



WHO COLLABORATIVE CENTRE
FOR ANTIBIOTICS



WHO INTERNATIONAL STANDARDS FOR ANTIBIOTICS (ISA)

During the 56th meeting of the WHO Expert Committee on Biological Standardisation (Geneva, October 2005), the European Directory for Quality of Medicines (EDQM) has been designated as the future WHO collaborative centre for the International Standards for Antibiotics (ISA) to replace NIBSC.

Thus, from the 4th of May 2006, EDQM is in charge of the establishment and distribution of the WHO International Standards for Antibiotics. Details of how the new service will work and how you can order ISAs from the EDQM are outlined below.

1. FROM NIBSC TO EDQM

- *What will not change?*

EDQM continues to distribute batches previously established and distributed by NIBSC using their previous identification code but adding the prefix ISA.

- *What will change?*

From now on, EDQM will conduct international collaborative studies to replace batches or to introduce new international standards for which an ISA is needed.

2. CONDITIONS OF USE

- ISAs are primary standards intended to establish national/regional secondary standards. ISAs should not be used as working standards in routine assays as they are produced in a limited quantity.

Existing well-established secondary standards, which fulfil your requirements (activities/potencies expressed in IUs, etc...) such as regional, national or in house standards, should be used as working standards.

If you considered you are a National Control Authority, please contact us before your order to define the availability of the substances for setting up your National/Regional Working Standards should you so decide.

3. TO ORDER

- *How?*

Send the EDQM official order form (downloadable from the website of EDQM, ISA section) or your own official order form ensuring you provide all the necessary information by:

- Fax: +33 (0) 3 88 41 27 71
- E-mail: orders@pheur.org (only for EDQM official form or your organisation's official order form/Purchase order)
- Post: Council of Europe, EDQM, Sale Section, BP907, F-67029 Strasbourg Cedex, France

It is the responsibility of the customer to check if a special authorisation is needed in the importing country for the given product or if, for the given product, no importation at all is allowed. All necessary documentation has to be provided with the order.

- *Prices*

Each standard ordered will be invoiced at the price of 79 Euros. In addition, delivery charges will be applied per shipment. Details on the delivery charges can be found in the ISA catalogue or on the EDQM website.

- *Payment*

All invoiced will be established in Euros. Our normal payment terms are: Full payment of the invoice is due in the 30 days of the date of the invoice. However for certain countries, especially those with strict monetary regulations, new clients and large orders, we reserve the right to ask for pre-payment and will issue a proforma invoice.

4. **THE WEBSITE** (http://www.pheur.org/site/page_656.php)

A new page on the EDQM website, dedicated to ISA, has been created where you can find more information including: news, FAQ, catalogue, Material Safety Data Sheet, Leaflet and order form, etc...

5. **THE CATALOGUE**

The ISA catalogue lists all WHO International Standards for Antibiotics.