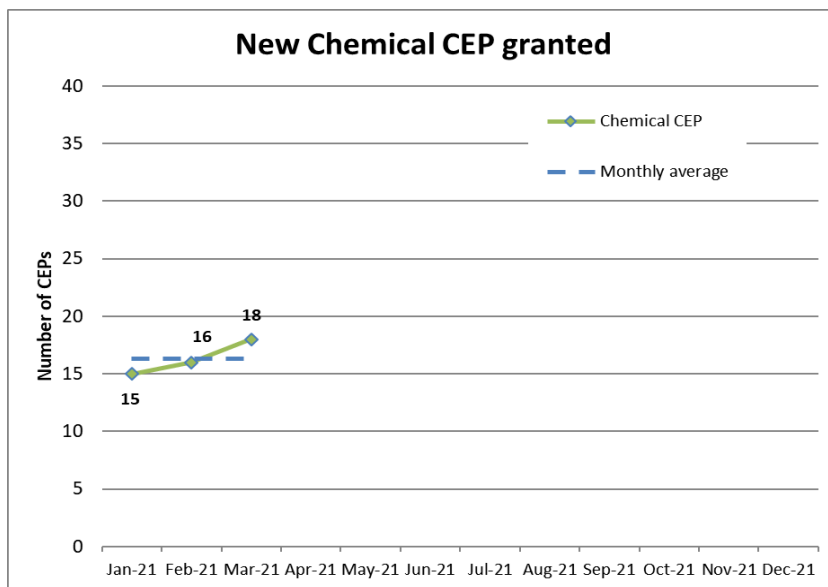


Certification of Substances Department

Strasbourg, April 2021

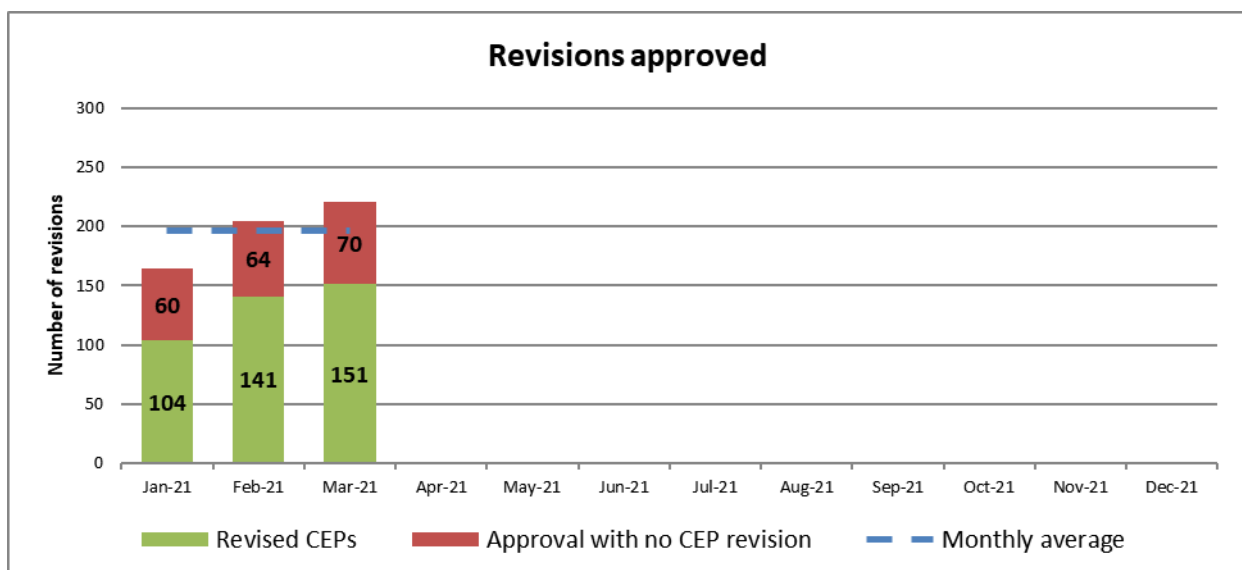
CERTIFICATION MONTHLY REPORT March 2021

New granted CEPs

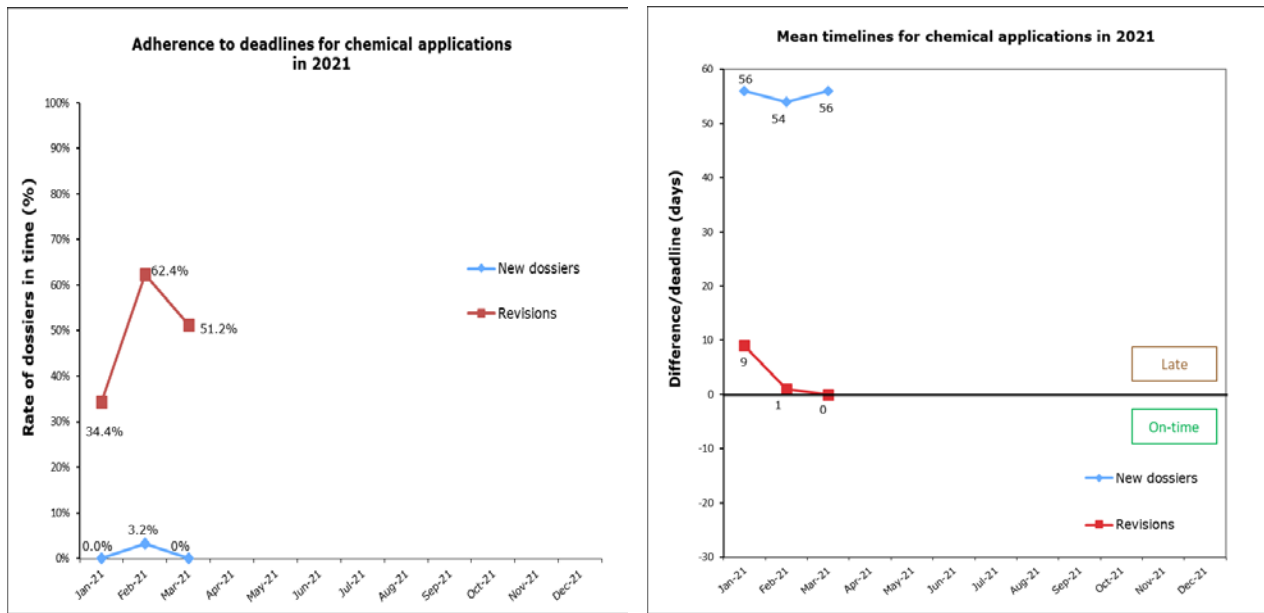


	New CEPs granted (total 2021)
TSE	2
Herbal	1

Revisions approved

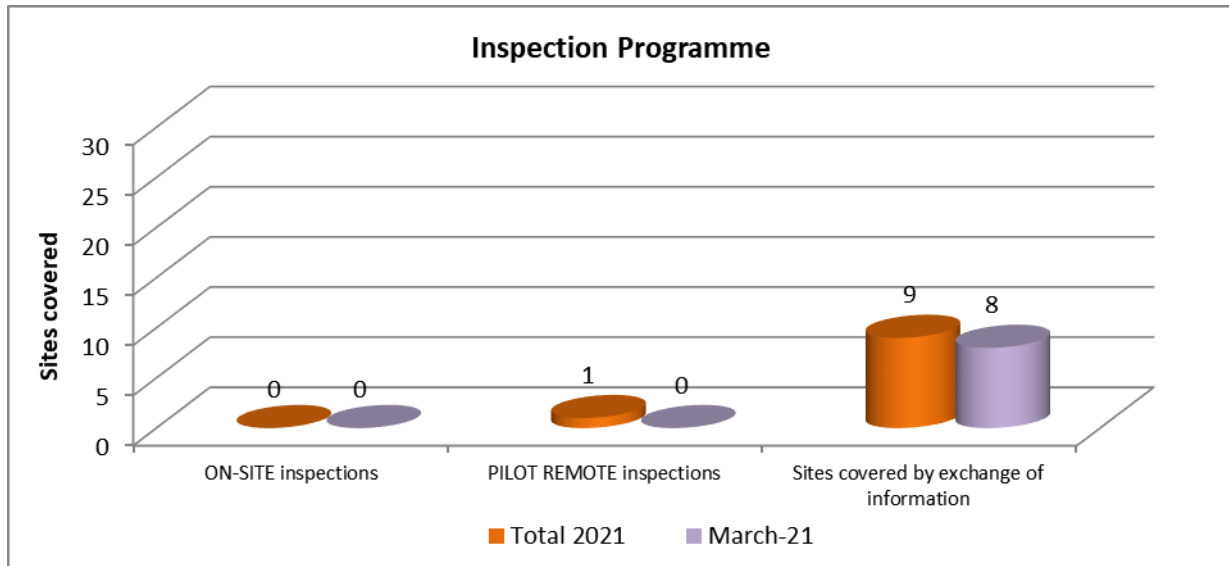


Time for treatment (rate of dossiers treated in time for chemical applications)



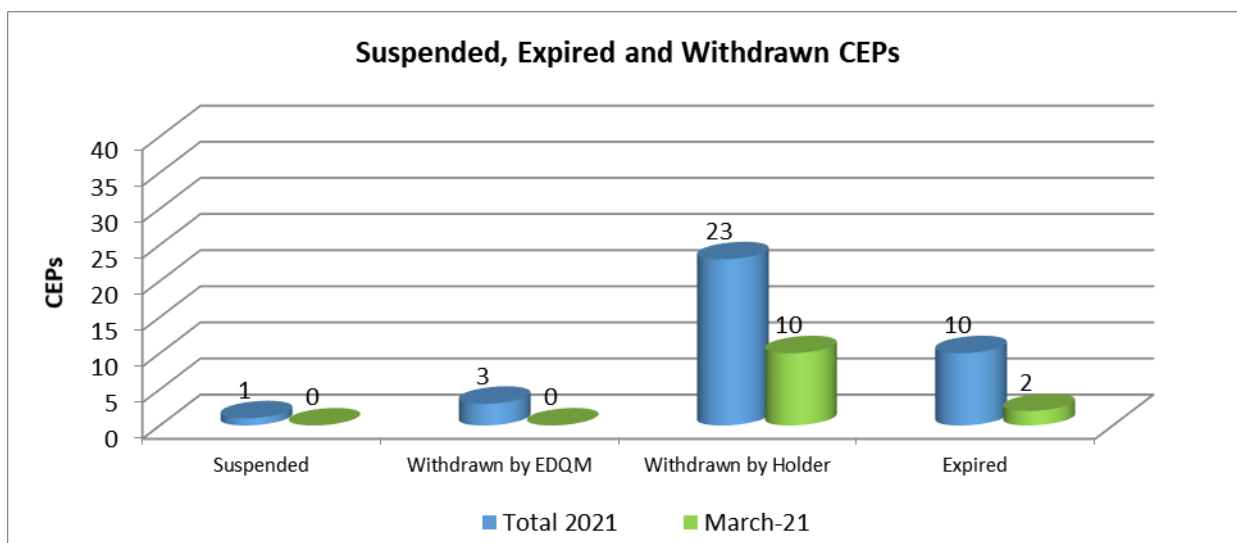
Delays are still observed in the treatment of New Dossiers and Revisions, however the situation with regards to the treatment of revisions applications is improving.

Inspections



On-site inspections are still postponed due to travel restrictions. The EDQM continues monitoring GMP compliance of sites through exchange of information with international partners and pilot real-time remote inspections.

Actions on CEPs



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

- Restoration of suspended CEPs:
 - CEP 2013-044 Adenosine
 - CEP 2008-149 Simvastatin
 - CEP 1999-176 Ivermectin
 - CEP 2002-009 Pravastatin sodium
 - CEP 2002-172 Simvastatin
 - CEP 2006-144 Acarbose
 - 01/03/2021: Information on revisions of CEPs referring to one of the “sartan” monographs following their rapid implementation
 - 11/03/2021: Recommendations on How CEP holders can avoid the rejection of notifications.
-