CHARTER FOR THE QUALITY OF MEDICINES, VACCINES, DIAGNOSTIC PRODUCTS AND SMALL MEDICAL MATERIALS

Introduction

Be-cause Health (**www.be-causehealth.be**) includes all Belgian actors active in international health care and the promotion of access to high level health care. Through consultation, coordination and the organization of common activities, this platform tries to be the bridge between the academic world and field workers. As to medicines, Be-cause Health takes as reference the World Health Organization (WHO) and other agencies with recognized expertise and credibility.

The quality of medicines administered to patients currently represents one of the major concerns of many national and international organizations working in international health care.

As medical organizations, we are expected to deliver medicines, vaccines, medical materials and diagnostic equipments to the patients in our programmes. To make sure that curative and preventive health care are of appropriate quality, we have to assure the quality of the medicines, vaccines, small medical materials and diagnostic equipments that are used in our health care programmes.

That is why our organizations commit themselves to contribute to the installation or strengthening of a quality assurance system for medicines, vaccines, small medical materials and diagnostic materials. To achieve this aim, we will adopt essential quality criteria for the purchase of these products, as defined in this Quality Assurance Charter.

This decision is expected to contribute to an improvement of the regulation of the international pharmaceutical market, in a cultural and ethical framework where quality and shared responsibility are of high importance for all the concerned agents.

The organizations who sign up to this charter:

As every patient, no matter where he or she lives, has the right to be treated with medicines of verified quality, and vaccines of verified quality with small medical materials and diagnostic materials of verified quality;

As the products at the disposal of our teams must have the same quality and

safety standards as in our own countries; As the current situation is worrying.

We adopt the following Quality Assurance system for medicines, vaccines, small medical materials and diagnostic devices:

To guarantee the quality of the products at the disposal of the projects of our organizations in resource-poor situations, the medicines, vaccines, medical materials and the in vitro diagnostic medical devices which we consider essential, must comply with:

- the norms and standards defined by the WHO (see technical reports[1])
- the acknowledged International Pharmacopeias[2]
- the norms and the standards defined by the International Society for Blood Transfusion (ISBT)(see technical reports[3])
- or the norms and standards defined by the European Union (EU), **only** for the products mentioned in the Annex II A and B of the Directive 98/79/EC of the EU (see technical reports[4]).

We consider the following products de facto to be qualified for our organisation:

1. all pharmaceutical products pre-qualified by the WHO Pre-qualification Project;
2. all pharmaceutical products registered in a high-regulated country (list of ICH: European Union, United States and Japan) and are on the list of essential medicines;
3. all vaccines pre-qualified by the WHO;
4. all vaccines registered in a high-regulated country and are on the list of essential products;
5. all medical materials and in vitro diagnostic medical devices, qualified of pre-qualified by WHO and/or by the International Society for Blood Transfusion (ISBT);
6. and in vitro diagnostic medical devices authorised in Europe and included in the annex 11 A and B of the directive 98/79/EC from the European Union and are on the list of essential products;
7. all medical materials and diagnostic medical devices authorized in a high-regulated country and are on the list of essential products.

(5, 6, 7: insofar as the contained elements contribute to the treatment of medical conditions.)

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1 WHO Technical Report Series 937/WHO Expert Committee on specification for pharmaceutical preparation, 40th report and any updates: http://www.who.int/diagnostics_laboratory/evaluations/en/; http://www.who.int/std_diagnostics/publications/manuels/default.htm; http://www.wpro.who.int/sites/rdt

2 WHO Pharmacopoeia, US Pharmacopoeia, British Pharmacopoeia, European Pharmacopoeia

3 http://www.icbs-web.org/page11.html

4 http://europa.eu.int/eur-lex/LexUeiServ/site/en/consleg/1998/L/01998L0079-20031120-en.pdf

We reserve the right to verify that products that do not meet the above criteria comply with the appropriate standards (see annexes 1 and 2). These evaluations may be delegated to institutions or organizations which we consider to have the appropriate tools to perform this control.

The members of Be-cause Health who sign this charter commit themselves to work with professional auditors[5] who will be responsible for the supervision and of the approved manufacturing sites. The audits will be conducted according to the standards of Good Manufacturing Practices (GMP of the WHO).

After purchase and delivery, samples of the purchased products can at any time be sent to an accredited laboratory for analysis.

Declaration of Honour

The distributor or manufacturer gives his word of honour:

- that he agrees to collaborate, if necessary, with the auditors appointed by our organizations
- that the information provided to the members of Because Health is accurate and correct
- that any changes in the manufacturing process or any changes of the source of a product will be promptly communicated

Every mistake or omission, whether intentional or not, can lead to an immediate disqualification of the product(s) and/or the manufacturer.

It can also lead to the annulment of all commercial contract concluded on this basis.

5 WHO Technical Report Series 937/Who Expert Committee on specifications for pharmaceutical preparation, 40th report and any updates.