



IRISH MEDICINES BOARD

**CONFIDENTIALITY COMMITMENT AND STATEMENT OF AUTHORITY  
FROM IRISH MEDICINES BOARD  
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED  
BY THE U.S. FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT  
OF HEALTH AND HUMAN SERVICES**

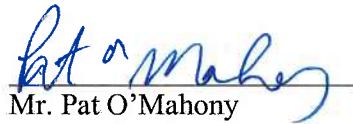
The United States Food and Drug Administration, a part of the United States Department of Health and Human Services (HHS/FDA), is authorized under 21 C.F.R. § 20.89 (“Communications with Foreign Government Officials”) to disclose non-public information to the Irish Medicines Board (IMB) regarding HHS/FDA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

IMB understands that some of the information it receives from HHS/FDA may include non-public information exempt from public disclosure under the laws and regulations of the United States of America, such as confidential commercial information; trade secret information; personal privacy information; law enforcement information; or internal, pre-decisional information. IMB understands that this non-public information is shared in confidence, and that HHS/FDA considers it critical that IMB maintains the confidentiality of the information. Public disclosure of this information by IMB could seriously jeopardize any further scientific and regulatory interactions between HHS/FDA and the IMB. HHS/FDA will advise IMB of the non-public status of the information at the time that the information is shared.

Therefore, IMB certifies that it:

1. has the authority to protect from public disclosure the non-public information provided to IMB in confidence by HHS/FDA;
2. will not publicly disclose HHS/FDA-provided non-public information without the written authorization of the owner of the information, the written authorization from the individual who is the subject of the personal privacy information, or a written statement from HHS/FDA that the information no longer has non-public status;
3. will inform HHS/FDA within two working days of any effort made by judicial or legislative mandate to obtain HHS/FDA-provided non-public information from IMB. If such judicial or legislative mandate orders disclosure of HHS/FDA-provided non-public information, IMB will take all appropriate legal measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure; and

4. will promptly inform HHS/FDA of any changes to IMB's laws, or to any relevant policies or procedures, that would affect the IMB's ability to honor the commitments in this document.



Mr. Pat O'Mahony  
Chief Executive  
Irish Medicines Board  
Kevin O'Malley House  
Earlsfort Centre  
Earlsfort Terrace  
Dublin 2  
Ireland  
Tel: 00 353 1 6764971  
Fax. 00 353 1 661 4764

20 Sept 2005.  
Date