

Malta, 13 October 2005  
Circular No. P18/2005

**RE: Post-licensing requirements with respect to submission of Periodic Safety Update Reports (PSURs) for products licensed through the PMA-MA procedure.**

Article 104(6) of Directive 2001/83/EC as amended by 2004/27/EC and Article 75(5) of Directive 2001/82/EC as amended by Directive 2004/28/EC set new PSUR cycle that is applicable as from 20 November 2005. Marketing Authorisation Holders for products licensed through the PMA-MA procedures are required to submit PSURs to the Medicines Authority according using the current PSUR cycle (old legislation) until renewal, and after the renewal the PSUR shall be submitted at three-yearly intervals. It is acceptable to the Medicines Authority for MAHs to set the PSUR cycle on the International birth date of medicinal product.

The table below illustrates the proposed approach for marketed and non marketed products

	Marketed products	Non-marketed products
<b>MAAs <u>not yet renewed</u> before 20 November 2005</b>	The current PSUR cycle ( <b>old</b> legislation) will <b>apply until the renewal</b> , <b>and after</b> the renewal the PSUR shall be submitted at <b>three-yearly intervals</b>	<b>6-months PSUR</b> cycle: (i) for products currently on <b>6-months</b> PSUR: <b>maintain</b> cycle (ii) for products currently on <b>1-year</b> PSUR: <b>change</b> to a 6-months cycle <b>by June 2006</b>
<b>MAAs <u>already renewed</u> at least once before 20 November 2005</b>	A <b>5-years PSUR</b> shall be submitted together <b>with</b> the application for the next <b>renewal</b> of the MA. <b>After</b> the renewal PSUR shall be submitted at <b>three-yearly intervals</b> .	<b>6 months PSUR</b> cycle (iii) for products currently on <b>5-years</b> PSUR: <b>change</b> to a 6-months cycle <b>by June 2006</b>