White Paper: Medical device industry recommendations to GHTF and AHWP on Free Sales Certificate (CFS) for pre-market approval

WHITE PAPER

Medical Device Industry recommendations to GHTF and AHWP on Free Sales Certificate (FSC) required for pre-market approval

Statement of the Issue:
The current requirement for a Free Sales Certificate (FSC), as a pre-requisite for the pre-market approval evaluation, is requirement that is potentially discriminating and may lead to barriers to trade. This requirement should be reconsidered, as National Competent Authorities (NCAs) move towards conformity assessment model for pre-market approval evaluation.

Current Situation:
A summary of the current FSC requirements for various economies/region can be found in Annex I. From information presented, it is clear that, out of the 14 economies /region listed, 50% of them require FSC from the country of origin, and none of the GHTF countries require FSC for their pre-market evaluations.

The industry concerns and recommendations have been presented in the following two reports:

- COCIR Proposal: Medical Device Industry recommendation to GHTF and AHWP on Free Sales Certificate (FSC) required for pre-market approval (22 Feb 2008) (Attachment Annex II), and
- Study on Curren: Situation of Certificate of Free Sales & Certificate of Export in ASEAN (15 Jan 2007) (Attachment Annex III)

Consolidated Recommendations:
The following are consolidated recommendations based on the two reports:

No.	Recommendations	AHWP Action Points & Decision Needed:	To be done by whom	By when
1	**Concept of "Legal Manufacturer":** Recognize and harmonize the concept of "legal manufacturer", regardless of where the products are manufactured.	• "legal manufacturer" harmonized definition to be adopted by member economies • Recognition and acceptance of FSC issued to the legal manufacturer from economies other than country of origin.	• NCAs	2010
2	**Conformity Assessment Model Approach:** Replacement of CFS with conformity assessment certificates issued to the legal manufacturer/manufacturer.	• Member economies that currently request Conformity Assessment Certificates, should not request a FSC as well. • Member economies that currently do not request for Conformity Assessment Certificates, should consider requesting such certificates instead of a FSC.	• NCAs	2015
3	**Legalization of certificates should be removed:** Considering current pre-market requirements in some member economies, include Conformity Assessment certificates of legal manufacturer/manufacturer as well as information on product safety and effectiveness, making legalization redundant and does not increase the safety and effectiveness of the products listed in it.	• Member economies should remove the need for legalization of such certificates, including that of Conformity Assessment Certificates. • Validity of Conformity Assessment Certificates can be verified by the Notified Body that issued these certificates. So acceptance of copies of such certificates should be considered.	• NCAs	2010
4	**Remove FSC as it is discriminatory to importers:** Local manufacturers are not subjected to FSC requirement, but only importers.	• Member economies that do not currently require FSC from their local manufacturers for pre-market evaluation, should not require importers to submit FSC as well.	• NCAs	2010

National Competent Authorities Concerns:
Some NCAs have expressed their concerns in the following areas:

No.	NCA Concerns	AHWP To Consider	Action Plan
1	Highly dependent on FSCs, as it contains important info such as: • Name and address of NCA issuing the FSC • Name and address of manufacturer • List of products • Statement of Local Free Sales • GMP Statement or equivalent	• Such info can be requested from the legal manufacturer/local authorized representative, without the need for a FSC. • Conformity Assessment Certificate also includes info on Subcontract activities, which FSC does not. • Depending on when the FSC was issued, the product list may not be the latest. Legal manufacturer would have the latest product list. • Products, not sold locally, would not be listed in the FSC. • Such information can be provided as part of CSDT submission. • Products listed on the FSC, may or may not have been evaluated by the local NCA, depending on whether such evaluation process currently exists for some jurisdictions.	• Remove the requirement for FSC. • Replace it with Conformity Assessment Certificate and CSDT for pre-market evaluation.
2	Issues with tampered or forged certificates submitted by local distributors or legal manufacturers/manufacturers.	• Legalization of these documents does not ensure their authenticity • Stiff penalties to deter any attempt to tamper such documents.	• Ensure Establishment licensing be established and all Local authorized reps are registered with the local NCA in each member economy.

Estimate of Cost of Obtaining a Legalized CFG from US:

Stages	Time (working days)	Cost US$
New CFG Application with USFDA, including notarization in Maryland	25	175
Courier Fees (To and From Maryland)		40
Authentication of Notary	7	10
Courier Fees		30
Legalization at Consulate	14	20
Courier Fees		40
Total:	46	315

Note: The fees stated above are estimates, as fees can very depending on many factors, such as the number of products to be listed, the location of the consulate, the courier company charges etc..

If a company intended to register their products in 20 countries that require CFG, then the cost for CFG, alone will be, US$315 X 20 = US$6,300.

If the company intends to launch 10 new products over the course of a year, in each of these countries, then the cost will be, US$6300 x 10 = US$63,000. And if they have existing registration for 50 products that require to be renewed annually in these 20 countries, then this will increase the cost to (US$315 x 20 x 50) + US$63,000 = US$378,000

If a country has about 100 companies, each with similar launch plans, then collectively these 100 companies will need to spend an estimate US$37,800,000 annually just for these certificates.

Conclusion:

Removal of the requirement of FSC, will result in the following:

1. A great reduction on the burden on the industry, making it more cost effective for industry to operate, as well as expand their operations, by investing these savings back into the community.
2. Time spent by NCA, reviewing such certificates for authenticity, or issuance, can be better utilized to reduce the pre-market evaluation phase, thereby ensuring more efficient assessment of safety and effectiveness of devices and their timely release into the market.

END