

***Record of Understanding (ROU) dengan  
Therapeutic Goods Administration, Australia***

# RECORD OF UNDERSTANDING

between

National Agency for Drug and Food Control (NADFC),  
Republic of Indonesia

and

Therapeutic Goods Administration (TGA),  
Department of Health and Ageing,  
Australia

## REGARDING THERAPEUTIC PRODUCTS

### 1. BACKGROUND

At the meeting on 27 February 2006 in Jakarta, Republic of Indonesia, the Head of the National Agency for Drug and Food Control of the Republic of Indonesia ("the NADFC") and the National Manager of the Therapeutic Goods Administration, Department of Health and Ageing of Australia ("the TGA") reached an understanding and wish to express the development of a cooperative relationship by exchanging information on legal and regulatory requirements in the area of therapeutic products with a view to ensuring the safety, quality and efficacy of therapeutic products used in their respective countries.

### 2. OBJECTIVES

The objectives of this Record of Understanding (ROU) are:

- a. to allow the NADFC and the TGA ("the Participants") to develop an understanding of each other's regulatory requirements and processes;
- b. to assist officials in each country to develop their professional competencies through exposure to the regulatory requirements and processes operating in another country; and
- c. to establish a framework for cooperative relationships between the Participants.

### 3. DEFINITIONS

In this ROU "therapeutic products" means:

- a. therapeutic goods as defined in Section 3 of the Australian *Therapeutic Goods Act 1989*, as amended from time to time; and

## **7. VARIATION**

Any provision of this ROU may be amended at any time by the mutual consent in writing of the Participants.

## **8. STATUS OF RECORD OF UNDERSTANDING OF COOPERATION**

This ROU reflects the intentions of the Participants. It is not intended to create legal obligations of any nature, either in domestic or international law.

## **9. EFFECTIVE DATE**

This ROU will come into effect upon the date of signature of both Participants and will continue in effect until terminated in accordance with clause 11.

## **10. AGENCY CONTACT**

The officers responsible for the administration of this ROU are:

- a. for the NADFC, the person holding the position of Permanent Secretary of the NADFC; and
- b. for the TGA, the person holding the position of Executive Director, Business Management Group.

## **11. TERMINATION**

11.1 Either Participant may, at any time, give written notice of termination to the other Participant and this ROU (with the exception of clause 5) will terminate six months after the date of receipt of the notice of termination.

11.2 The termination of this ROU will not affect the implementation of arrangements made under it before notice of termination was given.

Approved and signed in duplicate (in English only) on this 27 February 2006

for the National Agency for Drug  
and Food Control  
of the Republic of Indonesia

for the Therapeutic Goods Administration  
Department of Health and Ageing  
of Australia



by Mr H. Sampurno  
Head  
National Agency for Drug  
and Food Control  
of the Republic of Indonesia



by Dr David Graham  
National Manager  
Therapeutic Goods Administration  
Department of Health and Ageing  
of Australia

- b. therapeutics products as defined in the Head of National Agency for Drug and Food Control decree No. HK.00.05.3.1950, 2003 article 1, section 3, as amended from time to time.

#### **4. AREAS OF COOPERATION**

##### **4.1 Exchange of Information**

The Participants will establish avenues of communication to facilitate the exchange of information about the policies, practices, standards, testing technology, quality control, adverse drug reactions information, market compliance and requirements for the regulation of therapeutic products.

##### **4.2 Personnel Training**

Each Participant will provide such assistance as is possible to assist the other Participant to train in the areas relevant to the regulation of therapeutic products such as evaluation, Good Manufacturing Practice (GMP), post market monitoring and surveillance, and laboratory testing.

##### **4.3 Work Plan**

The Participants will develop a regular work plan setting out their goals under this ROU. While the Participants will use their best endeavours to implement the Work Plan, it is recognised that this will be subject to the availability of staff and funding.

#### **5. CONDITIONS OF EXCHANGE OF INFORMATION**

- 5.1 Information exchanged under this ROU will be used by the receiving Participant only for the purposes set out in this ROU.
- 5.2 Information that is exchanged will be treated as confidential and for the use of the Participants only and, subject to subclause 5.3, will not be released without prior written approval from the other Participant.
- 5.3 Dealings with information that may be exchanged or is exchanged are subject to such laws relating to the use and release of the information as may be in force from time to time.

#### **6. FINANCIAL ARRANGEMENTS**

- 6.1 Each Participant will bear its own costs in relation to initiatives undertaken under this ROU.
- 6.2 Any assistance provided by one Participant at the request of the other, will be provided on the basis of full cost recovery, unless otherwise consented to by the Participants.