Dear Sir/Madam,

The same rules should apply to all producers, including **producers of drugs (bulk or finished product) located in third countries that provide products to the EU market**. They buy API from various sources and they do not import API to UE but they import bulk or finished product containing API to UE.

If you do not include producers of drugs from third countries in the system, the measures to prevent of the entry into the legal supply chain of falsified medicinal products will not be efficient – there will be simply a "hole".

I am representing a medium-sized company.

Best regards,

Michal Krajewski Quality Manager Qualified Person

Nycomed: a Takeda Company NYCOMED Pharma Sp. z o.o. ul. Ks. Lowickiego 12 99-420 Lyszkowice T +48 46 830 94 36 M + 48 668 22 17 63

F +48 46 830 94 00

e-mail: michal.krajewski@takeda.com website: www.nycomed.com.pl