

# Implanon®

## Basic Information and A Feminist Perspective

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### What is Implanon®?

*Implanon® is a long-acting hormonal contraceptive implant in the form of a rod measuring 34 mm long and 2.4 mm in diameter that prevents pregnancy for a period of three years. Implanon® is inserted under the skin of a woman's upper arm. It prevents pregnancy by gradually dispensing etonogestrel, a progestogen hormone that inhibits ovulation and thickens the cervical mucus, thereby decreasing the mobility of sperm. Organon (the Netherlands), the pharmaceutical company, which developed the implant conducted studies with 1,700 women over 70,000 cycles and reported no pregnancies.*

### Where is Implanon® available?

*Implanon® has a marketing license in the European Union and is currently marketed in eight European countries. It is also available through the National Family Planning Programme in Indonesia. In the near future, Organon plans to introduce Implanon® into Australia and*

*Brazil. In 2000, the company also applied for USFDA approval for marketing in the United States, and is negotiating with USAID for possible inclusion of the contraceptive in family planning programs in different countries that are funded by the US government.*

*Organon has developed a training program for doctors to ensure that Implanon® is inserted and removed correctly and that women are provided with the necessary information. The company plans to maintain a database of trained doctors to help women locate a doctor in their area. Company officials emphasize that woman considering Implanon® as a method of contraception should seek a trained doctor.*

### What are Implanon®'s side-effects?

*Implanon® has the side-effects<sup>1</sup> of progestogen-only contraceptives, such as the following.*

- *Virtually all women will experience a change in bleeding pattern; this could include prolonged bleeding, frequent bleeding, infrequent bleeding or amenorrhea. Some women may even experience a range of these bleeding patterns while using Implanon.*
- *Weight gain (20% of women experienced a weight increase of 10% or more)*
- *Headaches, nausea, breast pain and mood swings*
- *Acne (14% of women); 10% of pre-existing acne worsened*
- *Beneficial side-effects: some women experienced an improvement in pre-existing acne (59%) or dysmenorrhea (88%) after the insertion of Implanon®.*

### Hormonal implants as contraceptives...

*The women's health movement has raised serious criticism regarding hormonal implants because they are long-acting and the woman has no control over them. Use of implants can be highly problematic in an environment where women are targets of population control programmes. Furthermore, administration of implants is questionable when access to healthcare is limited and the public health care system is weak, because women may not get medical check-ups or may not be able to have the implant removed on demand, in case they experience negative side effects or desire a pregnancy.*

*Norplant®, the first contraceptive implant, was introduced in 1983. It consists of a six silicone capsules filled with levonorgestrel and is effective for five years. Meanwhile, Norplant II®, Jadelle®, (3 capsules, 3 years) has been introduced. Women's health advocates have opposed Norplant® because it has been used coercively on poor women and women of color both in so-called Third World countries and in the U.S. Norplant® lends itself to abuse in eugenic and population control programs. Some specific examples of abuse include: women being denied removal on demand or discouraged from early removal, the insertion of Norplant® free of charge but charging the full cost for early removal, and the stipulation that women on social welfare accept Norplant®. The two latter examples are from the USA.*

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<sup>1</sup> Affandi, B. "An Integrated Analysis of Vaginal Bleeding Patterns in Clinical Trials of Implanon." *Contraception*, December 1998: 58: 6 Suppl. Urbancsek, J. "An Integrated Analysis of Nonmenstrual Adverse Events With Implanon." *Contraception*, December 1998: 58: 6 Supplement

Along with these ethical concerns, serious health problems have been associated with use of Norplant<sup>®</sup> including blindness, depression and ectopic pregnancy. It was discovered that during clinical trials with Norplant<sup>®</sup>, little emphasis was placed on recording the actual incidences of side-effects, and follow-up was inadequate.<sup>2</sup> As women's health advocates, we want to avoid this abuse of contraceptives and ensure that all side-effects experienced by women are taken seriously and studied thoroughly before the drug reaches the market. Since Implanon<sup>®</sup> is a contraceptive analogous to Norplant<sup>®</sup>; we fear that similar problems may surface.

### **Does Implanon<sup>®</sup> have advantages over Norplant<sup>®</sup>?**

Comparative studies have been performed between Implanon<sup>®</sup> and Norplant<sup>®</sup>, and the results indicate that there are few differences between the two contraceptives in terms of side-effects.<sup>3</sup>

#### **Implanon<sup>®</sup>**

- 30 -40% amenorrhea
- 10-20% prolonged bleeding
- 30-50% infrequent bleeding
- 20% gained 10% of their total weight

#### **Norplant<sup>®</sup>**

- é 20-30% amenorrhea
- é 49-56% prolonged bleeding<sup>4</sup>
- é 30-50% infrequent bleeding
- é 17% gained 10% of their total weight

The advantages that the company points out are: easier insertion and removal (1 rod vs. 6 capsules), inhibition of ovulation for at least two years, no pregnancies during clinical trials, and training programmes in all countries where Implanon<sup>®</sup> is on the market. Organon has voiced a commitment to introduce Implanon<sup>®</sup> only where health care systems are strong and women can have Implanon<sup>®</sup> removed on demand. This improvement in service delivery could be a step forward from the unethical promotion of Norplant<sup>®</sup>. However, when expanding the availability of Implanon<sup>®</sup> to countries in the South or selling Implanon<sup>®</sup> through family planning programmes, can and will Organon keep that promise, and if so, how?

### **Our Assessment**

Although there are some advantages of Implanon<sup>®</sup> over Norplant<sup>®</sup>, such as easier insertion and removal and a shorter duration of effects, they are similar in many respects. This leaves us with many questions: Will Implanon<sup>®</sup> also become a tool for population control?; Will serious health concerns arise when Implanon<sup>®</sup> is widely used in diverse populations?; Will Implanon<sup>®</sup> be useful for women?; and How will it affect women whose health and nutritional status is compromised?

After reviewing the clinical data available on Implanon<sup>®</sup>, we are not satisfied with the low number of trial participants and the way certain aspects were monitored. For example, return of fertility was measured by the return of ovulation within a period of three months following the removal of Implanon<sup>®</sup>. We think this does not sufficiently confirm a woman's ability to become pregnant or give birth to a healthy baby.

Wide variations in data were also a cause for concern. In all Indonesian trials, enrolling forty percent of women studied, the data for non-menstrual adverse effects differed considerably from the European and U.S. data. The fact that these variations are presented but not explained is a cause for concern, because it demonstrates a lack of sensitivity to the effects of Implanon<sup>®</sup> cross-culturally. The differences should be studied further instead of ignored. We are afraid that insufficient data make the market the testing ground to answer the remaining questions. In our view, this is not acceptable. Importantly, Organon insists that they have collected more data than would be necessary for licensing in Europe. This points to the weaknesses of drug approval requirements where contraceptives are concerned. As Organon expands the availability of Implanon<sup>®</sup> to countries in the South, feminists and health activists need to be alert regarding the implications for women in their countries. It remains to be seen whether the company implements their plans to ensure that users of Implanon<sup>®</sup> are given adequate information, and that doctors are trained properly.

As women's reproductive health and rights advocates, we would like to see greater emphasis placed on the development of contraceptives that can be controlled by women and methods that also protect against sexually transmitted diseases. Implants fulfill neither of these considerations. We think that interested women, doctors and women's health and rights advocates should critically examine the advantages and disadvantages of Implanon<sup>®</sup> in the specific context of their countries.

For more information, please e-mail: [office@wgnrr.nl](mailto:office@wgnrr.nl) or write to **WOMEN'S GLOBAL NETWORK FOR REPRODUCTIVE RIGHTS (WGNRR), VROLIKSTRAAT 453-D, 1092 TJ AMSTERDAM, THE NETHERLANDS**

September 2000, written by Erin Howe

<sup>2</sup> Ollila, Eeva. "Norplant in Context of Population and Drug Policies." STAKES Research Report, Finland 1999.

<sup>3</sup> Edwards, Jayne E. and Andrew Moore. "Implanon: A Review of Clinical Studies." *British Journal of Family Planning*. 1999: 4: 3-16.

<sup>4</sup> Bock von Wülflingen, Bettina: Norplant vs. Women – Women vs. Norplant. *WGNRR Newsletter* 70, 2000, pp. 24-28