

**DIVIZJONI TAS-SAHHA**

“PALAZZO CASTELLANA”  
15, TRIQ IL-MERCANTI  
IL-BELT



MALTA

**HEALTH DIVISION**

“PALAZZO CASTELLANA”  
15, MERCHANTS STREET  
VALLETTA

Website: <http://www.health.gov.mt>

Telephone: + 356 21224071

Telefax: + 356 21224071

DH 229/90/Vol I

DH Circular No. DH 303/2002

30<sup>th</sup> October 2002

To: Wholesaleddealers in Pharmaceuticals

**RE: MARKETING AUTHORISATIONS FOR MEDICINAL PRODUCTS (HUMAN USE)**

Further to **Circular No. 278/01** dated 22<sup>nd</sup> November 2001 regarding the **Market Authorisations for Medicinal Products for Human Use**, and following requests by several wholesale dealers as well as discussions held with the Chamber of Commerce, the deadline for submission of questionnaires referred to in DH 278/2001 was extended. This resulted in a delay in winding up the first phase of the project thus creating a setback in the launch of the second stage of the project and the publication of fees.

As a result the date of 1<sup>st</sup> September mentioned in the third paragraph of this DH circular has been extended to **15th November 2002**. Therefore products which are covered by a valid CPP, recieved at the MRU offices by this date, will be granted a Provisional Market Authorisation (PMA) as explained in the subsequent fourth and fifth paragraphs of the circular.

Moreover CPPs covering these products will have their validity date extended up to 31<sup>st</sup> March 2003.

In all other respects, the requirements and requisites stated in **Circular No. 278/01** will be maintained.

The application for the PMA, for the above mentioned products, together with the relevant fees, will be published imminently.

Dr. Kay Busuttil

Director General Health