PROPOSAL FOR A NEW WORK ITEM	
Date of proposal November 04, 2013	Reference number (to be given by ABBS)
Proposer Antigua and Barbuda Bureau of Standards	

A proposal for a new work item shall be submitted to the ABBS office, which will assign it a reference number and process the proposal. Proposals for a standard may originate from any sector of society, for example, consumers, stakeholders in industry, government policy, national NGOs/pressure groups, and the National Standards Body.

IMPORTANT NOTE: Proposals without adequate justification risk rejection or referral to the originator

Proposal (to be completed by the proposer)

Title of proposed deliverable:

Labelling of Pharmaceuticals

Scope of the proposed deliverable.

Specific requirements for the labelling of pharmaceuticals in order to provide all necessary information for the consumer. It will apply to all pharmacueticals which are imported, manufactured locally, sold or distributed in the country

Purpose and justification of the proposal.

Some countries do not yet have legislation that addresses pharmaceutical imports that are erroneously labelled and labelled in a foreign language. This is a dangerous practice that can result in harm or even death to consumers. Labelling also includes date marking which is also important for the health and safety or the consumer

If draft is attached to this proposal,:

Please select from one of the following options (note that if no option is selected, the default will be the first option):

X Draft document will be registered as new project in the committee's work programme (stage 20.00)

□ Draft document can be registered as a Working Draft (WD – stage 20.20)

□ Draft document can be registered as a Committee Draft (CD – stage 30.00)

□ Draft document can be registered as a Draft CARICOM Regional Standard (DCRS – stage 40.00)

Indication(s) of the preferred type or types of deliverable(s) to be produced

X National Standard □ Technical Specification □ Publicly Available Specification □ Technical Report

Proposed development track □ Fast track (12 months) **X** normal development (24.5 months)

Known patented items (see CROSQ directives, Part 1 Management of Technical work for important guidelines)

□ Yes **X** No **if "yes", provide full information as an annex**

A statement from the proposer as to how the proposed work may relate to or impact on existing work, especially existing CROSQ deliverables. The proposer should explain how the work differs from apparently similar work, or explain how duplication or conflict will be minimised.

We are not aware of any existing work in the region. However, some countries have Food and Drug regulations which address labelling of drugs (pharmaceuticals) – which will be incorporated in the process where appropriate

A listing of relevant existing documents at the international, regional and national levels

A search of the internet revealed the following (list not exhaustive):

Draft Guidance Document Labelling of Pharmaceutical Drugs for Human Use (Health Canada)

Guidance for Industry, Labeling for Human Prescription Drug and Biological Products – Implementing the PLR Content and Format Requirements (FDA)

A GUIDE TO LABELLING DRUGS AND POISONS in accordance with the Standard for the Uniform Scheduling of Drugs And Poisons (Australia)

A simple and concise statement identifying and describing relevant affected stakeholder categories (including small, medium and micro enterprises) and how they will each benefit from or be impacted by the proposed deliverable(s)

Manufacturers would have guidance on what information is required to be (and what information may be) on the label

Importers would have the necessary information to guide their suppliers

Consumers would have all the necessary information for using the drug safely and for making informed choices when purchasing non-prescription drugs.

Liaison organisations (list of relevant external international or Regional organisations or internal parties (or other CROSQ committees) to be engaged as liaisons in the development of the deliverable(s)

Preparatory work (at a minimum an outline should be included with the proposal)

X A draft is attached ☐ An outline is attached ☐ An existing document to serve as an initial basis

The proposer or the proposer's organisation is prepared to undertake the preparatory work required ☐ Yes ☐ No

Name and signature of Proposer (include contact information)

Name; Dianne Lalla-Rodrigues **Organisation: Antigua and Barbuda Bureau of Standards**

Contact number(s): (268) 562 4011 **Email: abbs@antigua.gov.ag** **Signature:**

Supplementary information relating to the proposal

- ☐ This proposal relates to a new CROSQ document
- ☐ This proposal relates to the amendment of an existing CROSQ document
- ☐ This proposal is for the revision of an existing CROSQ document
- ☐ This proposal relates to the re-establishment of a cancelled project as an active project

Annex(es) are included with this proposal (give details)

Comments of the CROSQ TMC / Council (to be completed by the CROSQ Secretariat)

Signature

CROSQ CEO