

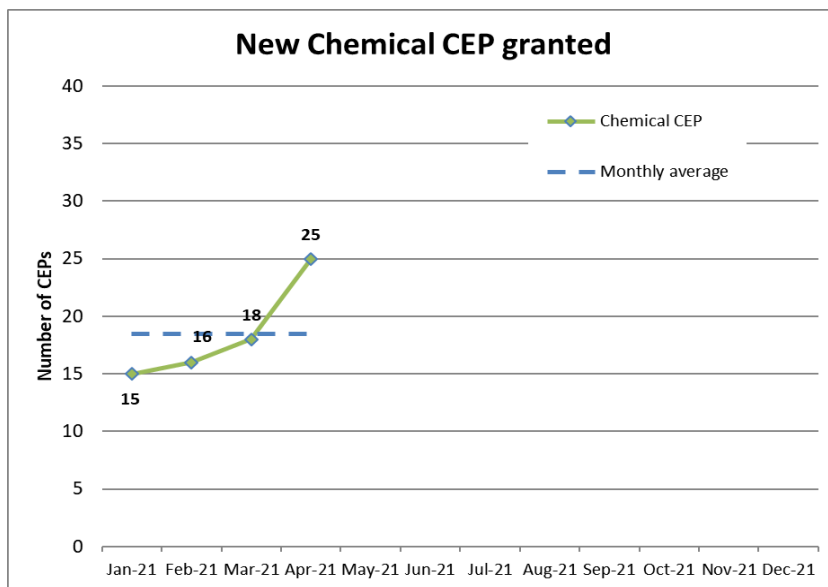
## Certification of Substances Department

Strasbourg, May 2021

# CERTIFICATION MONTHLY REPORT

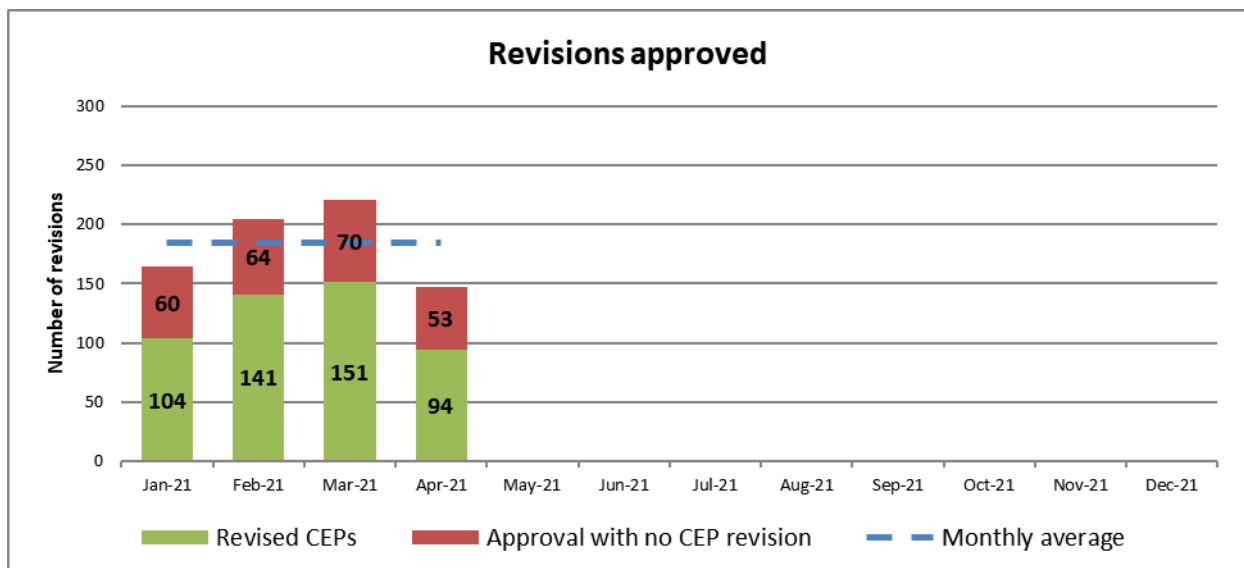
## End of April 2021

### New granted CEPs

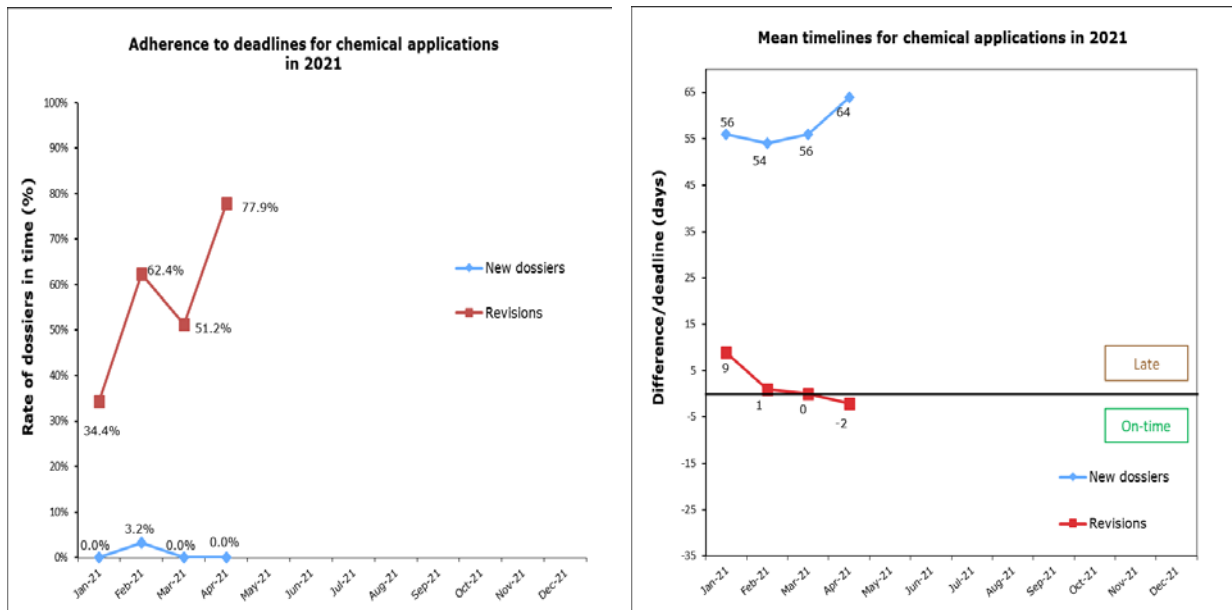


	New CEPs granted (total 2021)
TSE	3
Herbal	1

### Revisions approved



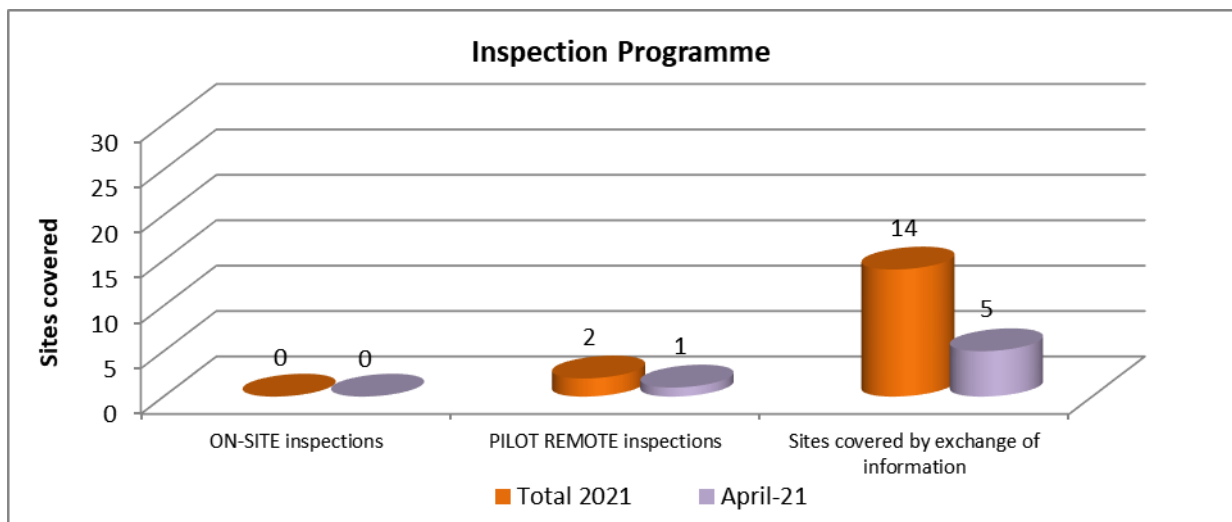
## Time for treatment (rate of dossiers treated in time for chemical applications)



Delays are still observed in the treatment of New Dossiers and Revisions, however the situation with regards to the treatment of Revisions continues to improve since about 80% of these applications are treated within established timelines.

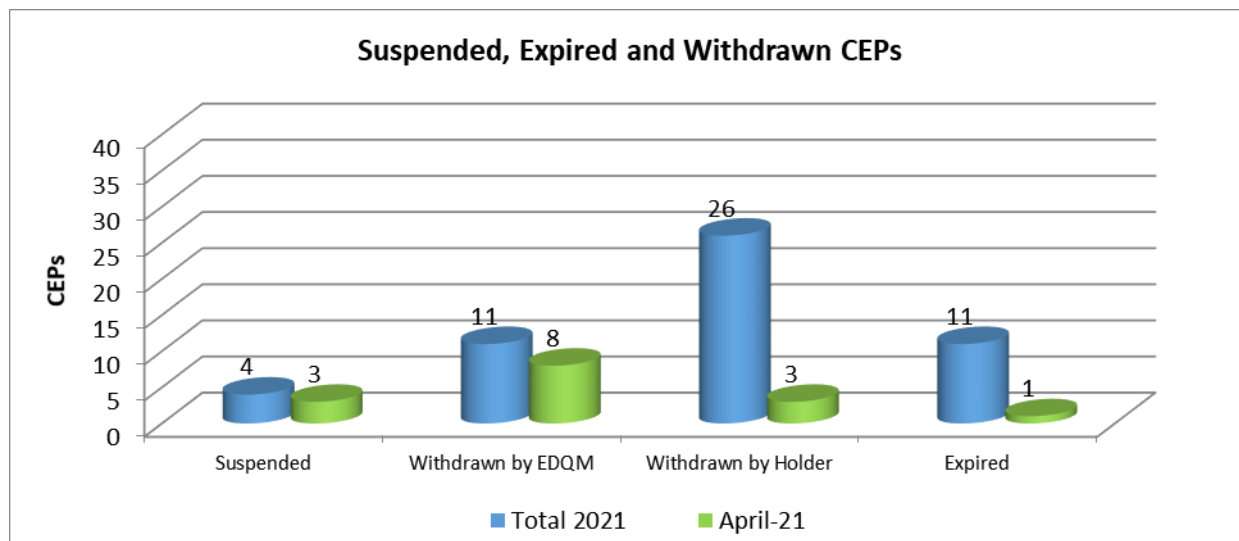
Delays in the treatment of New Dossiers are linked to a particularly high number of such applications received since the middle of 2020.

## Inspections



As part of the pilot phase, 1 real-time remote inspection took place in April 2021. On-site inspections are still postponed due to travel restrictions, and the EDQM is working mainly with distant assessments and exchange of information with international partners.

## Actions on CEPs



### Information published on the EDQM Website ([www.edqm.eu](http://www.edqm.eu))

- Suspension of CEPs due to a failure to fulfil the requirements of the Certification procedure:
  - CEP 2006-006 Ramipril
  - CEP 2008-124 Cefixime
  - CEP 2009-278 Lamotrigine
- Withdrawal of CEPs due to a failure to fulfil the requirements of the Certification procedure:
  - CEP 2001-448 Albendazole
  - CEP 2015-148 Meropenem trihydrate
  - CEP 1996-059 Ampicillin trihydrate
  - CEP 1996-060 Amoxicillin trihydrate
  - CEP 2004-120 Flucloxacillin sodium
  - CEP 2009-242 Ketoprofen
  - CEP 2009-299 Glimepiride
  - CEP 2010-089 Amlodipine besilate
- 21/04/2021: Invitation to CEP holders to comment on draft monographs published in Pharmeuropa 33.2
- 29/04/2021: Information on the risk of presence of mutagenic azido impurities in sartan active substances with a tetrazole ring.