WORLD HEALTH ORGANIZATION

First Global Consultation on
Regulatory Requirements for
Human Cells and Tissues for Transplantation

Ottawa, 29 November to 1 December 2004

Report

WHO Library Cataloguing-in-Publication Data

Global Consultation on Regulatory Requirements for Human Cells and Tissues for Transplantation (1st : 2004 : Ottawa, Canada)
First Global Consultation on Regulatory Requirements for Human Cells and Tissues for Transplantation, Ottawa, 29 November to 1December 2004 : report.

1.Cell transplantation – legislation 2.Tissue transplantation – legislation 3.Cell legislation – standards 4.Tissue transplantation – standards I.Title.

ISBN 92 4 159329 6 (NLM classification: WO 690)

Printed by the WHO Document Production Services, Geneva, Switzerland

Report

First Global Consultation on
Regulatory Requirements for
Human Cells and Tissues for Transplantation

Ottawa, 29 November to 1 December 2004

Introductory Note from the Secretariat

This publication reports on the deliberations and outcomes of the first Global Consultation on Regulatory Requirements for Human Cells and Tissues for Transplantation, held in Ottawa from 29 November to 1 December 2004. The Ottawa meeting represents the first step in WHO involvement in harmonizing global practices in the procurement, processing and transplantation of human cells and tissues, along the requirements of World Health Assembly Resolution WHA57.18 on Human Organ and Tissue Transplantation adopted in May 2004.

This meeting was made possible thanks to the support of the Canadian Ministry of Health, through Health Canada and the Public Health Agency of Canada. We gratefully acknowledge this aid and, in particular, we wish to thank the staff of these two organizations for their efficient assistance in preparing and supporting the consultation.

This report represents the views of the participants, not necessarily those of WHO. The report was prepared by the undersigned with the efficient administrative and secretarial support of Christine Faivre-Pierret. It is based on a draft prepared by the meeting Rapporteurs, Deirdre Fehily and Jill Hartzler-Warner, with the assistance of Martha Wells, who deserve thanks for their dedication and their success at capturing and summarizing complex material with clarity. Deirdre Fehily also played an important role in the preparation of this consultation and her input is gratefully acknowledged. All the participants in the consultation should be thanked for their active participation and their will to achieve consensus. The Secretariat owes special thanks to the Chairman of the meeting, Elwyn Griffiths, for his steady and thoughtful chairmanship.

The report was submitted to all participants for comment. We are grateful to them for their input. Any error or omissions are, of course, our responsibility, not theirs.

Luc Noël, Coordinator, HTP/EHT/CPR

Table of contents

Executive Summary

Cells and tissues for transplantation (CTTx) constitute a specific class of health products with important therapeutic value, as they have in many cases no equivalent in restoring life-supporting or essential functions. Yet many countries have poor access to essential CTTx, such as cornea. At national level in most countries CTTx activity data is not available. Many countries are lacking regulatory frameworks for CTTx despite the inherent disease transmission risks associated with the transplantation of human material. Many CTTx are circulating across international boundaries to meet patient needs, in physical or immunological characteristics, or simply to bridge a supply gap. A large proportion of these CTTx circulate outside of any regulatory oversight.

World Health Assembly Resolution WHA 57.18 urges Member States to "implement effective national oversight of procurement, processing and transplantation of human cells, tissues and organs, including ensuring accountability for human material for transplantation and its traceability". The development of regulations and planning for CTTx services are the responsibility of health authorities in order to ensure protection of the donor, patient safety and clinical efficacy. Beyond outcomes for the donor and the recipient, current developments in the area of cellular therapy and tissue engineering need to progress in a clear regulatory environment. The benefits of implementing a comprehensive regulatory framework outweigh the cost of the necessary investment.

A comprehensive regulatory framework encompasses defining a system of reference, such as standards, providing specifications for CTTx which should be legally mandated, a system for ensuring compliance and enforcement, surveillance system and accreditation. It is important that regulation address public and private activities alike. Both should be associated with the process of reaching an agreement on requirements and best practices, in particular through the input of professional societies and all stakeholders.

Requirements for CTTx must balance high quality with the need to ensure availability and must not limit innovation or serve as a barrier to international exchanges.

Participants in the consultation examined first drafts of core global specifications for basic essential tissue and cell products that are used globally and are moved between countries or marketed commercially (frozen bone or tendon, freeze-dried bone, skin, amniotic membrane, cryopreserved cardiac valves and vascular segments, cornea, fresh haematopoietic stem cells, cryopreserved allogeneic unrelated cord blood stem cells and cryopreserved