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	**42**	**105**
Others (TSE, double, herbal)	**0**	**2**
Total	**42**	**107**
Nr of treated applications	**33**	**77**
Nr of CEPs granted	**34**	**85**

Actual time vs. deadlines (day)	**+ 10**

(+) means delay

Revisions (including notifications and renewals) of CEP applications

	Month (current)	Cumulated/year
Nr of applications received		
Chemical (incl sister files)	**109**	**287**
Others (TSE, double, herbal)	**10**	**22**
Total	**119**	**309**
Nr of treated applications	**150**	**327**
Nr of CEPs granted	**120**	**294**

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

(+) means delay

Answers to an EDQM deficiency letter

	Month (current)	Cumulated/year
Nr of answers received		
Chemical	**40**	**153**
Others (TSE, double, herbal)	**1**	**5**
Total	**41**	**158**
Total treated applications	**83**	**173**

Actual time vs. deadlines (day)	**+ 17**

(+) means delay

Inspections:

	Month (current)	Cumulated/year
Nr of inspections	**2**	**7**
Place		
Asia	**2**	**6**
EEA	**0**	**0**
Other places	**0**	**1**

Suspended/Withdrawn CEPs:

	Month (current)	Cumulated/year
Nr of CEPs suspended	**1**	**1**
Nr of CEPs expired	**2**	**2**
Nr of CEPs withdrawn by EDQM	**5**	**9**
Nr of CEPs withdrawn by holder	**1**	**7**

Other activities

	Month (current)	Cumulated/year
Technical Advice meetings	**1**	**4**

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

- CEP Suspensions: Due to a temporary inability to produce API(s) under the approved conditions:
  - 09/03/11: Metronidazole CEP 1997-083

- CEP Withdrawals: Due to a failure to fulfill, after a suspension, the requirements of the CEP procedure with regards to updating the application and complying with GMP:
  - 14/03/11: Cloxacillin sodium CEP 1997-131
  - 11/03/11 : Amoxicillin trihydrate CEP 1997-129
  - 07/03/11 : Ephedrine hydrochloride CEP 2004-152
  - 07/03/11 : Pseudoephedrine hydrochloride CEP 2004-153