

# **GMP Inspections Survey**

**AIFD**

**September 2011**

# **GMP Inspections Survey Findings September 2011**

- Number of companies who responded: 34
- Number of companies analyzed: 31

# GMP Inspections Survey Findings

## September 2011

		Number of products	Number of Countries	Number of Manufacturing Sites	Number of manufacturing sites pending processing at IEGM QC Branch	Number of manufacturing sites referred to the Inspection Board/ awaiting assignment of an inspection date	Number of manufacturing sites referred to the Inspection Board/ assigned an inspection date	Number of manufacturing sites referred to the Inspection Board/ underwent inspection	Number of manufacturing sites referred to the Inspection Board/ inspection approved	Number of manufacturing sites referred to the Inspection Board/ issued a certificate
<b>Sep 2011</b>	<b>GMP Inspection Application Submitted*</b>	550	26	327	73	137	32	54	5	26
	<b>GMP Inspection Application Intended*</b>	124	26	70	-	-	-	-	-	-
<b>Jun 2011</b>	<b>GMP Inspection Application Submitted*</b>	483	26	289	105	100	21	39	14	10
	<b>GMP Inspection Application Intended*</b>	150	27	85	-	-	-	-	-	-
<b>Apr 2011</b>	<b>GMP Inspection Application Submitted*</b>	436	26	253	86	105	26	29	2	5
	<b>GMP Inspection Application Intended*</b>	138	41	89	-	-	-	-	-	-

\* Includes all products, i.e. holding, pending, or intending to apply for marketing authorization

# Overview of Products Awaiting Assignment of an Inspection Date by the Inspection Board

- An inspection date is yet to be assigned for 137 manufacturing sites where 242 products are manufactured.
- For these 242 products, an average of **9,6 months** have been elapsed since the initial application for GMP inspection.

Category & (# of Products)	Mean (months)	Median (months)	Min. (months)	Max. (months)
Category 1 (27 products)	7,5	5,3	4,2	19,1
Category 2 (74 products)	10,7	11,6	3,3	16,6
Category 3 (29 products)	9,1	9,0	1,4	16,4
Category 4 (24 products)	11,1	11,1	5,6	15,5

For some of the products, the category assigned by the Ministry is not known or not reported by the product owner.

# GMP Inspections Survey Findings

## September 2011

- ✓ During the period of March 2010 – September 2011, AIFD members submitted GMP inspection applications for **550 products - 327 manufacturing sites - 26 countries**.
- ✓ Applications for **73** of these manufacturing sites are currently under review by the QC Branch, IEGM.
- ✓ A total of **254** manufacturing sites were referred to the Inspection Board, of which
  - **137** are still awaiting assignment of an inspection date,
  - **32** were assigned an inspection date,
  - **85** underwent inspection, of which **26** were issued a certificate.
  - **97** products are produced in these 26 manufacturing sites which were certificated
- ✓ Average time to inspection approval, from the application date, is **11,5** months for products that actually underwent inspection.

# GMP Inspection Survey

## Summary Findings (Sept. 2011)

	Feb. 2011 (*)	April 2011	June 2011	Sept 2011
Number of products	251	436	483	550
Number of manufacturing sites	–	253	289	327
Number of underwent inspections	–	36	63	85
Number of issued GMP certificates	2	5	10	26
The ratio of inspected manufacturing sites to the total number of GMP inspections applications	–	14,23 %	21,80 %	26,00%
The ratio of certificated manufacturing sites to the total number of GMP inspections applications	–	1,98 %	3,46 %	7,95%
Average time to inspection approval, from the application date (month)	–	14	12,2	11,5

Source: AIFD GMP Inspections Surveys

(\*) Stemming from the structure of the February 2011 Survey, the information collected on GMP inspection applications were limited with respect to subsequent survey results . Hence, some data are not available for the February 2011 Survey.