

## Italian Official Gazette #224, published on September 26, 2005

The Italian Official Gazette published the official resolution by the Italian equivalent of the U.S. Food and Drug Administration regarding tricyclic antidepressants. The resolution was authorized by the AIFA (Agenzia Italiana del Farmaco - Italian Drugs Agency). Their purpose is to control and analyze drug utilization both at the national, regional and local levels. AIFA is under the direct control of the Minister of Health.

In the Gazette, the Administrator of the Italian Drugs Agency, seeing the opinion expressed by the Drugs-Surveillance Working Party of the Committee for Human Medicinal Products (CHMP) in a meeting in June 2005, declared that in order to guarantee the public health it was necessary to modify the labels on antidepressant drugs;

### IT IS DETERMINED:

#### Article. 1.

1. It is mandatory that all firms which have authorization to market tricyclic antidepressants at national level add to their labels what it is stated in Enclosure 1, which constitutes part of the present resolution.
2. The modifications stated in Enclosure 1 must immediately be added in the summary of the characteristics of the product and to the information sheet by the first lot of production following the present resolution.
3. The medical literature regarding tricyclic antidepressants will have to state what it is written in Enclosure 1 of the present resolution once the resolution goes into effect.

The present determination takes effect on the day after publication in the Official Gazette of the Republic of Italy.

Rome, 19 September 2005

Administrator: Rossi

#### Enclosure 1

Special warning and caution about use. Use with children and young adults under 18. Tricyclic anti-depressants must not be used for treatment in children and young adults under 18. Several studies on child depression in subjects falling in this age bracket have proven that this class of drug is not effective.

Studies regarding other antidepressants have shown that risks of suicide, self-injury and hostility are associated to the use of such drugs. Such risks can also arise with tricyclic anti-depressants. Moreover, tricyclic antidepressants are associated to the risk of heart attacks and conditions in any age bracket.

It must be kept in mind that no long-term data are available showing that such drugs have no effect in children and young adults as concerns growth, maturity and behavioral/cognitive development.