QUESTIONS FOR THE DRUGS CONTROLLER OF INDIA

A. Information which we have asked for

1. Nature and date of licence granted to Upjohn, Max Pharma, Schering AG, and German Remedies.
2. Data submitted by Upjohn for getting Licences, including Indian studies.
3. Results of Phase IV studies on Net En conducted by ICMR.
4. List of Centres/ Docters involved in Post Marketing Surveillance.
5. Protocol of P.M.S. being done for Depo-Provera.

B. Questions

1. What is the nature of licences granted for Noristerat and Depo-Provera. What is the nature of licences for Depo granted in other countries?
2. a) Date of granting licence in India
   b) Details regarding manufacture/sale/import/ - quantities.
   c) Have specifications for the package insert, physicians information, been guided by DC(I)
   d) Has any PMS been ordered for Net En?
   e) Has any review been set up after PMS?
   f) Has any stipulation been made to limit sales through outlets till PMS has been carried out?
3. How has the DC(I) satisfied himself with respect to dosage of DepoProvera for Indian women.
4. What data have been submitted to the DC(I) by the concerned applicants to show that these products are superior to alternat contraceptives available in India ?
5. How has the DC(I) tried to ensure that the drugs will not be misused :
   a) What is the feed back he will get regarding distribution ?
   b) How will contraindications be ruled out ?
   c) How are over-the-counter- sales to be restricted?
   d) How much information is being provided to Docters ?
   e) How much information will be carried in the package insert; how is the user going to be able to understand serious adverse reactions ?
6. How has the DC(I) satisfied himself that side-effects reported are not serious ?
   a) For bleeding disturbances. (Kindly provide us with the report of ICMR Phase III Trial with Depo Provera.)
   b) For metabolic changes.
   c) For teratogenicity.
   d) For immune suppression.
   e) For long term effedts on breast fed infants.
   f) For long term effects on infants accidentally exposed in utero.
   g) For carcinogenicity.
   h) Return of fertility not assured.
   i) For bone loss and osteoporosis.
   j) For the other nearly 75 adverse effects mentioned by Upjohn, and an equally high number experienced by Net En users.
7. What is the difference between Net En and Depo Provera, that Net En introduction (even though we are in total disagreement with it) was

preceeded by nearly 24 years of research in India, and Depo Provera, wh which was earlier rejected by ICMR, has been suddenly found to be acceptable without any new trials.

8. Why has no Post Marketing Surveillance been ordered for Net En ?

9. Has Net En been approved for urban centres ? What is the current status of Net En in the National Family Planning Programme ?

10. Why has the DC(I) not replied to our petition in the Supreme Court filed in 1986, regarding the safety of Net En ?

11. What are the plans for Introducing Depo Provera into the national FP programme ?

12. How has all the literature for injectables been printed ? Who has paid for it ? How many copies have been printed ?

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