European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Certification of Substances Division

MME/CB

PUBLIC DOCUMENT
English only/Anglais seulement

PA/PH/CEP (12) 44

Strasbourg, April 2012

Certification of suitability to Monographs of the European Pharmacopoeia

MONTHLY REPORT PUBLICATION
March 2012

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New applications for CEP

	Month (current)	Cumulated/year
Nr of applications received		
Chemical	**35**	**95**
Others (TSE, double, herbal)	**2**	**8**
Total	**37**	**104**
Nr of treated applications (chemical)	**29**	**72**
Nr of CEPs granted (all)	**25**	**73**

Actual time vs. deadlines (day)	**-7**

(+) means delay

Revisions (including notifications and renewals) of CEP applications

	Month (current)	Cumulated/year
Nr of applications received		
Chemical (incl sister files)	**101**	**293**
Others (TSE, double, herbal)	**15**	**26**
Total	**116**	**319**
Nr of treated applications (chemical)	**125**	**389**
Nr of CEPs granted (all)	**101**	**272**

Actual time vs. deadlines (day)	**-7**

(+) means delay

Answers to an EDQM deficiency letter

	Month (current)	Cumulated/year
Nr of answers received		
Chemical	**62**	**158**
Others (TSE, double, herbal)	**0**	**10**
Total	**62**	**168**
Total treated applications (chemical)	**95**	**209**

Actual time vs. deadlines (± day)	**+1**

(+) means delay

Inspections:

	Month (current)	Cumulated/year
Nr of inspections	**6**	**12**
Place		
Asia	**4**	**9**
EEA	**0**	**1**
Other places	**2**	**2**

Suspended/Withdrawn CEPs:

	Month (current)	Cumulated/year
Nr of CEPs suspended	**2**	**12**
Nr of CEPs expired	**0**	**0**
Nr of CEPs withdrawn by EDQM	**0**	**3**
Nr of CEPs withdrawn by holder	**1**	**8**

Other activities

	Month (current)	Cumulated/year
Technical Advice meetings	**1**	**3**

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

- Programme to rationalise international GMP inspections of active pharmaceutical ingredients/active substances manufacturers - Terms of reference (PA/PH/CEP (12) 30)

- Cases of falsification of data in the context of the CEP procedure (PA/PH/CEP (12) 11)

- Restoration of suspended CEPs:
  - 01/03/12 Isoniazid CEP 2008-108
  - 01/03/12 Zopiclone CEP 2001-203
  - 01/03/12 Pyrazinamide CEP 2000-036