Catalogue

WHO International Standards

for Antibiotics (ISA)

May 2006

I. TERMS OF SUPPLY

All items listed in this catalogue are supplied strictly on the basis of these Terms of Supply, whose provisions shall have effect notwithstanding any inconsistent provision contained in any document received from a purchaser.

1. Quality and purpose of items supplied

All biological preparations listed in this catalogue are supplied exclusively as WHO International Standards for Antibiotics (ISA) for use as primary standards in the establishment of National/Regional secondary working standards and for no other purpose.

It is for the purchasers of any such item who are responsible for persons in a workplace to determine independently the risks associated with the item according to the leaflet and to take appropriate safety measures, including provision of appropriate information to persons working with the substance. Any liability of the Council of Europe for injury, loss or damage arising from the supply or use of any such item is in any event hereby excluded the fullest extent permitted by law; in particular, no liability is accepted for loss of profits or indirect or consequential loss.

2. Prices

2.1. PRICE LIST

The price of each substance is 79 Euros per vial.

However, please note that prices and package sizes are subject to change without notice.

If you are a National Control Authority, please contact the European Directorate for the Quality of Medicines (EDQM) via the Helpdesk on the EDQM website:
http://www.edqm.eu/en/FAQ_Helpdesk-521.html

The EDQM does not operate a discount policy. The sale prices are exclusive of duties and taxes and are given in Euros. It is the responsibility of the buyer (or the recipient of the delivery if different from the buyer) to contact the national fiscal or customs authorities to pay the duties and taxes. In no event shall the said duties and taxes be paid by the Council of Europe (EDQM).

In the European Union (EU), there is no VAT identification number for organisations with diplomatic status. The Council of Europe (EDQM) therefore has no VAT identification number and is not subject to duties and taxes.

The goods remain the property of the Council of Europe (EDQM) until the invoice has been paid in full. Catalogue items are not returnable for exchange or refund.

2.2. DELIVERY AND RELATED COSTS

Unless otherwise stated below or specifically agreed with the customer, the goods are shipped to the buyer on a DDU (Incoterms 2000) basis, namely, delivered duty unpaid insurance included. Where the shipment is identified below as airport consignment only, the goods are shipped to the buyer on a CIP (Incoterms 2000) basis, namely carriage and insurance included.

— The Council of Europe (EDQM) delivers the goods to the buyer not cleared for import and not unloaded by any means of transport.

— The Council of Europe (EDQM) bears the cost and risks of packing, transport to the delivery site and insurance.

— In no event shall the Council of Europe (EDQM) be held responsible for any deterioration of the goods due to their delayed delivery by the carrier.

— The buyer is responsible for the cost of import customs clearance, for paying the duties and taxes required in the country of import and for unloading the goods. The buyer shall be entirely responsible if the goods are held up at customs at the time of import into the buyer's country. In addition, the buyer is responsible for any risks associated with use of their own carrier.

  Where the shipping costs are paid by the customer, the goods are shipped to the buyer on an EX Works (Incoterms 2000) basis, with neither carriage nor insurance included. Therefore, the Council of Europe (EDQM) takes no responsibility in any case of deterioration or loss of goods.

— In no event shall the Council of Europe (EDQM) be able to provide any assistance.

Delivery charges

All shipments are at ambient temperature.

Where the buyer requests shipping conditions other than those recommended in our catalogue, or another carrier, the Council of Europe (EDQM) takes no responsibility in any case of deterioration of the goods or loss of parcel.

Extra charges (postage and packaging) will be applied in the following cases (for larger quantities, prices are given on request). Please note that prices are subject to change without notice:

— France: no extra charge, price is inclusive of packaging and postage. At the client's request, Express Courier delivery is charged at 18 EUR per shipment

— EU: 18 EUR per shipment

— Other European countries : 80 EUR per shipment

— Outside Europe: 120 EUR per shipment

  (Note: for India, South America and Africa, our shipment is by airport consignment only)

— Shipping costs paid by the customer: 10 EUR per shipment

Delivery Lead-time

Dispatching conditions vary from substance to substance. It can be very difficult, sometimes impossible, to import certain substances in certain countries. For a substance sent under ambient conditions by express courier we estimate it will arrive within 4 working days for delivery within the EU and within 10 working days for deliveries outside the EU

3. How do I order?

DO NOT MIX ORDERS FOR EP AND WHO ISA REFERENCE STANDARDS ON THE SAME ORDER FORM

3.1. ORDER FORM

Please send your order using the ISA order form or by sending an official purchase order on company letterhead to the EDQM:

Fax: +33 (0)3 88 41 27 71 – for the attention of

E-mail: orders@edqm.eu

Letter: Council of Europe, European Directorate for the Quality of Medicines, FAO Sales, BP907, F-67029 Strasbourg Cedex, France

The ISA order form may be downloaded from www.edqm.eu under WHO ISA Standards.

Customers are financially responsible for duplicate orders in the following cases:

— confirmation orders that are not clearly marked as being a confirmation of an order that has already been sent to the Council of Europe (EDQM)

— submission of the same order multiple times (i.e., via fax, e-mail, mail or any combination thereof)

Please note that we do not accept orders by telephone.

If you are using your own official order form please ensure you have included:

— details of the Invoicing/Billing address including name of company, post code, town, country and telephone number

— details of the Delivery/Dispatch address (if different) including name of company, post code, town, country (please note STREET ADDRESS ONLY, no P.O. Boxes)

— contact name, telephone number, fax number and email address: an e-mail address is required for order confirmation and shipping notification purposes

— VAT number (mandatory within the European Union)

— Your order reference/purchase order reference

— Item order code

— Official name of the ISA as set out in this catalogue

— Sales/unit quantity

— Name and account number of the carrier (if you wish to use your own)

— Confirmation if you are a National Control Authorities (laboratory).

If orders are received without the official name of the ISA and the full item order code (as set out in the catalogue) the EDQM takes no responsibility for an incorrect item being dispatched.

Unfortunately, we will not be able to process any orders received without the above information.

3.2 Quantities

The EDQM will do everything possible to ensure all orders are dispatched in their entirety, but when quantities of ISA are limited, the EDQM will try to dispatch orders in such a way that as many customers as possible will receive at least some of the limited quantities.

3.3 Modification/cancellation

You can cancel /modify your order up to 09:00 CET following the date of your order, by either

- replying to our order confirmation e-mail with "cancellation" written in the subject line and return it to us by 09:00 CET of the day following the date of receipt of the original order confirmation e-mail.
- Write clearly "cancellation" on an otherwise identical duplicate of your order and fax (33 (0)3 88 41 27 71) or e-mail it to us

Orders cannot be cancelled after this deadline.

3.4. SPECIAL DOCUMENTATION

It is the responsibility of the customer to check if a special permit 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 (especially as regards biological products).

For customers requesting delivery to China please complete the declaration on page X of this catalogue or on the website: http://www.edqm.eu/en/WHO-ISA-Standards-656.html

3.5. ORDER PROCESSING AND INVOICING

On receiving the completed order, the EDQM aims to invoice and dispatch all orders within 3-5 working days with the exception of certain countries, especially those with strict monetary regulations, new clients and large orders, where we reserve the right to ask for pre-payment and will issue a proforma invoice. If you have provided an e-mail address with your order, we will e-mail you with an order confirmation normally within 3 working days after receipt of your order. As soon as we have dispatched you order, we will send you a further e-mail with details of your shipment to enable you to track it.

4. Payment

BY CREDIT CARD. Credit cards may be used for online payment of invoices (Carte Bleue, Visa, Eurocard, MasterCard, American Express, JCB through our web-site https://www.edqm.eu/store and choose E-payment invoices. You can also provide your credit card details at the bottom of the invoice and send it back to us. Please note that we do not accept credit card numbers by telephone.

BY BANK TRANSFER to our bank - Société Générale, 255, route de Mittelhausbergen, 67200 Strasbourg, France IBAN Account Number for International Transfers:(FR 76) 30003 02360 00550034256 76 SWIFT: SOGEFRPP. Please quote your invoice number when you pay.

BY CHEQUE Send your cheques made payable to "the Council of Europe" or "European Directorate for the Quality of Medicines" to the address of the EDQM, BP907, F-67029 Strasbourg Cedex, France.

In all cases, the payment should be net of charge for the Council of Europe. Payment by letter of credit is not accepted.

Any other fees, such as customs duties, taxes, or tariffs are also the responsibility of the customer. Payment by letter of credit is not accepted.

In case of doubt, please visit the HelpDesk at http://www.edqm.eu/en/FAQ_Helpdesk-521.html

5. Regulatory procedures and SH/NDP (harmonised system – nomenclature for customs clearance of goods)

In the event of special requirements in the buyer's country, the buyer shall obtain the import authorisations and resolve any regulatory matters before the goods are ordered and shipped. The buyer shall be entirely responsible if the goods are held up at customs at the time of import into the buyer's country. In no event shall the Council of Europe (EDQM) be able to provide any assistance.

Origin of the goods: Diplomatic, Council of Europe-France.
SH/NDP 000009.

The SH/NDP is strictly limited to export operations out of France.

The importer shall be personally responsible for the tariff classification in the country of import and will assume the ensuing regulatory, fiscal, health and safety obligations.

6. Complaints

If you wish to make complaint please do so via the HelpDesk

Complaints related to delivery

Any delays in delivery do not entitle the buyer to cancel the sale, refuse the goods or claim damages.

Complaints can be made by the buyer upon delivery of goods only if the goods do not correspond quantitatively or qualitatively (if the package containing the goods is badly damaged).

Complaints must be made to the carrier in writing at the time of delivery.

A copy of the complaints must be sent to the Council of Europe (EDQM) (by e-mail or fax) no later than 12 hours after the complaints were made.

Complaints related to the order

Complaints can be made by the buyer upon delivery of goods only if the goods do not correspond quantitatively or qualitatively to the initial order.

Any complaints should be sent within 48 hours of the time of delivery of the goods in the original package.

For airport deliveries, any complaint should be sent within a week of the time of delivery at the airport.

If the complaint made at the time of delivery is shown to be justified because the package and the goods are badly damaged or because an error clearly has been made, the Council of Europe (EDQM) will be free to choose between issuing a credit note, refunding the customer or making another delivery of similar goods.

In the event of complaints, shipping costs and other costs (customs) to return goods to the Council of Europe (EDQM) will be borne by the buyer.

In no event shall the customer return goods to the Council of Europe (EDQM) unless the Council of Europe (EDQM) has been notified and has given its written consent.

We will not accept or exchange any returned goods unless the customer complies with the terms and conditions and the above procedure.

7. Responsibility

The Council of Europe (EDQM) cannot be held responsible for failure to meet the requirements of the legislation of the country where the goods are delivered. It is the customer's responsibility to check with the local authorities to make sure that the goods or services that they intend to order can be imported or used in that country.

The customer is solely responsible for the choice of products, their storage from the time of delivery and their use. In no event shall the Council of Europe (EDQM) be liable for any consequent damage.

The Council of Europe (EDQM) guarantees that the goods have been submitted to the carrier in perfect condition. This is the only guarantee given by the Council of Europe (EDQM). No other guarantees, whether express or implied, are given by the Council of Europe (EDQM). In particular, the Council of Europe (EDQM) does not guarantee that the goods will meet the customer's specific expectations.

The Council of Europe (EDQM) cannot be held responsible for the contract not being fulfilled in the event of goods being out of stock or unavailable, disturbances or total or partial strike action affecting in particular postal services and means of transport, and flood or fire.

8. Disputes

In accordance with the provisions of article 21 of the General Agreement on the Privileges and Immunities of the Council of Europe, all disputes between the Council of Europe (EDQM) and the customer as regards the application of this contract shall be submitted, if a mutual agreement cannot be reached between the parties, to arbitration as laid down in Order No. 481 of the Secretary General, approved by the Committee of Ministers.

Answers to Your Questions: please consult FAQ/ISA section or contact us via the Helpdesk at http://www.edqm.eu/en/FAQ_Helpdesk-521.html

An electronic version of the ISA Catalogue (using Adobe Acrobat version 5) and other information is available on our website http://www.edqm.eu/en/WHO-ISA-Standards-656.html

II. EDQM LONG TERM STORAGE CONDITIONS

All ISA substances are stored at -20℃.

III.USE OF REFERENCE SUBSTANCES AND PREPARATIONS

It is recommended to purchase only a sufficient amount for immediate use and to use the products as soon as possible.

The stability of the contents of opened vials or ampoules cannot be guaranteed.

Toxic substances. The potential toxicity of certain reference substances is such that special precautions are needed during use to avoid contact.

Such substances should be manipulated in a glove box, otherwise protective gloves, eye protection and a mask should be worn.

Safety Data Sheets

Safety data sheets are available on the Internet Site or on request.

Information provided by the EDQM on the safety data sheets is compiled from information provided in the usual way by suppliers or manufacturers of the products and has not been independently verified by EDQM staff. The accuracy of such information cannot therefore be guaranteed.

V. LEAFLET AND WHO/ECBS STUDY REPORT

In all cases, an explanatory leaflet is sent with the product and may be downloadable on the EDQM website, ISA section.

In some cases, copy of the WHO/ECBS Study Reports are available on-line in the International Standards for Antibiotics Database at http://www.edqm.eu/en/Databases-10.html. It details how the collaborative studies have been managed and the results of the experiments.