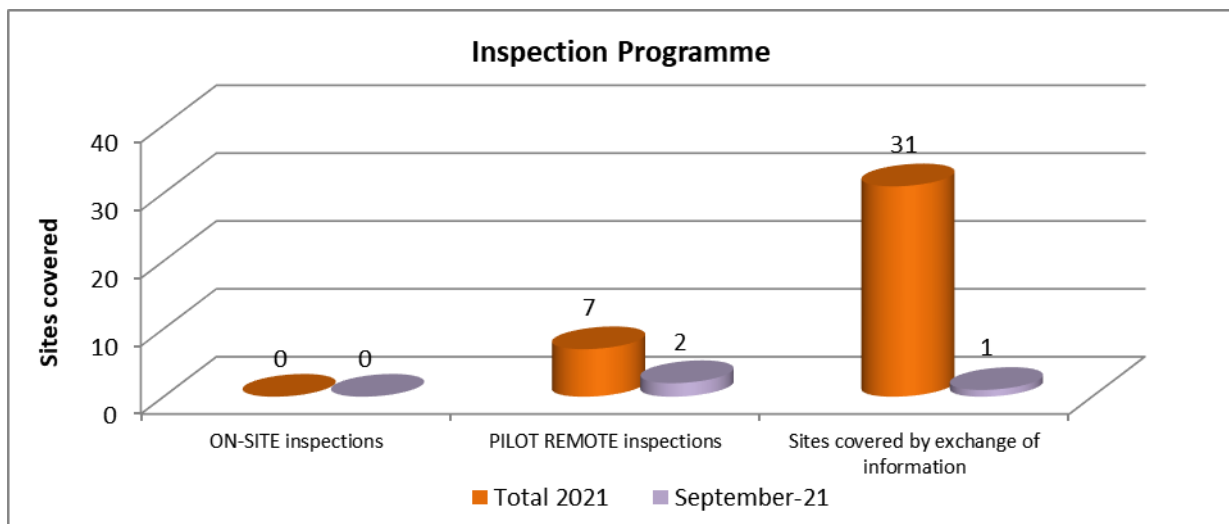
Revisions approved



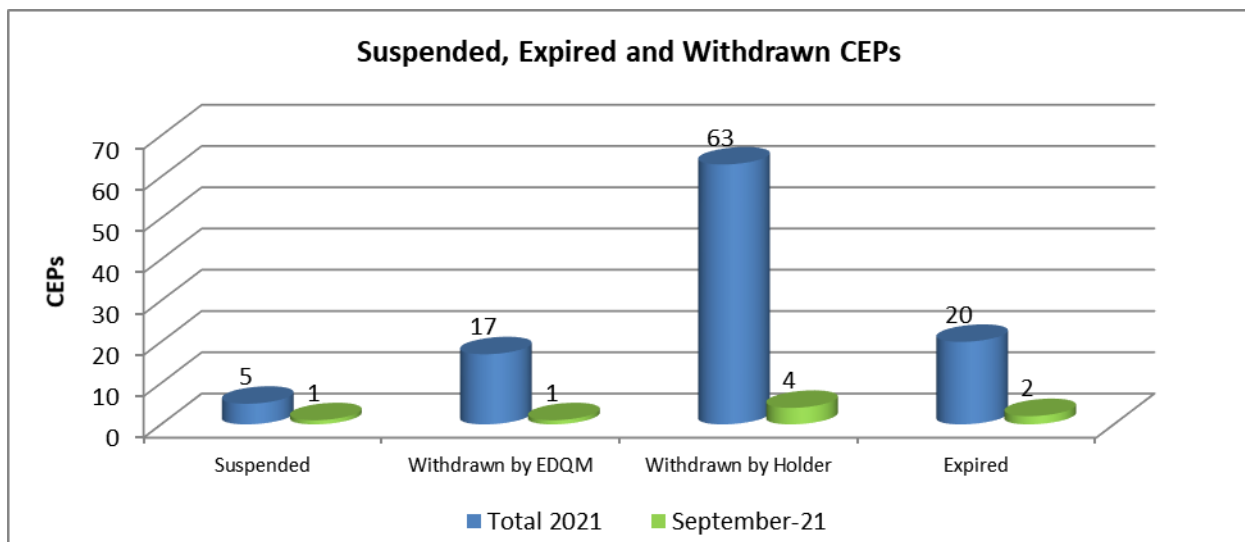
Time for treatment (rate of dossiers treated in time for chemical applications)



Inspections



Actions on CEPs



- Suspension of CEPs due to a failure to fulfil the requirements of the Certification procedure:
 - CEP 2019-317 Losartan Potassium Process II
- Withdrawal of CEPs due to a failure to fulfil the requirements of the Certification procedure:
 - CEP 2008-210 Glipizide.

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

- 01/09/2021: Revision of the “Guidance for electronic submissions for CEP applications”
 - 24/09/2021: Announcement on the new EDQM IT tool for the management of CEP activities and the impact for CEP applicants and CEP holders
 - 27/09/2021: Revision of the “Terms of Reference and Rules of Procedure” for the Certification Procedure (CEP)
 - 29/09/2021: Announcement on the risk of the presence of mutagenic azido impurities in losartan active substance.
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