European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Certification of Substances Division

NV/CB

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Certification of suitability to Monographs of the European Pharmacopoeia

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New applications for CEP

	Month (current)	Cumulated/year
Nr of applications received		
Chemical	**32**	**166**
Others (TSE, double, herbal)	**2**	**4**
Total	**34**	**170**
Nr of treated applications	**38**	**147**
Nr of CEPs granted	**38**	**171**

Actual time vs. deadlines (day)	**+ 6**

(+) means delay

Revisions (including notifications and renewals) of CEP applications

	Month (current)	Cumulated/year
Nr of applications received		
Chemical (incl sister files)	**66**	**447**
Others (TSE, double, herbal)	**4**	**32**
Total	**70**	**479**
Nr of treated applications	**108**	**553**
Nr of CEPs granted	**85**	**487**

Actual time vs. deadlines (day)	**+ 4**

(+) means delay

Answers to an EDQM deficiency letter

	Month (current)	Cumulated/year
Nr of answers received		
Chemical	**67**	**284**
Others (TSE, double, herbal)	**5**	**12**
Total	**72**	**296**
Total treated applications	**81**	**344**

Actual time vs. deadlines (± day)	**in time**

(+) means delay

Inspections:

	Month (current)	Cumulated/year
Nr of inspections	**2**	**9**
Place		
Asia	**0**	**6**
EEA	**0**	**1**
Other places	**2**	**2**

Suspended/Withdrawn CEPs:

	Month (current)	Cumulated/year
Nr of CEPs suspended	**0**	**5**
Nr of CEPs expired	**0**	**2**
Nr of CEPs withdrawn by EDQM	**0**	**9**
Nr of CEPs withdrawn by holder	**4**	**16**

Other activities

	Month (current)	Cumulated/year
Technical Advice meetings	**0**	**7**

Information published on our Website (www.edqm.eu)

- Note concerning CEPs for gelatin and impact of the revised EU Note for Guidance on the TSE risk
- Policy document on Suspension and Withdrawal of a CEP