STATEMENT

Delivery of Kibion's products to countries outside of EEA

Current product list:

- HeliCap™ 37 kBq, capsule hard(Pharmaceutical product)
- BreathCard™ (IVD Medical Device)
- Heliprobe® Analyzer (IVD Medical Device)
- Diabact® UBT (Pharmaceutical product)
- IRIS® and/or its spare parts (IVD Medical Device)

Kibion AB has a world-wide responsibility to ensure that the products mentioned in the current product list are delivered in a correct way. This includes the responsibility to secure that products only will be delivered to markets were we have permission to be represented.

The demands from the national authorities vary hugely from country to country outside of Europe. Kibion does on a regular basis review the validity of the documents that are required in order to deliver our products on concerned markets.

According to Kibion´s interpretation of the requirements, the products can only be delivered to markets were the products either is:

1) Registered & approved by the national authorities:
   A copy of a registration certificate that is issued, approved and signed by the competent authorities must be delivered to Kibion.

2) Imported and used during an on-going registration:
   A copy of an approval letter that is issued, approved and signed by the competent authorities must be delivered to Kibion.

3) Imported and used on a patient name basis:
   A copy of an approval letter that is issued, approved and signed by the competent authorities must be delivered to Kibion. To ensure traceability, documents describing the established procedure at responsible physician's office must be included.

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4) Imported on the basis of an import permit/license etc.:
A copy of an import permit/ license etc. that is issued, approved and signed by the competent authorities must be delivered to Kibion.

The import permit/ license etc. should contain the following information:
- type of permit/license etc.
- issuing date on permit/license etc.
- expiry date of permit/license etc.
- product name
- amount
- strength
- limitations of any kind related to the product /product use
- importing company

5) Imported on the basis of a distributor statement
A statement, in which the distributor declares that the national authorities do not require any license or registration approval to handle and import the product(s) into the country, must be delivered to Kibion.
The statement should be written on an official company template, signed by the responsible person within the company and stamped with the official company stamp.

According to Kibion´s QRA (Quality & Regulatory Affairs Agreement - Distributors), the distributors are required to send updated or new documents to Kibion within 5 working days after receiving them.

Please note that without a valid copy of the required documents, Kibion cannot continue to support the concerned market with Kibion products.

Place and date: Uppsala, 2012-Oct-10
Signature:

Printed name: Eva Kjaer

Position: Manager Quality & Regulatory Affairs

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