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	**31**	**282**
Others (TSE, double, herbal)	**1**	**13**
Total	**32**	**295**
Nr of treated applications (chemical)	**23**	**264**
Nr of CEPs granted (all)	**20**	**254**

Actual time vs. deadlines (day)	**+ 13**

(+) means delay

Revisions (including notifications and renewals) of CEP applications

	Month (current)	Cumulated/year
Nr of applications received		
Chemical (incl sister files)	**116**	**847**
Others (TSE, double, herbal)	**6**	**63**
Total	**122**	**910**
Nr of treated applications (chemical)	**158**	**1004**
Nr of CEPs granted (all)	**136**	**868**

Actual time vs. deadlines (day)	**+ 2**

(+) means delay

Answers to an EDQM deficiency letter

	Month (current)	Cumulated/year
Nr of answers received		
Chemical	**37**	**497**
Others (TSE, double, herbal)	**2**	**32**
Total	**39**	**529**
Total treated applications (chemical)	**45**	**568**

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

(+) means delay

Inspections:

	Month (current)	Cumulated/year
Nr of inspections	**3**	**15**
Place		
Asia	**3**	**12**
EEA	**0**	**1**
Other places	**0**	**2**

Suspended/Withdrawn CEPs:

	Month (current)	Cumulated/year
Nr of CEPs suspended	**1**	**6**
Nr of CEPs expired	**0**	**5**
Nr of CEPs withdrawn by EDQM	**4**	**13**
Nr of CEPs withdrawn by holder	**3**	**25**

Other activities

	Month (current)	Cumulated/year
Technical Advice meetings	**0**	**11**

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

- Packaging information within the certification procedure
- Clarification concerning the assessment of stability data within the Certification procedure