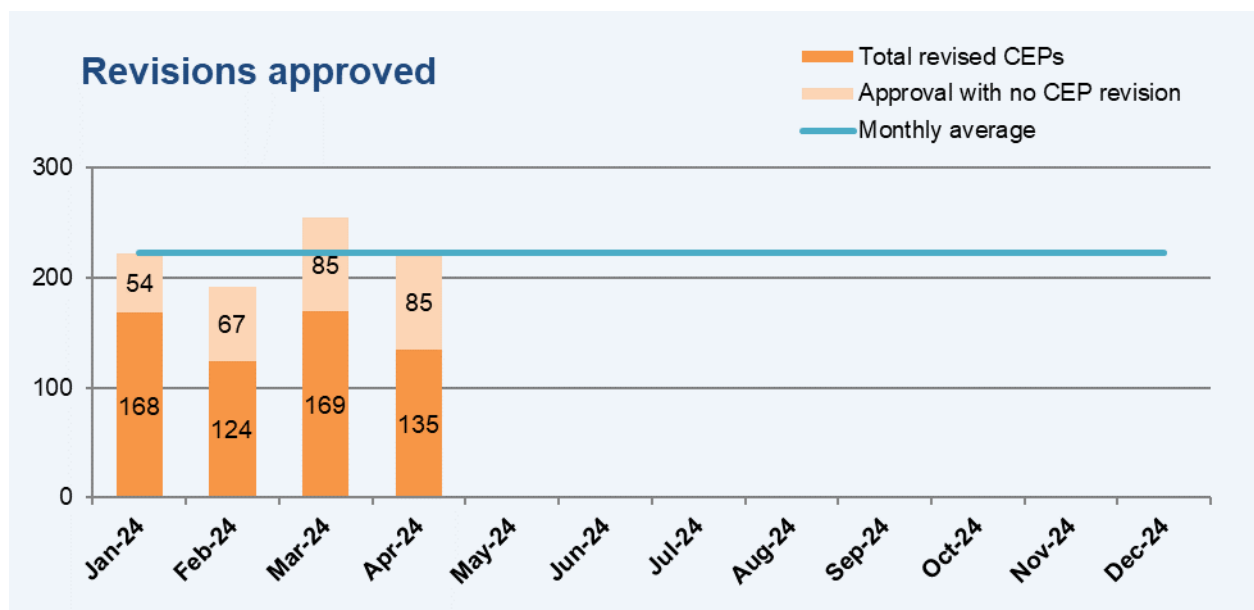
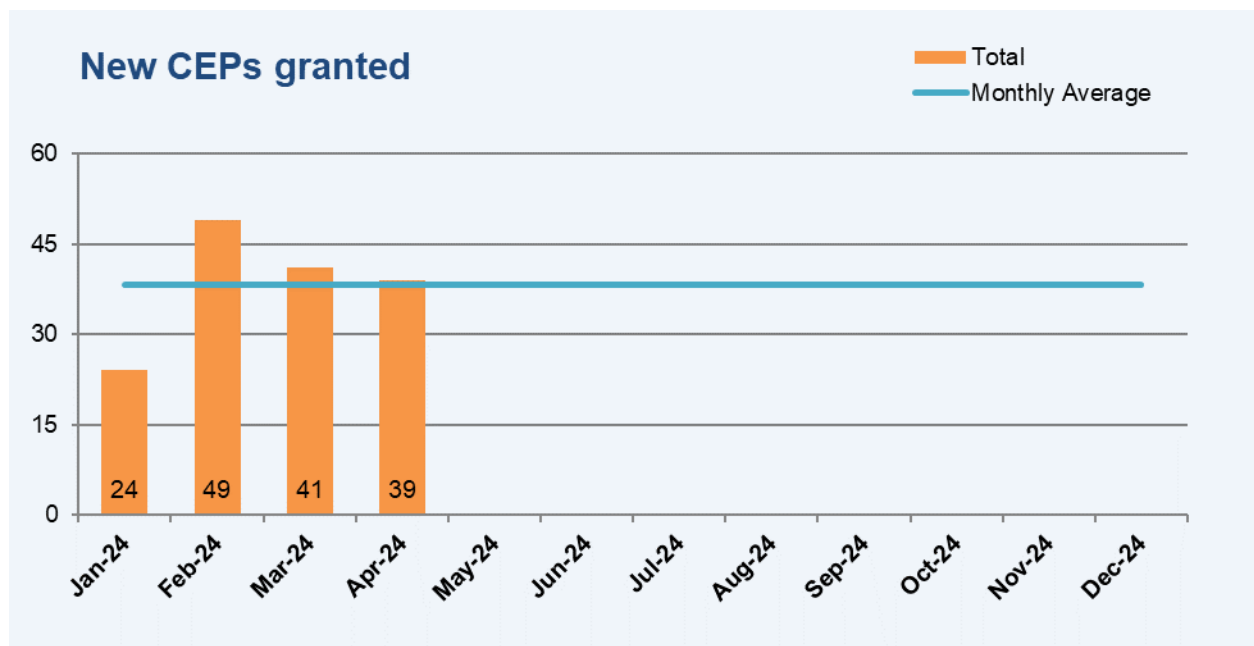


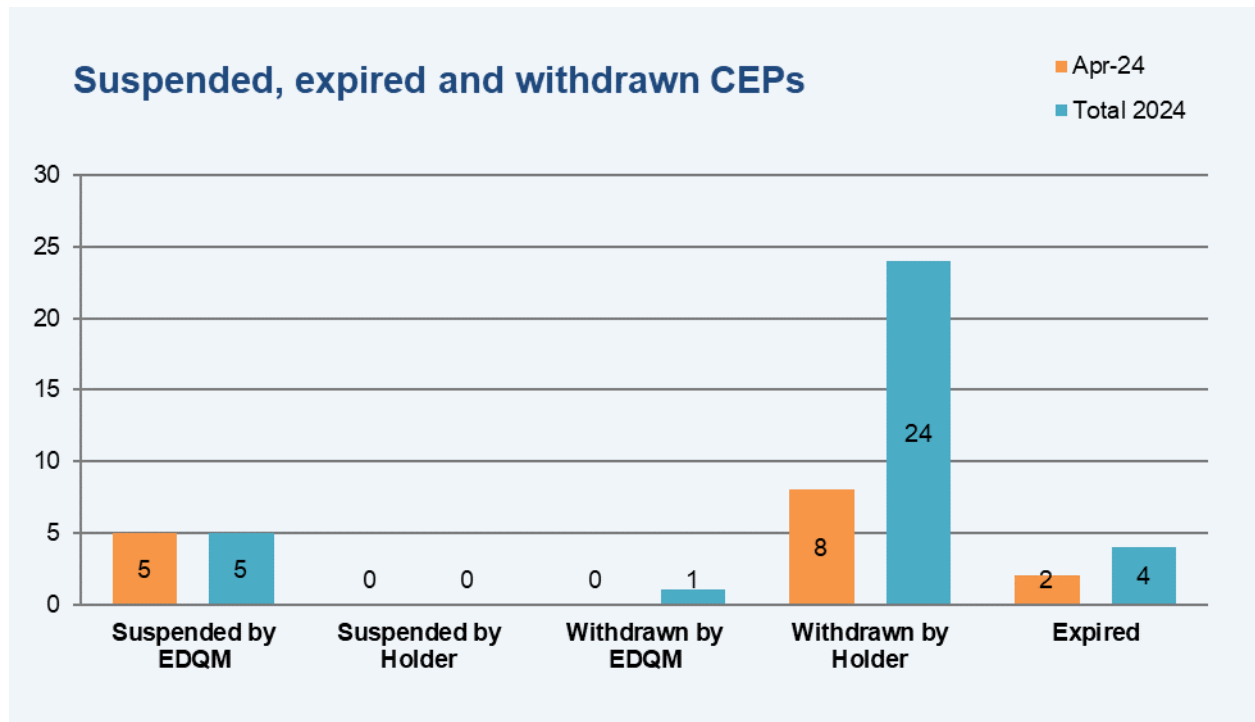
Certification of Substances Department

CERTIFICATION MONTHLY REPORT

End of April 2024

Certificates of Suitability





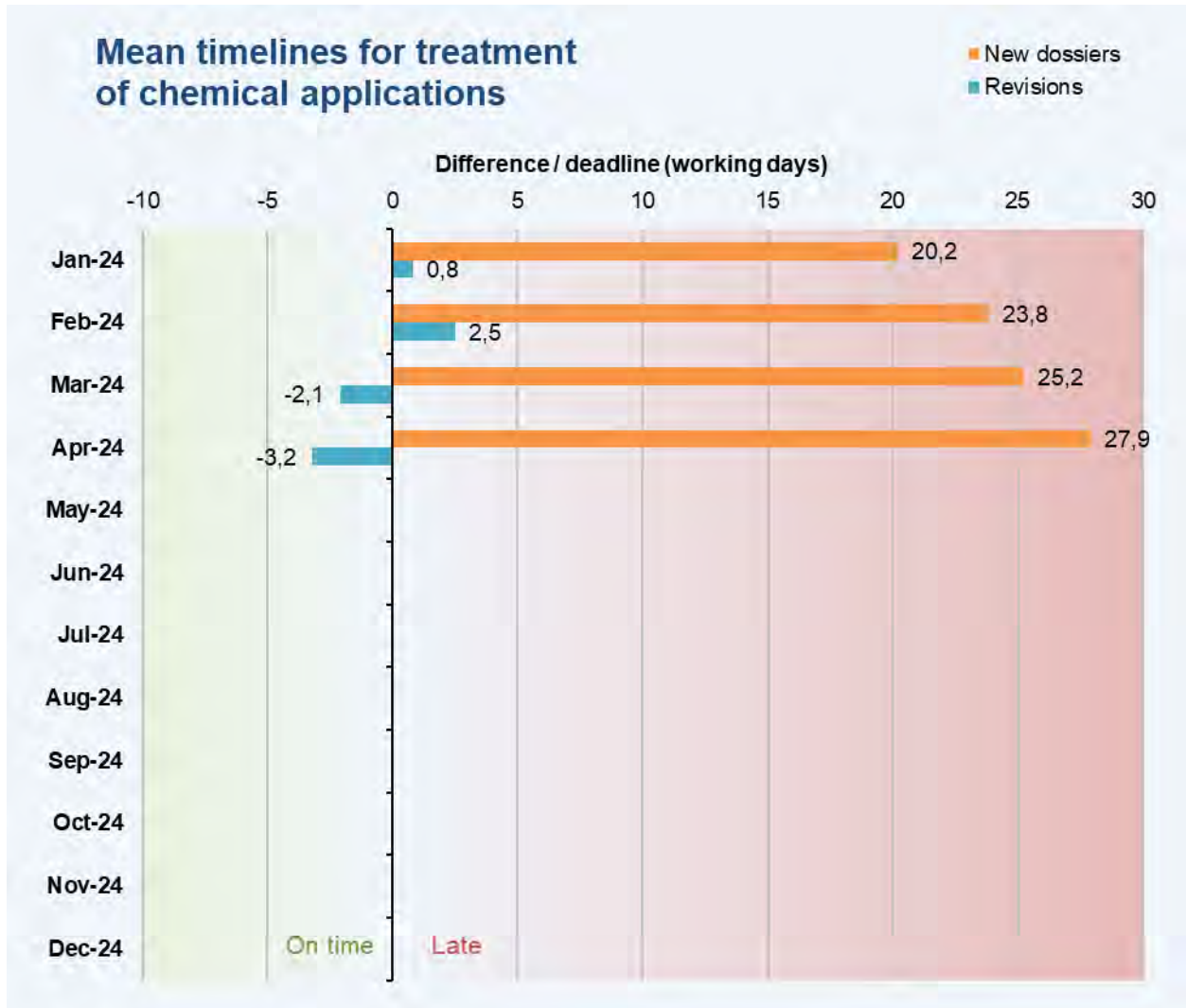
CEPs suspended by EDQM due to GMP non-compliance:

- CEP 2014-147 Esomeprazole Magnesium trihydrate
- CEP 2014-035 Omeprazole
- CEP 2020-260 Irbesartan - Process II
- CEP 2023-057 Torasemide - Process II
- CEP 2021-510 Solifenacin succinate

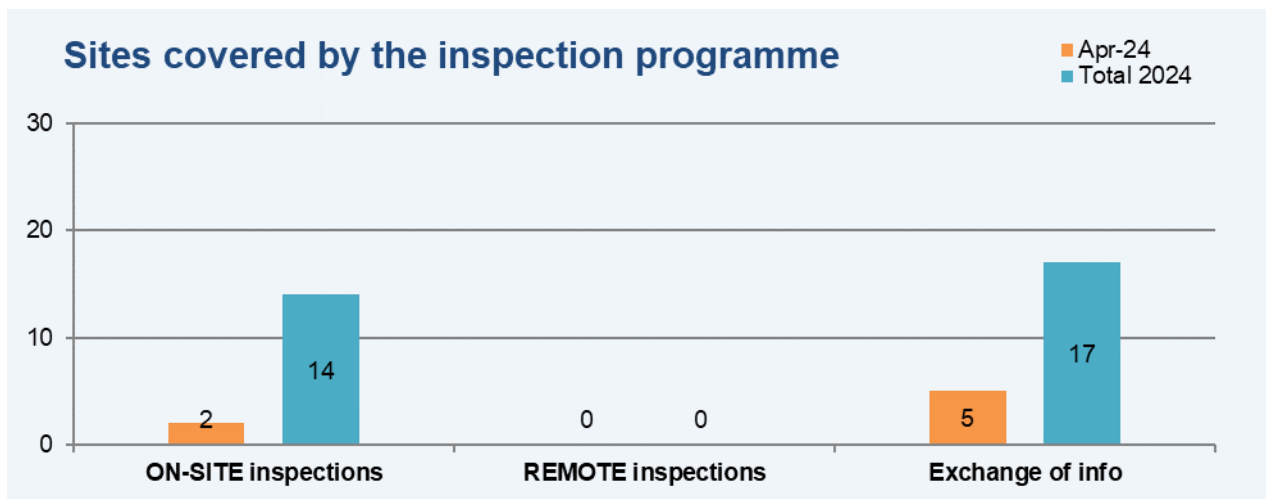
Restoration of suspended CEPs:

- CEP 2019-329 Bicalutamide
- CEP 2018-063 Irinotecan hydrochloride trihydrate
- CEP 2020-074 Etoposide
- CEP 2019-024 Etoposide
- CEP 2015-141 Pemetrexed disodium heptahydrate
- CEP 2012-251 Cytarabine

Time for treatment



Inspection programme



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

- **04/04/2024:** Revised EDQM guideline “Content of the dossier for chemical purity” ([link](#)) and other useful key documents.
 - **08/04/2024:** CEP holders invited to comment on draft monographs published in Pharmeuropa 36.2.
 - **08/04/2024:** Revised policy for unique identification of the manufacturing sites linked to CEP applications ([link](#))
 - **17/04/2024:** Presentation from webinar “CEP 2.0: fresh feedback from stakeholders” ([link](#))
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