High Dose EP Drugs—I

Responsibility of Industry, Doctors and Government

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The proliferation of irrational and dangerous drugs in India has generated a well-informed and dynamic drug consumer's movement. Of the several issues that it has taken up the issue of banning high dose oestrogen progesterone drugs illustrates best its capability. On the other hand, the issue has also revealed inefficiency of the drug control authorities, their inability to implement the rules in the book designed to protect the consumer.

This inefficiency on the part of government institutions is compounded by their close collusion with the drug inaustry. The medical profession has also played a crucial role in opposing the ban of these drugs. The article highlights the unethical practices and actions of the different sections who have been involved in pressing for the continued marketing of high dose EP drugs.

IN 1982, the Indian Council of Medical Research recommended:

> "Fixed dose combination of oestrogens and progesterone may be totally banned in the country, even for the treatment of secondary amenorrhoea as other substitute are available in the market for management of secondary amenorrhoea"

Based on this recommendation, the ministry of health and family welfare banned HDEP in June 1982. Today five and half years after, the drug is freely available in India! The industry, medical profession, courts of law even the government departments played their role in undoing the govt's ban order.

For the first time in India the question of banning of a drug is being discussed and debated; consequently it has exposed the low level of ethics followed by the people involved in the medico-technical establishment.

It must be pointed out that the issue of harmful effect of a drug and therefore, its banning had never been raised by the medical profession. Even the issue of harmful effect of 'thalidomide' was taken up by the journalists and the ripple created in the so-called 'lay press' raised a wave which not only washed away any effort to defend the crime made by Gruanthal (its manufacturer) but exposed the menace of the industry in collusion with certain famous opinion maker medical personnels. In India similarly nothing is being said or no action had been taken by the famous doctors or opinion makers against the horde of drugs banned in developed countries but freely and legally available in India. It is again the 'lay press' *Onlooker* which raised the issue through the write up—"Pregnancy Test Drugs can Detorm Babies—Ban them". The issue, thereafter was widely taken up by the press and excepting one or two write ups till date none of them had spoken against the ban of HDPE.

Role of Industry

Harmful effect of the drug on pregnant women was detected as back as 1967 for. Pioneering task in this area had been taken by Dr. Isabel Gal. She writes:

> "The unfavourable effect of synthetic sex hormones on animal reproduction was known long before the introduction of HPT products in 1958. Despite this the manufacturers recommended HPT products as a safe and reliable method of pregnancy diagnosis and gave assurance that it does not interfere with the physiological course of pregnancy"

Following the reports of adverse drug reaction with HDEP, Rousel in 1970, Schering in 1971 and Organon in 1970 did not refer to use of the drug for pregnancy test in UK. The government of India issued order that this drug should not be used for pregnancy testing and the order be printed on the labels of the drugs marketed. The drug was established in India as an abortificient. It was promoted widely for inducing abortion. Even after the said order issued by the government, the companies promoted the drug through marketing staff as an abortificient.

Immediately after the ban order was issed, Organon India Ltd., (now Infar) placed a writ petition in Calcutta High Court and was interested to see that the writ was not contested by the Drug Controller of India during its hearing. It happened exactly as desired by the company and the case was heard and injunction was passed exparte against the ban order. It is interesting to note that neither M/s. Organon nor M/s. Unichem and M/s. Nicholas contested the finding of ICMR on the potential hazard of the drug but simply challenged that the ban order was not issued in accordance with the provisions of law. It was submitted that Sec. 18 of Drugs and Cosmetics Act allows the state govts only to ban a drug after issuing official Gazette Notification. That too the Act only provides banning of misbranded, sub-standard or adulterated drugs. This was an eye opener for the legislators, who after much shouting from the consumers and by some Members of the Parliament amended the law later giving the same power to the Central Govt also. Even now the question remains that HDPE or any harmful drug, if banned, should be done according to which law?

The industry did a lot to utilise medical profession in their favour. In the submission to the Supreme Court and high courts, the company placed letters written by a number of general practitioners and gynaecologists stating that HDEP should not be banned. In reality this was again done with the help of the marketing staff who went to the doctors with the draft of such letters and requested them to write according to the draft, a letter on their own letterheads. Therefore, it was found that the letters are not only the matically similar but, so is the language and text of the letters. In some cases the marketing staff of the companies wrote the letters on the doctor's letter pad and asked the doctors to sign them. The text of these letters more or less read:

> "I support the order of the government in banning the use of high dose E. P. Drugs in pregnancy testing.
>
> The drug is highly needed for treating secondary amenorrhoea, dysfunctional uterine bleeding, endometriosis and dysmenorrhoea. I have used this drug for a long time and never seen any adverse effect. I recommend that this drug should not be banned".

The industry made another attempt to mislead the courts on the information regarding the status of the drugs in different countries. Organon (I) Ltd stated that

> "It's not a fact that many countries have banned these preparations. These preparations are available in countries like UK, West Germany, France, most of the Western European countries and many South West Asian and African countries" (Infar, 1987).

One can easily find out how far this is a fact. Table 1 will clarify the position (UN List, 1986).

Infar (I) Ltd had no reply when asked at the public hearing why HDEP was not allowed to be marketed in their

parent country, Netherlands. Similarly, the company could not say why the drug was not allowed to be introduced in many other developed countries. The company's honesty was again questioned when Hermann Schulte-Sasse of the Institute for Clinical Pharmacology, Hamburg confirmed that.

"Two German pharmaceuticals marketed such drugs in Germany but withdrew them at the end of 1979".

Was the company confident that Indian consumers did not have any access to information from 'civilised European countries'? In fact Dr N N Roy Chowdhury, the president of Federation of Obstetrics and Gynaecological Societies of India (FOGSI) wrote to DCI to the same tune of Infar Co that the drug was available in most of the developed countries. He had also submitted a list although he did not care to mention any reference. From this list it appears that 'Shering' (he does not know that the real name of the company is Schering Aktiengesellschaft) market HDEP in West Germany, UK, Turkey, Japan, Argentina, Mexico, Belgium, Denmark, Australia. The drug is not enlisted in the 'Red List' (Rote Liste) 1984, 1985, 1986, 1987, a list of drugs approved by the government of FRG. Corroborative statement from Schering issued by Dr H Richter informs that only one brand of HDEP was marketed by them in third world countries that two had been withdrawn from October, 1986.

In the absence of any system of dissemination of unbiased information to the medical profession, the industry takes the fullest advantage to misinform the profession to mislead them with the help of their own tailored and distorted facts. As regards high dose EP drugs, the industry had taken the fullest advantage of this situation. The Voluntary Code of Marketing Practices adopted by International Federation of Pharmaceutical Manufacturers Association (IFPMA) suggests that

"Scientific and technical information shall fully disclose the properties of pharmaceutical products as approved in the country in question based on current scientific information...

"Information on Pharmaceutical Products should be accurate, fair and objective, and presented in such a way as to confirm not only to legal requirements but also to ethical standards and standard of good taste." (IFPMA)

Classical example can be sited from the promotional literatures of Infar(I) Ltd as to how they have violated all such codes of ethics. Even the Guidelines of Introduction of New Drugs by Government of India say that "the product monograph should comprise the full prescribing information necessary to enable a physician to use the drug properly. It should include description, actions, indications, dosage, precautions, warnings, and adverse reactions."

A product monograph of Orgalutin, a high dose of EP used to promote the drug to the doctors is captioned as—'A Woman's Strength Is a Woman's Weakness'.

On page three of the monograph to emphasise that the drug is 'safe for the patients' the following lines are mentioned quoting a write up of two doctors Dr Choudhury and Dr Mitra that with the use of the drug there was—

"No alteration in blood pressure.
No alteration in blood-sugar level.
No hepato-toxic effect observed".

The said monograph had given indications of composition and dosage only but nothing was mentioned about precautions, warnings and adverse reactions.

If the warnings and precautions circulated by the company a few years back are consulted, one can find the following facts in the Therapeutic Index of the company and judge how safe the product could be,

"Since such preparations may cause an increase in blood pressure in predisposed women, this should be checked regularly. In case of serious hypertension the use of the preparation should be stopped immediately."

"Since the glucose tolerance may diminish during the use of oestrogen/progestogen preparation, diabetic patients should be kept under strict control."

"Hepatic adenomas have been reported in women on oestrogen-progestogen combinations."

This gives us an opportunity to question the standard of ethics maintained by the company and of the two doctors who had shamelessly concealed the facts.

It is also interesting to note that the manufacturers of HDEP were really frightened of the ban order issued by the governments. In the Therapeutic Index printed by Infar(I) Ltd at the time the ban order was issued, the company deleted all HDEP drugs namely, Menstrogen, Menstrogen Forte and Orgalutin. But their effort to promote the drug in the market remained unhindered. The company has never forgotten to mention these drugs in their price list!

Role of Statutes

Important statute applicable to import, manufacturing, etc of any drug is the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. This is not only ancient but highly inadequate also. Although it is a central statute but it has given authority to the State Drug Controllers for approval of a drug for registration and sale. Because of such inadequacy of law, the Central Drug Standard Control Organisation has prepared 'Guidelines on Introduction of New Drugs'. We shall see how even the scanty restrictions under the said Acts and Guidelines have been violated by the industry.

Organon (India) Ltd, now Infar (India) Ltd had introduced the HDEP about 20 years before. Earlier, these hormones had been marketed separately as single ingredients or in combination as oral contraceptives. The drug was imported and the definition of a 'New Drug' under Rule 30A of the Drugs and Cosmetics Rules (DCR) says:

"The importer of a new drug when applying for permission shall produce before the licensiong authority all documentary and other evidences, relating to its standards of quality, purity and strength and such other information as may be required by the licensing authority including the results of therapeutic trials carried out with it." (Drugs and Cosmetics Rules)

At the time of introduction of the drug it could be defined as a Fixed Dose Combination (FDC) of the third group according to the Guidelines on Introduction of New Drugs. This Guideline requires:

"(c) the third group of FDC includes those which are already marketed, but in which it is proposed either to change the ratio of active ingredients or to make a new therapeutic claim.
For such FDC, the appropriate rationale should be submitted to obtain a permission for clinical trials and reports of trial should be

Table 1: Status of EP Drugs Worldwide

Countries	Status	Year
1. Norway	Withdrawn	1970
2. Sweden	Banned	1970
3. Finland	Banned	1971
4. Federal Republic of Germany	Withdrawn	1979
5. USA	Banned	1975
6. UK	Withdrawn	1977
7. Australia	Withdrawn	1978
8. Austria	Withdrawn	1978
9. Belgium	Withdrawn	1978
10. Italy	Withdrawn	1978
11. Greece	Withdrawn	1980
12. New Zealand	Withdrawn	
13. Denmark	Banned	1974
14. Bangladesh	Banned	1982
15. Venezuela	Banned	1975

submitted to obtain marketing permission."

The clinical trials required to be carried out in India before a new FDC is approved for marketing depend on the status of the drug in other countries. If the drug is approved/marketed, phase III trial is usually required to be conducted in India. If it is not approved/marketed, trials are generally allowed to be initiated at one phase earlier to the phase of trials made in other countries.

On going through the records one can easily find out that the company never obtained any permission to initiate clinical trials in India as required by Drugs & Cosmetics Rules (through form 11 and form 12) for a test licence. No protocols for any trials were ever submitted by the company—this is required according to the Guidelines for Introduction of New Drugs. No case report forms were ever submitted.

As required in the Appendix III of the said guidelines the following reports on the studies are to be submitted by the company. (1) Human/clinical pharmacology (2) Exploratory Trials. (3) Confirmatory Trials. This was never done. Neither the company nor the Director of Drugs Control, Government of West Bengal, who allowed the company to sell the drugs in India can produce the following records relating to trials supposed to have been conducted by the company and approved by the government authority.

Title of the Trial
Name of Investigator and Institution
Objective of Tribals
Design of Study: open, single-blind, or double blind, non-comparative or comparative, parallel group or cross over.
Number of patients, with criteria for selection and exclusion, whether written informed consent was taken.
Treatments given: drugs and dosage forms, dosage regiments method of allocation of patients to the treatment;
Observations made before, during, and at the end of treatment, for efficacy and safety, with methods used.
Results: exclusions and dropouts, if any, with reasons, description of patients, with initial comparability of groups where appropriate, clinical and laboratory observations on efficacy and safety, adverse drug reactions.
Discussion of results: relevance to objectives, correlation with other report/data, if any guideance for further study if necessary.
Summary and conclusions.

In order to maintain a minimum standard of ethics, trials should be conducted with any drugs prior to their introduction in the country. For the purpos, 'licence for examination, test or analysis' has to be procured under Rule 21(c) which was never done by Infar in this case. While applying for manufacture of 'New Drugs' as per Rule 75-B of the DCR one needs to supply "informations as may be required including the results of therapeutic trials carried out with it" (sub sec ii). This was never done either by the manufacturers of HDEP.

It is striking to note that a controversial drug was introduced in our country at the time when enough controversy was raised elsewhere. The manufacturers never cared to conduct any trials in India. They were not only given licence to manufacture such a drug but it was periodically renewed by the drug control authority.

The guidelines for the introduction of new drugs per sec 9.2 under the title 'Regulatory status in other countries' state. "It is important to state if any restriction have been placed on the use of the drug in any other country, e g, dosage limits, exclusion of certain age groups, warning about adverse drug reaction".

This was not done at any time—either at the time of introduction of the drug nor any time thereafter by Infar. On the contrary, as discussed before, the manufacturers have attempted to misguide authorities with false information that the drug is in use in many developed countries.

The guidelines also require (sec 9.3) a 'Free sale Certificate from the Country of Origin'. It would be almost impossible for Infar to submit such a 'free sale certificate' as it was never allowed to be manufactured and marketed in Netherlands, their country of origin.

Not only question of ethics but the failure of the regulatory authorities and the lacuna in the laws are exposed when we consider that the manufacturers have not cared to submit to the minimum requirements of law and the government guidelines and have developed a large market of Rs 6.18 crore yearly.

Role of Doctors and Professional Bodies

A famous gyaenocologist C S Dawn has written in his widely used text book.

Secondary amenorrhoea has had spontaneous cure rate in more than 50% cases where any treatment becomes empirical. New therapies of pituitary gonadotropin, clomiphene and bromocryptine showed promising results in the treatment of selected cases where these are indicated. Longer the secondary amaneorrhoea persists poorer becomes the prognosis.

He, as a professor, never vouched for the use of HDEP in secondary amenorrhoea in the classrooms and thus hid his other face. For, as a member of the Federation of Obstetrics and Gynaecological Societies of India (FOGSI) he says exactly the opposite. He attended the public hearings held at Madras, Delhi and Calcutta just to say that as an eminent teacher and famous gynaecologist he had never seen any adverse reaction with HDEP, and the drug was very much needed for treating secondary ameneorrhoea.

His notoriety had not stopped here. After the Delhi public hearing, he had submitted a study report on May 10, 1987 of a purported trial as a chairman of the family welfare committee of FOGSI. The report was titled as 'Use of Common Drugs in Pregnancy—Indian Experience'. It is only two-page monograph but the dimension of the study is enormous as the first paragraph of this report says:

"An all-India multicentric study was conducted during 1982 and 1983 by the Food, Drugs and Medicosurgical Committee of FOGSI by the author as the chairman of the committee. Fourteen teaching and rural centres participated in this study. Statistically controlled protocol was prepared in consultations with Department of Hygiene and Public Health, Calcutta. The protocol covers 78 factors".

No further methodology and materials used in the study was mentioned. The result was:

"There were 245 congenitally malformed newborns in this study. The incidence of congenitally malformed newborns at various centres varied from 2 to 10 per 1000 births".

The report never mentioned directly as to *how many pregnant women were covered in the study*. If the average incidence of malformation of newborn babies are considered, according to the study, say five per 1000 and a total number of malformed newborn babies reportedly were 245 then we arrive at the fact that in order to get such result, the trial covered 49,000 pregnant women. That such a phenomenally high number of patients were covered in only one year from "14 teaching and rural centres" is noteworthy as this type of trial is impossible even in developed countries.

In the Calcutta public hearing Dr. Dawn was asked that in order to prove that his trial was not fake, he should submit papers relating to the ten protocols as required by the government. Dawn is yet to prove that it is not fake. Obviously the sole objective of producing such a report, which has never been published in any professional journal was to prove that no congenital malformation could be found with the use of hormonal drugs during pregnancy. When the government had banned the use of HDEP during pregnancy and the manufacturers have accepted it, the eminent doctors like Dawn, C L Jhaveri, P K Khan, Sharma are all rejecting it.

Dr. Sharma of Delhi and Khan of Calcutta had without any hesitation said at the public hearings that they would continue to use HDEP for pregnancy testing. We are yet to see the Medical Council of India react to such violations by cancelling the registration of these doctors.

Dr. Jhaveri of Bombay, seniormost and famous gyaenocologist and many times president of FOGSI went even further that estoprogin (HDEP) drug came as a blessing. It had helped—in the second world war women who had been assaulted by the soldiers had used HDEP drugs to abort unwanted feluses! He stated in the Delhi and Bombay hearings that in his 40 years' of gynaecological practice he had used the drugs *for inducing abortion* and had not found a single case of malformation of babies. His statements were recorded by the Drug Controller of India during the public hearings.

One may conclude that Jhaveri had committed punishable offences in two cases. First, he had practiced MTP when it was not legalised. Second, that he had violated the government order in using the drug on pregnant women. We are yet to see that DCI take any action against Jhaveri. This octugenarian doctor was so loyal to the arguments put by the industry that he rushed to the dias at the Bombay hearing to assault one speaker who was dissecting a point of law placed by the industry.

A good number of famous gynaecologists have attend almost all the public hearings leaving their generally over crowded chambers and have said the same things repeatedly. They had not cared to place any pharmacological and clinical evidence in support of their statement that the drug is safe and necessary.

In the Delhi and Calcutta hearing N N Roy Chowdhury, president of FOGSI stated that the Federation had unanimously adopted a resolution that the government should not ban HDEP as they were safe and needed to treat secondary amenorrhoea, dysfunctional uterine bleeding, endometriosis, menopausal symptoms, etc. and there was no substitute for this drug. This statement was challenged by a professor of gynaecology at Calcutta who as a member of FOGSI wanted to know where and when such 'unanimous' resolution was taken. He also produced a statement by Dr J Mitra, Honorary Joint Secretary of FOGSI which states

> "I am of opinion that high dose combination of oestrogen-progesterone should not be used during pregnancy.
>
> I also feel that it is not essential to use this high dose combination for treating gynaecological condition like dysfunctional uterine bleeding, menopausal syndrome, etc. These combinations should not be used indiscriminately as there are potential hazards."

Roy Chowdhury could not provide any proof to substantiate his statement which was openly challenged.

Another instance of violation of minimum standards of ethics can be cited with reference to the activities of P K Banerjee, Honorary Treasurer of the Indian Medical Association. There are complaints by his professional colleagues that he is an obedient supporter of Infar (India) and defended the company's interest in using anabolic sterioid for promoting growth in children. Banerjee wrote a letter to DCI dated April 6, 1987 in the capacity of honorary treasurer, IMA stating that the drug is much needed and harmless. On inquiry, it was found that he had misused the good name of the IMA. As the President of IMA stated that

> I would like to mention that the letter issued by Dr Banerjee is his own view and he is not authorised to communicate the views of IMA. It is unfortunate that he has used IMA stationary for expressing his personal views".

It is necessary to mention here the role of the two doctors who were involved with banning the drug—P Das Gupta, Deputy Drug Controller and P K Dutta of World Health Organisation. The Deputy DCI had no scruples about favouring the industry openly. He tried to dilute the issue.

The Supreme Court had clearly asked the DCI to conduct public hearings on banning of high dose combinations of E P drugs. The Deputy DCI, at the Calcutta hearing, attempted quite something else. He stated that the question of banning HDEP should not be taken as an ego fight. Although the Drugs Controller's office had once banned it, it did not mean that they should stick to such decision for- ever. He also appealed to the gynaecologists that they should come forward and suggest a 'cut off' dose for estrogen-progestogen combinations. He wanted to confuse the issue on the question of high dose and low dose EP. He wrote letters without the knowledge of DCI to FOGSI and Indian Associations of Fertility and Sterility asking them to give their views on a questionnaire on estrogen progestogen combinations, dated March 23, 1987. He carefully dropped words 'high dose' in the questionnaire. The questions are tailored in the following way which is suggestive of the desired answers.

> 1. Whether fixed dose oestrogen and progestogen is necessary in the management of secondary amenorrhoea?
> 2. What are the possible side effects of fixed dose oestrogen and progestogen combination?
> 3. Do you feel that with a suitable cautionary label the use of fixed dose of oestrogen and progestogen combination in pregnancy be prevented?
> 4. Whether fixed dose oestrogen and progestogen combinations are marketed in other countries?
> 5. Whether fixed dose oestrogen and progestogen drugs should be banned?
> 6. Do you have any other suggestions on this issue?"

Nowhere in the above questionnaire had Das Gupta mentioned '*high dose* estrogen and progestogen'. It can be noted that oral contraceptives are also fixed dose oestrogen and progestogen combination. The president of these two organisations C L Jhaveri and N N Roy Chowdhury made full use of such questionnaires and pumped the arguments of the industry in their reply which was considered by Das Gupta as an important document at the public hearing held at Bombay where Prem K Gupta, DCI who was absent at the Calcutta public hearing said that this was done without his knowledge and offered an apology for the action of the Deputy DCI.

At the Calcutta hearing Das Gupta was openly supporting the manufacturers of HDEP. He, along with Dr P K Dutta helped the management of Infar to create a stir at the public hearing and cancelled the hearing with a plea that they may be physically assaulted when there was no valid reasons to do so.

It is necessary to mention the role of other doctors and professional organisations. The reactions of famous gynaecologists and pharmacologists of UK on the need of HDEP were different. Some of these doctors are members of the Committee on Safety of Medicines. Some of the responses are as follows;

> 1. "I feel strongly that there is *no justification* for the use of these drugs in amenorrhoea, menstrual irregularities and other "gynaecological disorders". Amenorrhoea and menstrual irregularities require investigation and specific causes identified and, if necessary, treated. If menstrual regulation is required in patients who have no periods and who have irregular (and perhaps heavy and painful) period then the treatment of choice is either the conventional *low dose* estrogen-progesterone oral contraceptive pill, or progestogen alone.
>
> I think it would be irresponsible and dangerous to encourage the use of high dose estrogen-progestogen combinations in management of these gynaecological symptoms". (Dr. Stephen Franks, Reproductive Endocrinology; St Mary's Medical School, London).
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> 2. "I was alarmed and disturbed to learn that high dose combinations of oestrogen and progestogens are still marketed, and used in the Indian sub-continent. I understood that steps had been taken in 1983, to withdraw these products and I find it extraordinary that four

years later it is still possible to promote, prescribe and purchase such medicines.

They are associated with significant risks to the factus, if administered during pregnancy. The Committee on Safety of Medicines (of which I am a member) issued warnings to all doctors about these hazards in 1975 and 1977. The British Medical Journal drew attention to the problem in an editorial in 1974. As a result of these publications, and of professional opinion, pharmaceutical companies in the UK voluntarily withdrew their products containing high dose oestrogen and progestogen from the market. (M D Rawlins, Professar of Pharmacology, University of Newcastle upon Tyne).

3. "I find that I am in complete agreement with the opinions expressed by Dr Steven Franks and Professor Rawlins and I have no reason to change my own views, as expressed therein. Perhaps the only thing I could add is that now, with four years experience as a member of the United Kingdom's Committee on Safety of Medicines, I'd like to emphasise Professor Rawlin's point—that is, that these drugs would be unacceptable in the United Kingdom, that our attitude is that the obligation is on the pharmaceutical company to prove quality, safety and efficacy of preparation and not on the drug regulatory agency to prove the converse and that, while those drugs are certainly not banned in the United Kingdom, were any attempt to be made to introduce them I have very little doubt they would fail to secure a licence". (Dr H S Jacobs, professor of Reproductive Endocrinology, The Middlesex Hospital Medical School and University College, London).

The Public Hearings

Thus, famous professors of the medical institutions did not hide their surprise and disgust at the use of the drug and role of government regulatory authority, nor did a large number of the specialists in Calcutta and Bombay hearing. The DCI initially decided to close the public hearing after Delhi. About 150 doctors including professors of gynaecology and pharmacology wrote to the DCI to hold the hearing at Calcutta as well. Initially there was no respond from the DCI. This gave raise to such a reaction that at the instance of the Association of Health Service Doctors, West Bengal about 200 doctors assembled in a convention condemned the activities of the DCI and resolved to start a campaign against the drug manufacturer and the government of India for not banning the hazardous drugs. This compelled the DCI to announce public hearings at Calcutta and Bombay four months after the Delhi hearing.

During the Calcutta hearing, a large mass action for banning the drug took place. For the first time the trade unions, doctors, consumers and health activists demonstrated before a drug company and condemned them for production of banned drugs. It was encouraging to see that for the first time, famous doctors who had been vouching for the industry were challenged by other well-known professors, gynaecologists, pharmacologists.

At the Bombay hearing it was also quite amazing to see that when Jhaveri said, that he would give an award to anyone who could place any evidence of foetal malformation by HDEP, it was accepted by other group of doctors. The real drama took place at the Bombay public hearing when this group of doctors placed a little girl and her mother as evidence of the foetal abnormality and placed a letter which had congratulated them for their effort to detect such drug induced malformation of the baby. The author of the letter was none other than Dr. Jhaveri himself.

Role of People

Long back, after the publication of the write up in *Onlooker*, certain health activists tried to take up the issue but it could not spread. Even when the issue reached the Supreme Court, Vincent Panikulangara a lawyer from Kerala had to fight for a ban quite alone.

In Madras, Delhi and Calcutta hearing some people appeared as 'consumer activists'. Their expressed concern was more on 'illegal' and 'unjust' blames being attributed to the industry than on the harm to consumers. They forgot that this hearing was most important because for the first time merits and demerits of a drug were being publicly heard. They also forgot that their counterparts in developed countries have forced the companies to obey a minimum code of conduct and Infar was admonished by the International Federation of Pharmaceutical Manufacturers Association for violation of its voluntary code however biased, weak and ineffective that may be.

It has also true that the trade unions had palyed different role in different places. While at Madras and Delhi there was no scope for their intervention they responded remarkably positively at Calcutta. Unions of medical representatives, the Federation of Medical and Sales Representatives Associations of India (FMRAI) and the Organon(I) Ltd Workers Union organised a demonstration in front of the gate of the Infar factory. The workers attended it and the president of their union announced that if the company failed to convince them that the drug cannot cause any harm to the people they would refuse to produce it. The representatives of FMRAI appeared before the public hearing and narrated how they were being directed by their employers to misguide the medical profession with partially or totally false information. They also exposed how the Infar and Unichem had been entertaining and spending money for providing travelling expenses of a particular group of famous doctors who had been appearing before the public hearing on repeated occasions. They also stated that the drug was sold by the companies without any promotional effort. The companies are manufacturing the drug and through their distributioin channel it is reaching the outlets where it is automatically sold. The margin of profit in this drug is among the highest.

In contrast to this, the role of the Shiv Sena Union of Unichem at their Bombay factory not only favoured the industry but workers openly threatened the audience that if anyone spoke against their management, they would be forced to take drastic actions. There was a large number of Shiv Sena activists at the Bombay hearing who had been booing and shouting at the women's group whenever they expressed their concern which was often tinged with emotion. This shows the difference in level of consciousness among the workers of the two places.

There was remarkable response from womens groups. In 1979 some women's groups of northern and western India took up the issue. The issue of banning a drug cannot be solely seen in terms of exploitation of female by male. It is also not because Dr Isabel Gal was a women that she first explored the hazards of the drug. The question of banning a drug concerns the profit motive of industry and the low standards of ethics of some eminent opinion-makers of the medical profession in India. During the public hearings. Most of the women's groups identified the crux of the issue—that the existing condition in our country is conducive to industry-government clique. Some of them asked a pertinent question: Why had the court not first banned the drug in the interim which is said to be causing danger. Who would be held responsible for any damages which are being caused even now (if at all) the drug is officially banned in future? They have also declared that they would file litigations against any future malformation of newborns and would ask for compensations from the Drugs Controller and the industry. However the question remains that when there is dearth of ethics among all levels of the decision/opinion-making in the establishment can the judiciary remain un affected?

[While preparing this paper help had been sought from the excellent compilation of documents and different monographs prepared by Mira Shiva, Coordinator, All India Drug Action Network.]