



# STATEMENT

---

## **Merck Reaffirms Commitment to Family Planning in Resource-Limited Regions**

WHITEHOUSE STATION, N.J., July 11, 2012 – Merck, known as MSD outside the United States and Canada, supports the goals of today's London Family Planning Summit, co-hosted by the U.K. government and The Bill & Melinda Gates Foundation, in its ambition to make "affordable, contraceptive information, services and supplies available to an additional 120 million women and girls in the world's poorest countries by 2020<sup>1</sup>." The Summit aims to generate commitment and resources from developing countries, donors, the private sector, civil society, and other partners to meet the family planning needs of women in resource-limited regions. Merck/MSD is committed to researching and developing innovative women's health products and to supporting access to contraceptives for women around the world.

"Merck recognizes the importance of the Family Planning Summit," said Terrie Curran, senior vice president and general manager, Women's Health and Endocrine, Merck. "At Merck every woman counts. Developing solutions that support family planning is part of Merck's broader commitment to addressing the health needs of women in the developing world and providing access to health care remains one of Merck's guiding principles."

### **Improving access to medications around the world**

Merck has a long legacy of supporting efforts to improve access to its products, in resource-limited settings. We are an active partner with global organizations such as the Reproductive Health Supplies Coalition (RHSC), a global public-private partnership organization that helps address healthcare challenges around the world related to reproductive health. RHSC is championing the United Nations' Millennium Development Goal (MDG #5) to improve maternal health through its HANDtoHAND campaign.

Long-acting reversible contraceptives (LARCs) are often important options for women's family planning choices. Through this partnership with RHSC, Merck/MSD is working to enhance access to IMPLANON<sup>®</sup> (etonogestel implant) in resource-limited countries.

IMPLANON is indicated for the prevention of pregnancy in women. IMPLANON is a progestin-only implantable rod that provides up to three years of pregnancy prevention. IMPLANON must be removed by a physician at the end of the third year, but may be replaced by a new rod at the time of removal if continued contraceptive protection is desired.

Merck is also actively engaging with local ministries of health, the local and global development community, donors, governments, and non-governmental organizations (NGOs) to improve access to contraceptives. By increasing supply of IMPLANON to these organizations, Merck is hoping to enhance women's access to this contraceptive option. Merck/MSD has also established a lower price for IMPLANON in certain least-resourced countries. In addition, the U.N. Foundation's Pledge Guarantee for Health's financing mechanism will allow donors' funds to go further to increase access to contraceptives. Donors, governments and NGOs will be eligible for the reduced access price for IMPLANON in these eligible countries.

Because there are multiple barriers to access beyond the cost of contraception, Merck is supporting healthworker education and training in reproductive health as part of Merck's overall commitment to in-country capacity building. In the countries where Merck products are included in family planning programs, we work closely with Ministries of Health and local implementing partners who play a pivotal role in training, counseling and other related activities. We support medical education programs to help ensure the appropriate use of our medications. Merck is involved in a wide variety of partnerships, including a partnership with Jhpiego, an affiliate of Johns Hopkins University, and Tupange (also known as Kenyan Urban Reproductive Health Initiative) to sponsor Health Wagons serving underserved urban communities. Merck also supports the Ethiopian government Health Extension Worker program.

#### **About IMPLANON® (etonogestel implant)**

IMPLANON is indicated for use by women to prevent pregnancy.

#### **Selected Safety Information about IMPLANON**

IMPLANON should not be used in women who have known or suspected pregnancy; current or past history of thrombosis or thromboembolic disorders; liver tumors, benign or malignant, or active liver disease; undiagnosed abnormal genital bleeding; known or suspected breast cancer, personal history of breast cancer, or other progestin-sensitive cancer, now or in the past; or allergic reaction to any of the components of IMPLANON.

IMPLANON should be inserted subdermally so that it will be palpable after insertion, and this should be confirmed by palpation immediately after insertion. Failure to insert IMPLANON properly may go unnoticed unless it is palpated immediately after insertion. Undetected failure to insert the implant may lead to an unintended pregnancy. Failure to remove the implant may result in continued effects of etonogestrel, such as compromised fertility, ectopic pregnancy, or persistence or occurrence of a drug-related adverse event.

Complications related to insertion and removal procedures, such as pain, paresthesias, bleeding, hematoma, scarring, or infection, may occur. Occasionally in post-marketing use,

implant insertions have failed because the implant fell out of the needle or remained in the needle during insertion. If IMPLANON is inserted too deeply (intramuscular or in the fascia), neural or vascular injury may occur. Implant removal may be difficult or impossible if the implant is not inserted correctly, inserted too deeply, not palpable, encased in fibrous tissue, or has migrated. Deep insertions may lead to difficult localization of the implant and may also result in the need for a surgical procedure in an operating room in order to remove the implant.

After starting IMPLANON, women are likely to have changes in their menstrual bleeding pattern. These may include changes in frequency, intensity, or duration. Abnormal bleeding should be evaluated as needed to exclude pathologic conditions or pregnancy. In clinical studies of IMPLANON, reports of changes in bleeding pattern were the most common reason for stopping treatment (11.1%). Women should be counseled regarding bleeding pattern changes that they may experience.

Be alert to the possibility of an ectopic pregnancy in women using IMPLANON who become pregnant or complain of lower abdominal pain.

The use of combination hormonal contraceptives increases the risk of vascular events, including arterial events (strokes and myocardial infarctions) or deep venous thrombotic events (venous thromboembolism, deep venous thrombosis, retinal vein thrombosis, and pulmonary embolism). It is recommended that women with risk factors known to increase the risk of venous and arterial thromboembolism be carefully assessed. There have been postmarketing reports of serious arterial and venous thromboembolic events, including cases of pulmonary emboli (some fatal), deep vein thrombosis, myocardial infarction, and stroke, in women using IMPLANON. IMPLANON should be removed in the event of a thrombosis. Due to the risk of thromboembolism associated with pregnancy and immediately following delivery, IMPLANON should not be used prior to 21 days postpartum. Women with a history of thromboembolic disorders should be made aware of the possibility of a recurrence. Consider removal of the IMPLANON implant in case of long-term immobilization due to surgery or illness.

If follicular development occurs, atresia of the follicle is sometimes delayed, and the follicle may continue to grow beyond the size it would attain in a normal cycle. Generally, these enlarged follicles disappear spontaneously. Rarely, surgery may be required.

Some studies suggest that the use of combination hormonal contraceptives might increase the incidence of breast cancer, and increase the risk of cervical cancer or intraepithelial neoplasia. Women with a family history of breast cancer or who develop breast nodules should be carefully monitored. IMPLANON should be removed if jaundice occurs.

The IMPLANON implant should be removed if blood pressure rises significantly and becomes uncontrolled.

Studies suggest a small increased relative risk of developing gallbladder disease among combination hormonal contraceptive users. It is not known whether a similar risk exists with progestin-only methods like IMPLANON.

Prediabetic and diabetic women using IMPLANON should be carefully monitored. Women with a history of depressed mood should be carefully observed. Consideration should be given to removing IMPLANON in patients who become significantly depressed.

In clinical trials, the etonogestrel levels in blood decreased below sensitivity of the assay by one week after removal of the implant. In addition, pregnancies were observed to occur as early as 7 to 14 days after removal. Therefore, a woman should re-start contraception immediately after removal of the implant if continued contraceptive protection is desired.

Hormonal contraceptives may cause some degree of fluid retention. They should be prescribed with caution, and only with careful monitoring, in patients with conditions which might be aggravated by fluid retention. It is unknown if IMPLANON causes fluid retention.

Contact lens wearers who develop visual changes or changes in lens tolerance should be assessed by an ophthalmologist.

The most common adverse reaction causing discontinuation of use of the implant in clinical trials was change in menstrual bleeding patterns, specifically irregular menses (11.1%). The most common adverse reactions ( $\geq 10\%$ ) reported in clinical trials were headache (24.9%), vaginitis (14.5%), weight increase (13.7%), acne (13.5%), breast pain (12.8%), abdominal pain (10.9%), and pharyngitis (10.5%).

Drugs or herbal products that induce enzymes, including CYP3A4, that metabolize progestins may decrease the plasma concentrations of progestins and may decrease the effectiveness of IMPLANON. In women on long-term treatment with hepatic enzyme inducing drugs, it is recommended to remove the implant and to advise a contraceptive method that is unaffected by the interacting drug. Significant changes (increase or decrease) in the plasma levels of progestin have been noted in some cases of coadministration with HIV protease inhibitors or with non-nucleoside reverse transcriptase inhibitors.

CYP3A4 inhibitors, such as itraconazole or ketoconazole, may increase plasma concentrations of etonogestrel.

Hormonal contraceptives may affect the metabolism of other drugs. Consequently, plasma concentrations may either increase (for example, cyclosporin) or decrease (for example, lamotrigine).

#### **Rule out pregnancy before inserting IMPLANON.**

Based on limited clinical data, IMPLANON may be used during breast-feeding after the fourth postpartum week. Use of IMPLANON before the fourth postpartum week has not been studied. Small amounts of etonogestrel are excreted in breast milk. The health of breast-fed

infants whose mothers began using IMPLANON during the fourth to eighth week postpartum (n=38) was evaluated in a comparative study with infants of mothers using a non-hormonal IUD (n=33). They were breast-fed for a mean duration of 14 months and followed up to 36 months of age. No significant effects and no differences between the groups were observed on the physical and psychomotor development of these infants. No differences between groups in the production or quality of breast milk were detected.

Safety and efficacy of IMPLANON have been established in women of reproductive age and are expected to be the same for postpubertal adolescents. However, no studies have been conducted in women less than 18 years of age. Use of this product before menarche is not indicated.

The efficacy of IMPLANON in women who weighed more than 130% of their ideal body weight has not been defined because such women were not studied in clinical trials. Serum concentrations of etonogestrel are inversely related to body weight and decrease with time after implant insertion. Therefore, IMPLANON may be less effective in overweight women.

**IMPLANON does not protect against HIV infection (AIDS) or other sexually transmitted diseases.**

### **About Merck**

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit [www.merck.com](http://www.merck.com) and connect with us on Twitter, Facebook and YouTube.

### **Forward-Looking Statement**

This news release includes “forward-looking statements” within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Such statements may include, but are not limited to, statements about the benefits of the merger between Merck and Schering-Plough, including future financial and operating results, the combined company's plans, objectives, expectations and intentions and other statements that are not historical facts. Such statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements. The following factors, among others, could cause actual results to differ from those set forth in the forward-looking

statements: the possibility that all of the expected synergies from the merger of Merck and Schering-Plough will not be realized, or will not be realized within the expected time period; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; Merck's ability to accurately predict future market conditions; dependence on the effectiveness of Merck's patents and other protections for innovative products; and the exposure to litigation and/or regulatory actions. Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2011 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)).

# # #

Please see the Prescribing Information for IMPLANON at ([merck.com/product/usa/pi\\_circulars/i/implanon/implanon\\_pi.pdf](http://merck.com/product/usa/pi_circulars/i/implanon/implanon_pi.pdf)) and the Patient Information for IMPLANON at ([http://www.merck.com/product/usa/pi\\_circulars/i/implanon/implanon\\_ppi.pdf](http://www.merck.com/product/usa/pi_circulars/i/implanon/implanon_ppi.pdf))

---

<sup>1</sup> Reproductive Health Supplies Coalition (RHSC). Family Planning Summit 2012. Zero Draft Summit Document. London Summit on Family Planning – July 11, 2012; available at: [http://www.rhsupplies.org/fileadmin/user\\_upload/News/London\\_Summit\\_on\\_Family\\_Planning\\_Overview\\_Version\\_1\\_on\\_14\\_June.pdf](http://www.rhsupplies.org/fileadmin/user_upload/News/London_Summit_on_Family_Planning_Overview_Version_1_on_14_June.pdf); last accessed June 27, 2012.