法規名稱：EXCHANGE OF LETTERS REGARDING TO THE MUTUAL EXCHANGE OF INFORMATION ON MEDICAL DEVICES
簽訂日期：民國 96 年 07 月 04 日
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February 8, 2007

Swissmedic
Swiss Agency for Therapeutic Products
Dr. Hans-Beat Jenny
Acting Director
Hallerstrasse 7
CH-3000 Bern 9

Dear Dr. Jenny:

I have the honor to propose an exchange of letters (EOL) regarding to the mutual exchange of information on medical devices, especially on requirements of quality systems and audits of quality systems. This exchange of information will be conducted by or through Swissmedic, the Swiss Agency for Therapeutic Products, Federal Department of Home Affairs (Swissmedic) in Berne and the Bureau of Pharmaceutical Affairs, Department of Health (BPA/DOH) in Taipei.

Swissmedic and BPA/DOH recognize that EN ISO 13485 reflects the requirements of the Medical Devices Directive 90/385/EEC, in particular its Annex II, and Directive 93/42/EEC, in particular its Annex II, in as far as the concern of GMP, and the relevant regulatory requirements of BPA/DOH on GMP. They acknowledge that the regulatory requirements on medical devices in both markets reflect the general principles developed by the Global Harmonization Task Force (GHTF).

BPA/DOH acknowledges that Switzerland has fully implemented EU

regulations for medical devices, and there is a fully operational Mutual Recognition Agreement (MRA) between the EU and Switzerland regarding medical devices. Swissmedic acknowledges that the competent Taiwanese authority has also established an EOL with the EU having a similar regulatory framework for quality systems, and that a Technical Cooperation Program (TCP) is established between Notified Bodies (NB) of the EU and the Designated Auditing Organizations (DAO) of DOH.

The cooperation between Swissmedic and BPA/DOH in the field of medical devices could be started immediately by using the instruments currently available and will include in particular the following activities and areas:

1.Manufacturers established in Switzerland exporting to the territory where the Pharmaceutical Affairs Law administrated by the Bureau of Pharmaceutical Affairs, Department of Health in Taipei, are applied can under this exchange of letters allow the EU Notified Bodies with TCP partnership to present the appropriate audit reports to the competent Taiwanese authority as part of the documentation regarding access to this market.

2.Swiss Conformity Assessment Bodies are given the possibility to participate to the Technical Cooperation Program (TCP) established between Notified Bodies (NB) of the EU and the Designated Auditing Organizations (DAO) of DOH.

3.To improve mutual understanding of respective inspection programs and eventually to eliminate duplication of on site inspection of manufacturers, Swissmedic and BPA/DOH will draw the attention of manufacturers on both sides to the advantage associated to the possibility of working with NB or DAO participating in the TCP.

4.For manufacturers established in the territory where the Pharmaceutical Affairs Law administrated by the Bureau of Pharmaceutical Affairs, Department of Health in Taipei, are applied exporting to Switzerland whose medical devices legally bear the CE mark according to the EU legislation, no additional conformity assessment procedure is required for the Swiss market. Swissmedic will recognize the accomplishment derived from TCP cooperation to eliminate duplicate inspection.

5.An exchange of vigilance information between the two parties can be best achieved through the participation of Swissmedic and BPA/DOH at the GHTF-Vigilance exchange program. For specific problems, both sides can request copies of vigilance reports from manufacturers on medical device failures/ malfunctions referring to products manufactured in the markets of both sides.

Swissmedic and BPA/DOH will designate primary contact points to be responsible under their auspices for overall coordination under this exchange of letters.

If the activities and the terms set forth in this letter are acceptable to your Agency, this letter together with your reply shall constitute an exchange of letters between Swissmedic and BPA/DOH and shall be implemented upon your reply.

Sincerely,

Chi-Chou Liao, Ph.D.
Director General
Bureau of Pharmaceutical Affairs
Department of Health

4 July 2007

Bureau of Pharmaceutical Affairs
Department of Health
Dr. Chi-Chou Liao
Director General
No.100, Ai Kuo E. Rd.
Taipei 10092

Dear Dr. Liao:

I have the honor to acknowledge receipt of your letter dated 08 February 2007 which reads as follows:

"I have the honor to propose an exchange of letters (EOL) regarding to the mutual exchange of information on medical devices, especially on requirements of quality systems and audits of quality systems. This exchange of information will be conducted by or through Swissmedic, the Swiss Agency for Therapeutic Products, Federal Department of Home Affairs (Swissmedic) in Berne and the Bureau of Pharmaceutical Affairs, Department of Health (BPA/DOH) in Taipei.

Swissmedic and BPA/DOH recognize that EN ISO 13485 reflects the requirements of the Medical Devices Directive 90/385/EEC, in particular its Annex II, and Directive 93/42/EEC, in particular its Annex II, in as far as the concern of GMP, and the relevant regulatory requirements of BPA/DOH on GMP. They acknowledge that the regulatory requirements on medical devices in both markets reflect the general principles developed by the Global Harmonization Task Force (GHTF).

BPA/DOH acknowledges that Switzerland has fully implemented EU regulations for medical devices, and there is a fully operational Mutual Recognition Agreement (MRA) between the EU

and Switzerland regarding medical devices. Swissmedic acknowledges that the competent Taiwanese authority has also established an EOL with the EU having a similar regulatory framework for quality systems, and that a Technical Cooperation Program (TCP) is established between Notified Bodies (NB) of the EU and the Designated Auditing Organizations (DAO) of DOH.

The cooperation between Swissmedic and BPA/DOH in the field of medical devices could be started immediately by using the instruments currently available and will include in particular the following activities and areas:

1.Manufacturers established in Switzerland exporting to the territory where the Pharmaceutical Affairs Law administrated by the Bureau of Pharmaceutical Affairs, Department of Health in Taipei, are applied can under this exchange of letters allow the EU Notified Bodies with TCP partnership to present the appropriate audit reports to the competent Taiwanese authority as part of the documentation regarding access to this market.

2.Swiss Conformity Assessment Bodies are given the possibility to participate to the Technical Cooperation Program (TCP) established between Notified Bodies (NB) of the EU and the Designated Auditing Organizations (DAO) of DOH.

3.To improve mutual understanding of respective inspection programs and eventually to eliminate duplication of on site inspection of manufacturers, Swissmedic and BPA/DOH will draw the attention of manufacturers on both sides to the advantage associated to the possibility of working with NB or DAO participating in the TCP.

4.For manufacturers established in the territory where the Pharmaceutical Affairs Law administrated by the Bureau of

Pharmaceutical Affairs, Department of Health in Taipei, are applied exporting to Switzerland whose medical devices legally bear the CE mark according to the EU legislation, no additional conformity assessment procedure is required for the Swiss market. Swissmedic will recognize the accomplishment derived from TCP cooperation to eliminate duplicate inspection.

5.An exchange of vigilance information between the two parties can be best achieved through the participation of Swissmedic and BPA/DOH at the GHTF-Vigilance exchange program. For specific problems, both sides can request copies of vigilance reports from manufacturers on medical device failures/malfunctions referring to products manufactured in the markets of both sides.

Swissmedic and BPA/DOH will designate primary contact points to be responsible under their auspices for overall coordination under this exchange of letters.

If the activities and the terms set forth in this letter are acceptable to your Agency, this letter together with your reply shall constitute an exchange of letters between Swissmedic and BPA/DOH and shall be implemented upon your reply."

In reply I have the honor to accept, on behalf of Swissmedic, the foregoing understanding and to confirm that your letter and this reply shall constitute an exchange of letters between Swissmedic and BPA/DOH. This exchange of letters has only legal implications of economic and technical nature. It shall be effective on today's date.

Sincerely,

Dr. Hans-Beat Jenny

Acting Director