

Medabon® receives first marketing authorizations in Europe

17 May 2012

Concept Foundation wishes to announce that Medabon® has received marketing authorizations from the Dutch Healthcare Inspectorate and the United Kingdom Medicines and Healthcare products Regulatory Agency. These marketing authorizations have been obtained by Concept Foundation's pharmaceutical partner, Sun Pharmaceutical Industries Ltd, and are the first to be received in Europe.

Medabon® is a co-packaged presentation containing one tablet of 200mg mifepristone and four tablets of 200µg misoprostol. Concept Foundation pioneered the development of the combination pack, under its agreement with, and using pivotal clinical data generated by WHO's Special Programme for Research, Development and Research Training in Human Reproduction (WHO/HRP), together with Sun Pharmaceutical Industries Ltd. This is an example of a successful outcome from a classic Product Development Partnership.

Although the number of abortions in Europe has not increased in recent years, the use of mifepristone together with misoprostol for medical abortion has been increasing significantly. Mifepristone is registered in most European countries, where it is usually used together with misoprostol. However, the use of misoprostol is generally on an off-label basis; Medabon® responds to this unmet need.

Since 2009, more than 1.5 million doses of Medabon® have been used in Cambodia, India, Nepal, Ethiopia, Ghana and Zambia. Both formal studies and routine use have shown Medabon® to have a high efficacy rate and high acceptability. It has made medical abortion easier to deliver and significantly improved compliance with the treatment regimen. This approach has now been copied by most other manufacturers in India, making medical abortion far safer in a country where neither users nor providers were well versed in appropriate drug use. Moreover, the work undertaken by Concept Foundation has allowed the development of a product to be supported by the only ICH-compliant regulatory dossier for the combination of mifepristone and misoprostol allowing registration in countries worldwide, including those with stringent regulatory agencies.

Concept Foundation is focused on ensuring that women in less-developed countries have equitable access to quality essential reproductive health medicines. Under its agreements with WHO and Sun Pharmaceutical Industries Ltd, Concept has ensured that Medabon® is available at a low preferential price to the public sector in developing countries. This has allowed medical abortion to become available for the first time in Cambodia, Nepal, Ethiopia, Ghana and Zambia. Achieving registration with a stringent regulatory agency in Europe means that there can be rapid approval by regulatory authorities in several lower and middle income countries either based directly on the European approvals or through a fast-track process. Hence the choice for women can now be rapidly expanded.

A resource pack, developed by Concept, PATH and Ipas, provides full supportive documentation, including "Medical and service delivery guidelines" and a "Framework for introduction". These documents can be found on the website, www.medabon.info.

About Concept Foundation

Concept Foundation is an international non-governmental organization, based in Bangkok, Thailand and Geneva, Switzerland. Its mission is to ensure that low income women worldwide have access to sexual and reproductive health products of assured quality at the lowest possible cost. This mission is being achieved through the support of several governmental and private donors. As well

as its work on injectable contraception and medical abortion, it is undertaking a major Quality of Reproductive Health Medicines programme, which it is managing on behalf of the Reproductive Health Supplies Coalition. The programme is assisting generic manufacturers to obtain prequalification of hormonal contraceptives and drugs for maternal health by WHO. See www.conceptfoundation.org.

About Sun Pharmaceutical Industries Ltd.

Established in 1983, listed since 1994 and headquartered in India, Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715) is an international, integrated, speciality pharmaceutical company. It manufactures and markets a large basket of pharmaceutical formulations as branded generics as well as generics in India, US and several other markets across the world. In India, the company is a leader in niche therapy areas of psychiatry, neurology, cardiology, nephrology, gastroenterology, orthopedics and ophthalmology. The company has strong skills in product development, process chemistry, and manufacturing of complex API, as well as dosage forms. More information about the company can be found at www.sunpharma.com.