



IIR Working Party on “Cold Chain for Pharmaceutical Products”

Working Party of Commission D2 with Commissions D1 and C2

TERMS OF REFERENCE

INTRODUCTION

In accordance with Article XIX of the International Agreement concerning the IIR and articles 15 to 18 of the Internal Regulations of the Scientific Council of the IIR, the setting up of a Commission **D2** Working Party (WP) is proposed. The following terms of Reference (ToR) further define the role of the WP.

CONTEXT

Pharmaceuticals transported and preserved under controlled temperature are increasing tremendously by roughly 20% per year. They represent approximately some 5% of the total number of references. This mainly concerns vaccines, pharmaceuticals against cancer or blood derivatives. On the other hand, distribution solutions are more and more diversified, complicated and long because of production globalisation, biotechnologies development and pharmacy reorganisation.

Sanitary and economical risks are important. Pharmaceuticals cold chain management is a major economical and public health challenge all over the world.

If some countries have already launched work on these items, as of now there is no general world scale synthesis for transports, that are generally intercontinental. An increasing need for harmonisation exists in the pharmaceuticals cold chain. International organisations in charge of the item are the most relevant to organise these discussions.

This item is at the crossroads of cold chain and pharmaceutical sciences. In France for example, the French Refrigeration Association (AFF) worked together with the French Association for pharmaceutical Science and Technology to write a practical handbook on the pharmaceuticals cold chain. At the scale of IIR, a partnership with WHO would be valuable.

The French practical guide for pharmaceutical cold chain management could be a good starting point for work on these issues. The French conference on this topic in March 2008 could be the best place to launch the work.

OBJECTIVES

The working group objective is to publish a practical guide book for cold chain users.

ACTIVITIES

Field of application:

It is proposed to first deal with pharmaceuticals, but this field could be extended to other health products such as organs, bloods, derivatives, reactives or components....



177, boulevard Malesherbes, F-75017 PARIS, France

Tél. 33-(0)1 42 27 32 35 – Fax 33-(0)1 47 63 17 98 – E-mail: iif-iir@iifiir.org – Web: www.iifiir.org

The work will also include veterinary pharmaceuticals.

Concerned segments:

The WP will cover all the stages of the pharmaceuticals cold chain from production to its delivery to the patient in the hospital or at home, through transport and storage operations. The work will focus on transport, the more complex segment.

The WP will work closely with the IIR working party “Cold Chain Optimization”.

Climatic conditions taken into account:

The WP will try to take into account all the climatic conditions the pharmaceuticals could encounter including the most extreme, either in the final stage, consumption level, or in different segments of logistic chain such as airports tarmac under tropical sun or peri-polar iced wind.

Health constraints and economical issues

The WP will take into account two kinds of risks that could be, following the cases combined or in contradiction:

- Health risk : when a pharmaceutical is inactivated (or denaturised) because of temperature differences, it might not reach the objective on the patient. In the field of research, degraded pharmaceuticals will certainly lead to bad interpretations of results and inefficient treatments. In case of non respect of temperature limits, a pharmaceutical product could become inefficient but toxic elements could also appear. Its use by a patient could then have no benefic effect on the treatment of his disease and cause a degradation of his health and vital prognostic.
- Financial risk : health risks listed above will of course entail at least useless health expenses or even be harmful. On the other hand the control of temperatures could have an important cost while the multiplication of precautions over the necessary level engenders useless costs. In the case of low cost pharmaceuticals it could even be too expensive.

COMPOSITION AND ORGANISATION OF THE WORKING GROUP

IIR Commissions interested

Main commission: Commission **D2**

Links with Commissions **D1** and **C2**

Chairman and bureau

President: **Gérald CAVALIER**

Vice-President: **to be defined**

Secretary: **to be defined**

The Working Party will designate its officers at its first meeting.



Membership

Members of the Working Party are experts with a higher-education background who are willing to cover all costs associated with the work in WP either personally or through his/her organization/affiliation.

Members must be active in the working group. Members will be excluded after missing 3 successive meetings. Members will preferably be private members or representatives of corporate members of the IIR. The members of the working party who are not private members or representative of corporate members of the IIR or members of commission must be introduced by a member of the commission and accepted by the other members.

Provisional members list (to be completed) :

- Gilles LABRANQUE (F),
- Abbes KACIMI (F),
- Vincent BOUDY (F),
- Louis LUCAS (F)
- Sylvia ESTRADA-FLORES (AUS),
- Don CLELAND (NZ),
- Giovanni PANOZZO (I),
- Richard LAWTON (UK),
- Nick SMALE (NZ),
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Structure

The working party will be able to create subgroups.

Partnership

A partnership with WHO would be valuable.

Meetings

The President and the Vice-President of the Working Party will organize meetings, preferably once a year. The first meeting will be held in France in early 2008.

Minutes of the meetings shall be prepared by the Secretary and a copy shall be sent to the IIR head office, to the President of the Science and Technology Council and to the President of Commission **D2**. If the meeting is enlarged to a workshop, the organizers will prepare proceedings of the papers presented.

Web Site

Web pages dedicated to the working party will be developed, hosted by the IIR and linked to the Commission **D2** Web pages, will be set up in order to disseminate relevant information and to promote the activities of the working party and of the IIR.

A working area will also be developed on the web site for the member of the Working Party.

It will be periodically updated under the responsibility of the President and of the Vice-President.