European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Certification of Substances Division

NV/CB

PUBLIC DOCUMENT
English only/Anglais seulement

PA/PH/CEP (12)13

Strasbourg, February 2012

Certification of suitability to Monographs of the European Pharmacopoeia

MONTHLY REPORT PUBLICATION
January 2012

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New applications for CEP

	Month (current)	Cumulated/year
Nr of applications received		
Chemical	**39**	**39**
Others (TSE, double, herbal)	**2**	**2**
Total	**41**	**41**
Nr of treated applications	**17**	**17**
Nr of CEPs granted	**17**	**17**

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)	**103**	**103**
Others (TSE, double, herbal)	**7**	**7**
Total	**110**	**110**
Nr of treated applications	**141**	**141**
Nr of CEPs granted	**90**	**90**

Actual time vs. deadlines (day)	**- 1**

(+) means delay

Answers to an EDQM deficiency letter

	Month (current)	Cumulated/year
Nr of answers received		
Chemical	**52**	**52**
Others (TSE, double, herbal)	**5**	**5**
Total	**57**	**57**
Total treated applications	**44**	**44**

Actual time vs. deadlines (± day)	**+ 14**

(+) means delay

Inspections:

	Month (current)	Cumulated/year
Nr of inspections	**5**	**5**
Place		
Asia	**5**	**5**
EEA	**0**	**0**
Other places	**0**	**0**

Suspended/Withdrawn CEPs:

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Nr of CEPs withdrawn by EDQM	**1**	**1**
Nr of CEPs withdrawn by holder	**2**	**2**

Other activities

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