net-en. not again.

another government attempt to introduce controversial injectable contraceptives

For over two decades, women's groups and health groups have been opposing the introduction of injectable contraceptives such as Net-En into the national family planning programme. In 1984, when the government was testing this contraceptive in primary health centres, our fears were confirmed– women were being recruited without being given information about the possible health implications and hazards of the contraceptive itself, other available options, or in fact, that they were subjects of a trial to study the impact and efficacy of Net-En on women! The consequent campaigns took a two-fold approach: to fight for meaningful, informed consent of women for the trial and/or use of such contraceptives, and secondly, to understand the hazards of (see box) and resist the introduction of long acting hormonal contraceptives in India.

A public interest litigation followed, and for the 15 years that it took for the case to be disposed of by the court, the introduction of Net-En was held at bay. Although in August 2000 in front of the Supreme Court, the Ministry of Health and Family Welfare had taken the position that Net-En would be introduced only where adequate facilities and counselling are available, once the court case was disposed of, the government lost no time in initiating yet another study with Net-En. One of the main stated objectives of this study was to assess women's perception and acceptability of the method in clinics where adequate quality care was ensured.

We call for an immediate stoppage to any plans of introduction of hazardous hormonal injectable contraceptives through the public health system.

In April 2008, even before the results of the study were made public, the Ministry of Health and Family Welfare hurriedly called a meeting to initiate pre-programme introduction studies, not just with Net-En but also with Cyclofem, a monthly combined injectable contraceptive. Saheli and many other women's and health groups which have been constantly involved in resisting the introduction of hazardous injectable contraceptives were not invited to this meeting, even though its ostensible purpose was to take the 'feedback of different stakeholders'. Not surprisingly, this government meeting sparked off renewed activity on the issue. With the Delhi-based Sama Resource Group for Women and Health taking the initiative, a collective letter, signed by several groups and individuals from all over the country, was sent to the Ministry of Health and Family Welfare, demanding:

- An immediate stoppage to any plans of introduction of hazardous hormonal injectable contraceptives through the public health system;
- That all documents and information regarding the recently completed trials for Net-En and Cyclofem - including study design, protocols, findings, content of informed consent forms, screening for contradictions, list of venues of the trials, as well as the legal and medical protection provided to the women who were research subjects be made public;
- That all documents regarding the study design, protocols and complete list of proposed district hospitals/medical colleges and NGO partners for Phase IV trials also be made public.

When the government failed to respond for two months, we finally pushed for a meeting with the Ministry which materialised only on 16th June 2008 with the Deputy Commissioner (Research, Studies & Standards), Dr Jayalakshmi and the Assistant Commissioner (Family Planning II), Dr Keerti Malvia, who said that reports of the studies with the two injectables would soon be posted on the official website and that we could raise further queries if we were not satisfied.

Significantly, the Ministry officials stated that the next stage of pre-programme introduction study, meant to commence in two to three months, would be carried out in 30 district hospitals and through 9 NGOs, whose names and locations would be provided. After detailed discussions on several ethical and medical issues regarding trials and use of injectables like Net-En and Cyclofem, Dr. Jayalakshmi suggested a meeting of activists and 'technical experts' to discuss the concerns

raised, as she was personally unable to respond to them. She also promised that the report of the studies - including the protocol, consent forms, research design, findings, etc., would be circulated prior to the meeting providing us time for us to examine/study it. Yet, five months later, despite repeated reminders, mails and phone calls from various groups, the Ministry has failed to schedule such a meeting.

The reports, however, were put up on the Ministry website in July. It is clear that the government has not moved an inch from its unethical and callous attitude towards women. What has changed is the fact that the government has now taken it upon itself to represent women's voices by way of an 'exit interview'. We give below some of the key loopholes and inconsistencies in the recently concluded trial by the country's premier research institute, the ICMR:

Family Planning centres all over the country have had a long and controversial history of coercing women into sterilisation, the use of provider-controlled contraceptives and enrolment in such studies.

Recruitment of women: The government, in the preamble to the study, reiterates that it will recruit only those healthy women who approach the family planning clinics after being given all the information about the cafeteria of choices available. But the fact of the matter is that, out of a total of 1208 participants, only 518 (43%) were from Family Planning (FP) clinics and the rest were postpartum and post-MTP cases. Recruitment of women in the last two categories clearly defies the research design. Additionally, FP centres all over the country have had a long and controversial history with women seeking abortion or delivery services being coerced into sterilisation, the use of provider-controlled contraceptives or enrolment in such studies as a precondition to accessing these services.

Although the study report claims that nearly half of the eligible women 'opted' for Net-En, there are wide inter-centre differences, and in places like Delhi, Cuttack and Nagpur, hardly any of the eligible women opted for any other contraceptive.

Informed consent: The study report, for a change, includes both, the information provided to the participants and the consent form used in the study. It is evident that no attempt was made to make women aware of even the acknowledged side effects of Net-En that can be found in the package insert. For instance, according to German Remedies Limited, India, Noristerat is particularly suitable for women who cannot take oral contraceptives regularly or who do not tolerate them well and should only be administered to women with a history of normal menstrual cycles. No serious side effects and adverse reactions find mention in the information shared with participants. There is no mention of thromboembolism, cardiovascular risks and potential cancers - all of which need to be ruled out before starting Net-En injections and require careful monitoring both, during and after their use.

The most common side effect of Net-En is the disruption of bleeding patterns. Changes in bleeding patterns are not completely understood scientifically and there is no established protocol to deal with excessive bleeding. Most recent publications of WHO confirm this to be true even today. Clearly, no progress has been made in the quarter century that has passed since ICMR reported that a volunteer had to be subjected to repeated D&C to control excessive bleeding. The risk to the foetus if it is exposed to Net-En is not fully known and the subjects are not informed of this.

Additionally, WHO recommends that non-hormonal methods of contraception should be the first choice for breast-feeding women - none of this finds mention in the informed consent sought by researchers. The study also ignored WHO guidelines and actively recruited a high number of postpartum women (36%).

Lost to follow up: Though the study makes an effort to state that only such women will be recruited who are accessible for follow up and monitoring, 10.9 % are lost to follow-up at 6 months and 16.7% at the end of two years, making it the single largest factor for discontinuation of the method. If this is the scenario in a closely supervised trial, it is a cause for great concern if this contraceptive is made available in the public health system, where women exposed to unusual amounts of hormones will be 'lost' without any monitoring of their health for potential adverse effects. In the absence of adequate infrastructure, to rule out potential risk factors for the women, introduction of hormonal injectables is hazardous, as we have been repeatedly saying over the years.

WHY DO WOMEN'S GROUPS OPPOSE LONG-ACTING CONTRACEPTIVES LIKE NET EN?

Women's groups the world over have been opposing long-acting, hormonal, invasive contraceptives like injectables (Net EN, Depo Provera, Cyclofem etc), implants (Norplant, Capronor). What is it that makes these contraceptives so unsuitable for women, especially in the Third World?

· **They are invasive**, meaning that they act on the entire body system for the one purpose of contraceptive effect. They affect several organs in the body - the hypothalamus and pituitary in the brain, the liver, the heart etc. in addition to the reproductive organs.

· **They are hazardous.** Studies so far have shown that these contraceptives have several short-term side-effects such as menstrual disturbances, headaches, fatigue, depression etc. and possible hazards like thromboembolism (formation of blood clots), cardiovascular problems, osteoporosis and cancer risk. Risks to the foetus, and future children have not been satisfactorily ruled out.

· **They are long-acting.** By their inherent nature, the effect of these contraceptives cannot be withdrawn before a given period of time. So, even a woman experiences a serious problem, she has to wait till the effect wears off, in about 12-15 weeks in the case of injectables. In India, where health care services are inadequate or absent, this can be a serious problem.

· **Return of Fertility is not assured.** Although these methods are promoted as spacing methods i.e. to ensure a gap between one child and the next, many women have experienced delay, or difficulty in conceiving. For instance, some women could not conceive even a year after stopping the use of Net En.

· **The risks to breast-feeding infants whose mothers are injected with Net En or implanted with Norplant, have not been satisfactorily ruled out.** This is a grave concern, since as a spacing method, a majority of women targeted for injectables will be breast feeding.

· **Risks to children conceived by accident during use of injectables or Norplant, or conceived before the effect of the drug has worn off, have not been satisfactorily ruled out.**

· **They are provider controlled**, which means that the health service provider (Auxiliary Nurse Midwife, doctor, paramedic) is the one who controls when to administer the contraceptive. With Norplant, the provider even has to remove it, and there is documented evidence that women were denied removal of Norplant even though they experienced problems with it.

· **The health care infrastructure is inadequate to ensure safe delivery** of long-acting hormonal contraceptives. Ruling out contraindications, monitoring the woman during use, responding to emergencies like anaphylactic shock, ectopic pregnancy, stroke (possible hazards of these contraceptives) needs well-equipped health facilities with well-trained personnel - a far cry from the present dilapidated health centres and absence of medical staff especially in rural areas.

· **Unethical testing** has been a hallmark of clinical trials of long-acting contraceptives in India. From lack of informed consent to outright coercion, scientific investigation on contraceptives have fallen short of meeting universally accepted ethical norms. It is our contention that the inherent nature of these contraceptives contributes to their misuse.

· **Potential for Abuse** given the nature of long-acting hormonal contraceptives - long-term effect and easy to administer - there is a high chance that they will be indiscriminately used in the population control programme. Women may be given injections without them knowing it is a contraceptive. Women's need for contraception may be misused, and they "agree" to take an injection or implant without being fully aware of the side-effects and hazards. Misinformation, lack of informed consent and "persuasion" through incentives have been women's experience in the past 5 decades in the Family Welfare Programme in India. In the West, injectables have had a history of abuse on Hispanic, Black, immigrants and women incarcerated in mental asylums and jails.

· **They offer no protection against HIV/AIDS.** The spread of HIV/AIDS is a very real threat for all sexually active persons (in India, 75% spread is due to heterosexual sexual contact). A method which offers protection against HIV/AIDS and sexually transmitted diseases would be a more suitable method in this situation.

· **Profit making by pharmaceutical companies** takes precedence over women's health. In the rush to win over the market, especially Third World governments, research norms are violated, and ethics take a back seat in the race to complete trials, get approval and apply for patents.

Contrary to the official perception of women as mindless breeder of babies, women do desire to control their fertility. We have been campaigning for safe, effective, reversible contraceptives which women are able to control. Barrier methods which do not interfere with the entire body system, but are effective contraceptives are the condom, diaphragm, cervical cap, female condom. It is no coincidence that safe and effective barrier methods for women like the diaphragm and cervical cap are not available in India. Since they are reusable for 2-3 years, they are also cheap (and obviously, no pharmaceutical company can make huge profits, as with injectables and implants). Alongside, we have been campaigning for increased male responsibility in contraception, and development of safe and effective male methods.

If the government is committed to try and introduce injectables like Net-En again and again, we must resist their introduction again and again.

What women prefer: Interestingly, many of the women recruited for the study (40%) were first time contraceptive users. They had had no experience with any other method and so their responses have a limited value even if, as the study claims, 79% of them said that they would recommend the contraceptive to others. Additionally, one must remember that the ideal spacing interval is three years and the woman should continue with the method for two years. Yet more than 40% (480 women) had dropped out before completing a year with the injection. So apparently what they are ready to recommend is not what they are ready to use!

Unexplained deaths: Two deaths are reported among the subjects, one at four months and one at six months. The cause of death is not reported. This is a cause for great concern, especially because only healthy young women were recruited for the study.

Net-En has been studied many times over in the country. In all the studies, the common element is the high drop out rate – with action and not with words women are saying NO to the injectable. Yet the government is pursuing it relentlessly, exposing women repeatedly to its hazards, and expending the already scarce trained manpower and infrastructure of the health department on an unviable, hazardous contraceptive option, with high attendant direct and indirect costs.

More than two decades after the first protests against such injectable contraceptives, we find that instead of addressing the medical and ethical concerns, the current emphasis on 'counselling', both in the ICMR study as well as government rhetoric, continues to prioritise the introduction and continuation of such hazardous, long-acting methods over the well-being of women.

So, if the government is committed to try and introduce injectables like Net-En again and again, we must garner ourselves to raise our voice and resist their introduction again and again. There is no other choice.