函

中華民國 103 年 8 月 25 日

中華民國西藥代理商業同業公會　　（103）全國西藥代雄字第 128 號
台北市西藥代理商業同業公會　　（103）北市西藥代蘇游字第 269 號

受文者：衛生福利部食品藥物管理署

速別：普通件
密等及解密條件：

主旨：懇請查證及確認接受印度衛生單位出具之 WHO GMP 有外銷專用字樣。

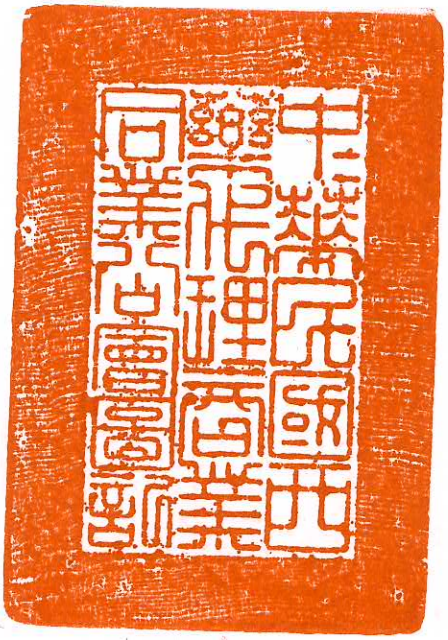
說明：

一、鈞署 103 年 6 月 13 日發文字號 1030021119 號函第 4 項回覆敬悉。

二、經本會與多家會員了解及查證，印度衛生單位出具之 WHO GMP 確實是應進口國之要求，證明其出口之印度廠符合 WHO 之條件，非一般印度當局或虛應外銷用之 GMP 證書。附上網頁(如附件一)為印度多家來函解釋(如附件二、三)，敬請查核示准，實感德便。

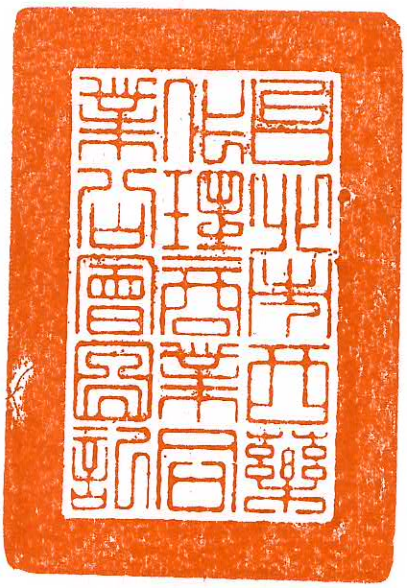
三、依上述亦請同理查核及示准接受印度衛生單位出具之 COPP 及 FCS 有外銷專用字樣為禱！

中華民國西藥代理商業同業公會　　理事長



陳世雄

台北市西藥代理商業同業公會　　理事長



蘇游常焜

附件一

Domestic drug makers will not need GMP certificate

Sushmi Dey, ET Bureau Feb 11, 2009, 09.19pm IST

NEW DELHI: Domestic drug makers will no longer need a certificate of good manufacturing practice (GMP) from the World Health Organisation (WHO) to sell their medicines within India.

The Drug Controller General of India (DCGI) has asked state drug controllers to let companies sell their brands in the country without the WHO s quality certificate, provided they comply with the quality norms set out in the Indian law.

That is, if they produce the DCGI's Certificate of Pharmaceutical Products (COPP), they can sell their brands in India. COPP and WHO certification are compulsory if the company wants to export, a government official, who asked not to be named, said. The DCGI would not issue WHO-GMP certificate to any company from now on.

"For marketing medicines within the country, only schedule M certification under the Drugs and Cosmetics Act (DCA) is required. State regulators have been directed that they no longer need to insist for a WHO-GMP certificate from manufacturers while giving them marketing permissions," the official said.

GMP is aimed at diminishing the risks inherent in pharmaceutical production. WHO GMP certificate is given based on certain guidelines laid down by WHO through which the regulator ensures that medicines and other medical products are consistently produced and controlled to the quality standards required for their best use.

The WHO-GMP certificate is a mandatory requirement in most global markets for companies to be able to sell their medicines. It is also required for specific drugs being supplied under the global disease control project to treat diseases like tuberculosis, malaria and AIDS.

However, the government claims that the Indian norms laid in the drug law is at par with the WHO-GMP guidelines and therefore there is no need to endorse the WHO norms. "We are also in talks with several international agencies in order to ensure that companies holding the COPP do not face problems in exports. It is important for the government as well to ensure that our own regulations find enough recognition in the international markets," the official said.

The drug regulator gives a COPP after conducting an inspection of the manufacturing plant. The certificate is valid for a period of two years. The Indian pharmaceutical market is estimated to be at around Rs 65,000 crore. Out of this, export accounts for around Rs 30,000 crore.

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附件二

Biop

寄件者: rumit shah <rumit.shah@megafine.in>
寄件日期: 2014年8月11日星期一 下午 5:33
收件者: Biop
副本: Rashmi
主旨: RE: FSC of Donepezil and Venlafaxine

類別: 雅新

Dear Sharon / Rachel,

The documents have gone to Delhi for legalization. As soon as we receive them, we will send them to you. As on today, we are not sure when will we receive the documents back. We are constantly following up.

There is no document with us whereby we can prove that WHO-GMP is more notarized than the local GMP.

The simple logic is, we do not require WHO-GMP to sell our products locally in India. Our local GMP is more than enough for us to sell our products locally within India. Certain countries do not accept our Local GMP and therefore we have to go for WHO-GMP so that we can sell our products in those countries. That is why the requirement to obtain WHO-GMP is mainly for export purpose only.

Thanks & Warm Regards
Rumit Shah
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附件三

Biop

寄件者: Sheekha J Lodaria <sheekhan@glenmark-generics.com>
寄件日期: 2014年8月4日星期一 下午 4:51
收件者: Biop
副本: Adarsh Singh; Amol M Kirtani
主旨: RE: Inquiry for Etoricoxib - Standard

類別: 雅新

Dear Sharon,

The revised WRS CoA shall be shared by August 11, 2014.

Wrt the WHO GMP please note:

1) CoPP is requirement for export shipments only (not needed for domestic sales within India)
2) To apply for CoPP WHO GMP and its guidelines have to be followed
3) To this effect our FDA instructed us to specify the underlined words on WHO GMP product list "**List of products for grant of COPP as per WHO guidelines (for export only)**". Meaning the CoPPs for the products will be granted and applicable for exports only.

Hope the explanation is sufficient to accept our WHO GMP.

If not we will initiate the application of CoPP. Same will take 15 to 20 working days.

We await your feedback to instruct our license department.

Kind regards,
Sheekha