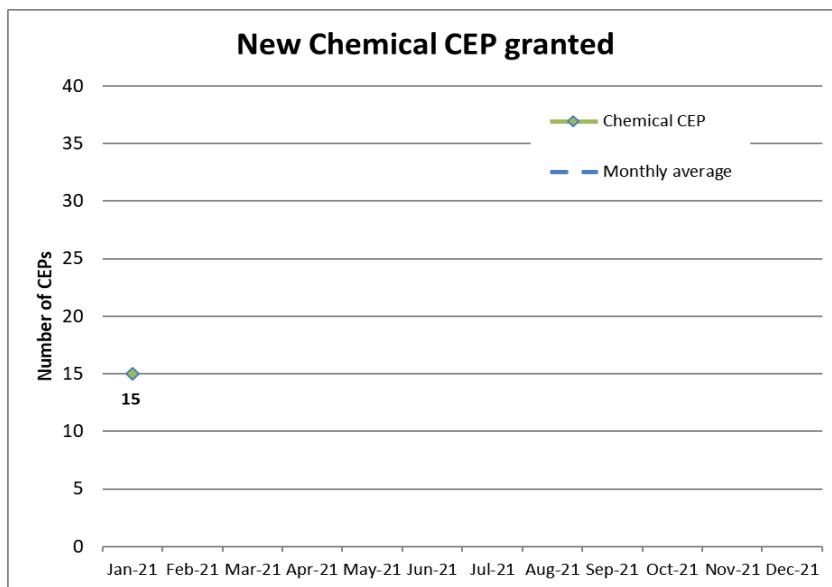


Certification of Substances Department

Strasbourg, February 2021

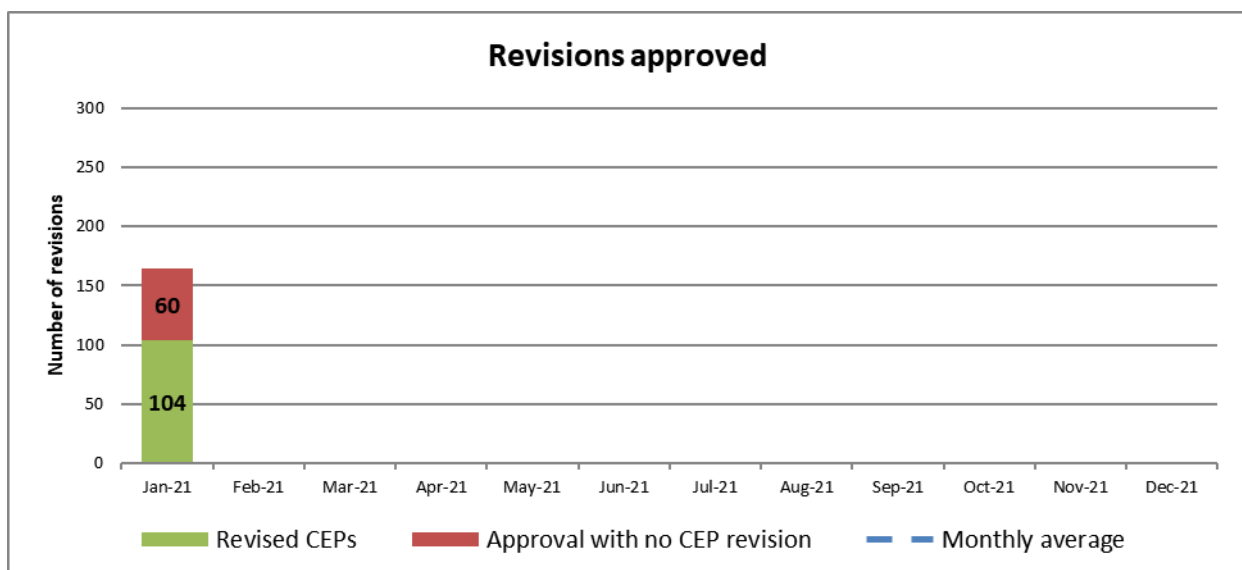
CERTIFICATION MONTHLY REPORT January 2021

New granted CEPs

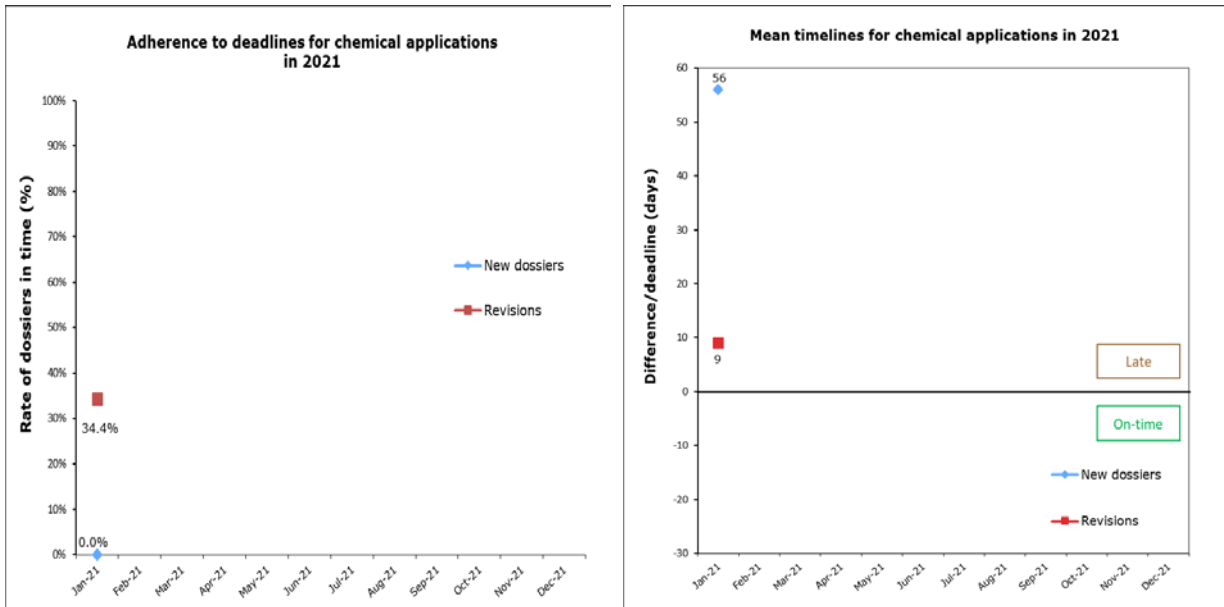


	New CEPs granted (total 2021)
TSE	1
Herbal	1

Revisions approved

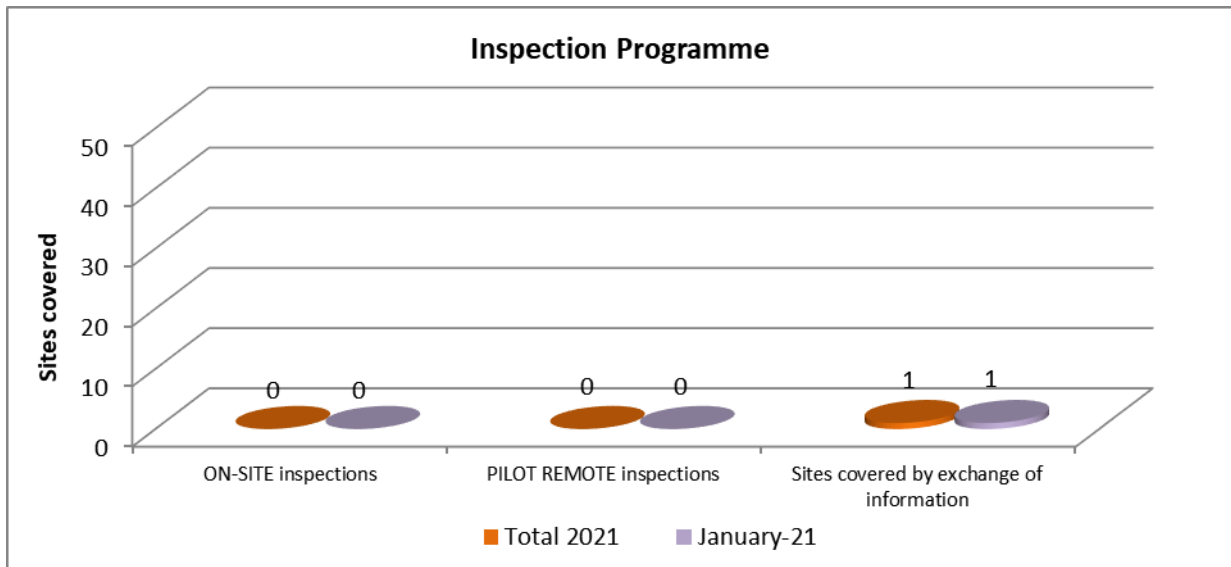


Time for treatment (rate of dossiers treated in time for chemical applications)

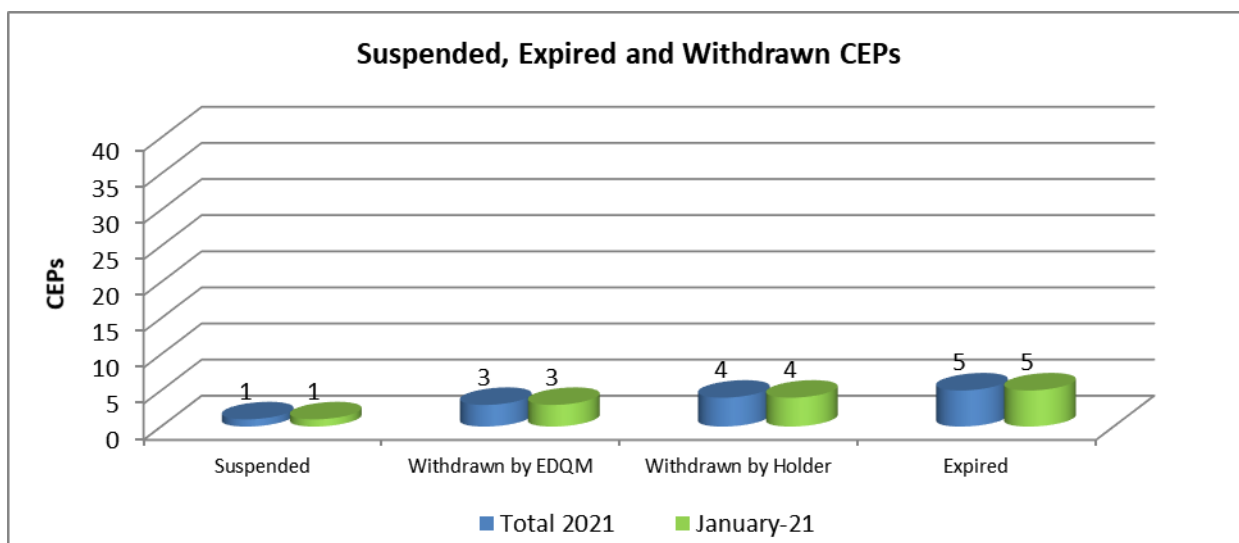


Delays are still observed in the treatment of New Dossiers and Revisions.

Inspections



Actions on CEPs



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

- CEP suspensions upon request from the holder, due to a temporary inability to produce under the approved conditions:
 - CEP 2013-170 Calcipotriol monohydrate
 - CEP withdrawals due to the deletion of the associated monographs from the Ph. Eur:
 - CEP 2009-322 Meprobamate
 - CEP 2009-216 Nalidixic acid
 - CEP 2011-088 Nalidixic acid
 - 18/01/2021: Announcement on implementation of the Ph. Eur supplement 10.5
 - 20/01/2021: Invitation to comment on draft monographs published in Pharmeuropa Volume 33 No 1, January 2021.
 - 26/01/2021: Implementation of risk assessment requirements to control elemental impurities in substances for veterinary use
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