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	**22**	**218**
Others (TSE, double, herbal)	**5**	**10**
Total	**27**	**228**
Nr of treated applications (chemical)	**29**	**225**
Nr of CEPs granted (all)	**36**	**221**

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

(+) means delay

Revisions (including notifications and renewals) of CEP applications

	Month (current)	Cumulated/year
Nr of applications received		
Chemical (incl sister files)	**85**	**637**
Others (TSE, double, herbal)	**9**	**45**
Total	**94**	**682**
Nr of treated applications (chemical)	**104**	**752**
Nr of CEPs granted (all)	**74**	**638**

Actual time vs. deadlines (day)	**+ 8**

(+) means delay

Answers to an EDQM deficiency letter

	Month (current)	Cumulated/year
Nr of answers received		
Chemical	**47**	**390**
Others (TSE, double, herbal)	**3**	**24**
Total	**50**	**414**
Total treated applications (chemical)	**82**	**471**

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

(+) means delay

Inspections:

	Month (current)	Cumulated/year
Nr of inspections	**0**	**10**
Place		
Asia	**0**	**7**
EEA	**0**	**1**
Other places	**0**	**2**

Suspended/Withdrawn CEPs:

	Month (current)	Cumulated/year
Nr of CEPs suspended	**0**	**5**
Nr of CEPs expired	**1**	**4**
Nr of CEPs withdrawn by EDQM	**0**	**9**
Nr of CEPs withdrawn by holder	**0**	**18**

Other activities

	Month (current)	Cumulated/year
Technical Advice meetings	**2**	**11**

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

- Updated list of assessors