

123 medico friend circle bulletin



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Dipyron, Hoechst and the Boston Study

Wilbert Bannenberg MD

Dipyron (synonyms: metamizole, noramidopyrine, novaminsulphone, avaminsulphone; brand names- Novalgin, Baralgin) is a controversial drug since 1934. It was developed by Hoechst as an analgesic, and belongs to the pyrazolones—group, of which we know since 1934 that they may cause a severe side effect: agranulocytosis. Between 1960 and 1977 the drug has been taken off the market (for safety reasons) in the USA, Canada, UK, Ireland, Australia, New Zealand and the Scandinavian countries. On the 10th Oct, 1986, the Journal of the American Medical Association will probably publish (it has since been published-ed.) a paper by Shapiro and Levy—the 'Boston Study' on the risk of agranulocytosis with dipyron. Hoechst and some 100 other companies who manufacture dipyron (the WHO list of dipyron brand names is very long!) will use this study to prove that dipyron is (more) safe than was thought. Hoechst had already started a mass media campaign stating that the risk of agranulocytosis from dipyron was "only 1 in a 1,000,000".

Some critical observers disagree. They maintain that the study does not bring any new information on the risk of agranulocytosis, and that the Boston Study presents the data in a way which makes it look better. It must be noted that the risk of 1 in 1,000,000 is valid for anyone who takes one or more tablet of dipyron during *one week* only. If dipyron is used for longer periods, the risks will be greater (this was actually confirmed by Shapiro during a press conference in Stockholm, and it was the only sentence which was missing in Hoechst verbatim records of the same meeting.). For example, if one uses it every week, the risk is 1:20,000 per year. With other calculations, one can estimate a risk of 1:70,000 packages

of dipyron. Obviously, this is a more appropriate way of quoting risk figures. It must be admitted however, that data from the 1950's (1 :300 or so) are clearly invalid, and that agranulocytosis in general is a rare disease: in most countries 6 to 10 cases per million inhabitants are diagnosed every year. The 'share' caused by dipyron differs, but ranges between 13 to 35 % in the current Boston study. The problem with dipyron is that it is so widely used. Its world use is quoted by Hoechst at 10,000,000 kilograms per year. This means that even with a low risk of 1:1,000,000 some 7000 cases of agranulocytosis can be expected every year. Most of the dipyron is used in communist and developing countries where standards of drug control or medical care are lower. This means many avoidable deaths and it is HAI's (and other such organizations') task to take up this issue.

To help you in dealing with this issue, I present here a summary of the problems with dipyron and the 'Boston Study'. It is recommended to read the BUKO 'Pharma Brief' for other view points. Please note that the Boston Study was limited to the study of agranulocytosis and aplastic anaemia (which is not related to dipyron). Other severe side-effects of dipyron such as shock, hypotension, Lyell syndrome, and Moscovitz syndrome were not studied.

Dipyron VS Aspirin and Paracetamol

The benefits of dipyron are not greater than simple aspirin or Paracetamol. Hoechst claims that dipyron has spasmolytic and anti-inflammatory properties besides the analgesic and anti-pyretic properties but that is not

at least in the normal dosages. Dipyron is neither better nor worse than aspirin or Paracetamol. To assess its place in the market, one should compare risks and benefits. Hoechst claims that the agranulocytosis side-effect of dipyron causes fewer deaths than aspirin (gastric bleeding) or Paracetamol (liver toxicity in high doses). This can be countered by the fact that these are *avoidable* risks because the aspirin risk group can be identified and packages of Paracetamol can be made small enough (e.g. 10 tablets only) so that it cannot kill while *agranulocytosis due dipyron cannot be prevented as it happens unexpectedly, sometimes even after years of 'safe' use.*

Other arguments against dipyron are:

- Even after 100 years of use, the mode of action is still unknown.
- Unknown is also which metabolite causes agranulocytosis or other side-effects (and how). It is known, for example, that the drug aminophenazone, banned worldwide because of severe side effects, has some similar metabolites as dipyron: does this mean that dipyron metabolites cause the same side-effects?
- Basic pharmacology data (e.g. use in renal, liver, or elderly patients) carcinogenicity, teratogenicity are not yet known, as it was developed before the 'thalidomide scandal' and could therefore get easier registration.
- There are 2 Japanese reports that link dipyron to a significant increase in hepatoma toxicity studies with mice. Hoechst has never challenged these reports.
- Interactions with other drugs such as anti-diabetics have never been investigated.

All this information is enough to refuse its registration under new drug safety criteria. So why should we allow a 'comeback' of dipyrones?

The Boston Study

Hoechst did not agree with the Swedish studies on the incidence of agranulocytosis in connection with dipyron, and commissioned a new study in 1978 to the Boston Drug Epidemiology Unit (Dr Shapiro) to find out the real incidence of agranulocytosis. This study looked only at agranulocytosis (and aplastic anaemia) and did not look into all other side-effects of dipyron.

The study is a 'case-control' study which basically compares the use of dipyron in all found cases of

agranulocytosis with the use of dipyron in 'normal' controls. If the agranulocytosis cases used more dipyron than the controls did, this is an argument for a link between dipyron and agranulocytosis. *The higher the difference is the more likely a connection between the disease and the drug.* Such case control studies are difficult to implement, and strict control is needed on its proper conduction, as it is easy to introduce bias. The most important criterion is that the 'controls' must be representative for the general population and have similar risk factors for agranulocytosis as the 'cases'. The Boston study aimed to detect all cases of agranulocytosis in defined areas in West Germany, Spain, Italy, Sweden, Israel, Bulgaria, Hungary, Brazil, and Indonesia. Later, Brazil and Indonesia were excluded, because it was not possible to get trustworthy data. In Sweden dipyron had been banned. Italy and Bulgaria were included later, but did not have enough cases for statistical analysis. So only the data of 5 study areas could be used: West Germany, (Berlin and Ulm), Spain (Barcelona), Israel and Hungary (Budapest).

1984: Letter to the Lancet

Shapiro published the intermediate results in the Lancet of 25th Feb 1984 (pages 451-2). It is interesting to compare this letter with the final paper. Some strange things happened:

- The frequency of pyrazolones use in the control group is quoted as 0.4 % to 5 %. However, the control group in the final paper quotes 1.27 % to 20.63 %. It means Shapiro has taken new or other controls who apparently used more pyrazolones than the first group. It is statistically highly unlikely that both control groups are representative for the same population, and this means that the results are questionable. *The threefold increased use in controls means also a three fold lower relative risk, which is beneficial to Hoechst.*
- Shapiro quoted a case fatality rate of 5 %. In the final report this figure doubles to 9 %.
- Shapiro said he needed 400 cases of agranulocytosis to assess the risk properly. However, due to large percentage of exclusions, only 221 cases are analyzed in the final study. Yet, he calculates risks without problems.

Results as in Final Paper

One of the strangest results is the wide regional variability in the 'relative risk' for agranulocytosis due to dipyron:

Ulm	12.2	Israel	1.8
Berlin	20.9	Budapest	0.9
Barcelona	30.5		

Incidence rates of agranulocytosis vary not only between countries, but also between community and hospital cases in the same country. This is illustrated with the following table.

This means that in West Germany and Spain dipyrone is strongly associated with agranulocytosis, but there appears to be little or no risk at all in Israel and Hungary. This result could not be explained by Shapiro or Levy. Of course it is possible that there is a real difference in the risk, but I think it is more likely to be a result of faulty methodology. Let us analyze the percentage of agranulocytosis cases who admitted the use of dipyrone:

Ulm	21%	Israel	20%
Berlin	35%	Budapest	13%
Barcelona	30%		

There appears to be not a 20-fold difference, so the lower relative risk should be explained by something else. I suggest that it is caused by biased selection of controls. Let us analyze the percentage of controls who admitted the use of dipyrone, and compare it with the IMS sales data of pyrazolones in that country (IMS sales quoted by Laporte):

Country	Controls who used dipyrone	Pyrazolone use (IMS) DDD'S PER 1000/days	Relative index
W. Germany	2.3%	13.3	1.7
Spain	1.2%	12.0	1.0
Italy	2.2%	10.6	2.0
Israel	11.0%	3.3	33.3

It appears that the controls in Israel used 5 times more dipyrone than the controls in other countries. How can be this related to the IMS sales data, which suggest that Israel actually uses 3 to 4 times less dipyrone? IMS data from Israel are known to be less reliable but would they be responsible for a 20 fold difference? The conclusion must be that the controls used in this study were not representative for the population or that the results were falsified. It must be realized that a 'higher' use in controls produces an equal 'lower' relative risk, which is beneficial for Hoechst.

The controls also used a lot of analgesics: 27 % of them mentioned the use of any analgesic drug in the week before. I do not have any figures to compare with, but this is definitely a drugged world!

	Comm. rate	hosp rate.	Hosp. / comm. index
Ulm	3.5	10.8	3.1
Berlin	2.3	9.4	4.1
Barcelona	4.2	5.6	1.3
Israel	5.6	3.1	0.6
Budapest	7.2	5.0	0.7

(all rates in agranulocytosis cases per million person years) Why is the hospital rate in Germany so high? Are German patients given more dipyrone or other agranulocytosis causing drugs than in other countries? Or is it that the community rate is relatively low? Could this be an indication that the community cases were undetected? The mortality due to agranulocytosis in developed countries was estimated in literature to be 15 to 25 %. Shapiro now finds a Case Fatality Rate of 9 %. From the data it can be concluded that the CFR in community cases (10%) was higher than the hospital cases (6 %). This is probably the effect of less effective or delayed medical care and it supports the expected higher CFR in developing countries where medical care is less likely to be available. For developing countries it is safe to expect a CFR of 25 to 50%. (as it was in Europe 30 years ago). Most cases will never be diagnosed, because they die of 'normal' pneumonia, and because they often obtained dipyrone without prescription or medical supervision. (The study should have given regional CFRs).

Criticism of Methodology

Due to a very strict criteria a high percentage of the agranulocytosis cases were actually excluded from the study: 31 % of the community cases (94 of 299), and all (130) hospital cases. Although this is scientifically correct, it increases the likelihood of increased bias. Shapiro does mention this himself in the study. But he fails to explain why they couldn't find proper matching controls for the hospital cases, whereas they did find enough controls (1751) for the community cases. The absolute incidence of all agranulocytosis might be underestimated due to missing patients (not admitted to hospital in study region, not diagnosed or died before diagnosis was made).

Many people died: an unknown number before diagnosis (agranulocytosis patients may die of 'normal')

opportunistic infections e.g. pneumonia, and might not be recognized by general practitioners. As the incidence of agranulocytosis rises with age, one expects elderly people to be more affected. They might get less intensive treatment and might be 'allowed' to die because of other factors (other severe diseases or euthanasia). A further 7 % of undiagnosed agranulocytosis cases died before interview could be done, and 9 % died after the interview. The interviews were different in structure in different countries because the number of dipyrene-containing drugs differed enormously. ca. 350 in West Germany, 173 in Spain, and only 3 in Hungary. As each drug name had to be read out to each patient and control the list was far longer in Germany than in other countries. This might have lowered the attention of the interviewer or the memory recall of the patient, and might have resulted in different reliability of interview techniques. Shaipiro mentions this problem too and he 'solved' it by reading only those drug names which belonged to the 90 % most sold drugs. As the study came up with enormous regional variability it must be excluded that some of the non-mentioned drugs carry a different risk (e.g. due to colorants, excipients, or method of use).

Shapiro stated in his article, that confounding remains possible and that methodological problem must be considered to explain the strange regional variability.

Conclusion

The 'Boston Study' does not necessitate a new policy regarding dipyrene. The study design is difficult to interpret and there is unexpected and unexplained regional variability in risks. The study authors even state that the *results cannot be interpolated towards other countries*. Even when the risk is as low as Hoechst says, the drug is used so massively that every year 7000 cases of agranulocytosis can be expected in our world. The drug is not better than aspirin or Paracetamol, but has some very serious side effects. Therefore it should be

—*severely restricted* (prescription only) in countries where adequate medical facilities are available.

—*banned* in developing countries or any other country where its (mis) use cannot be controlled or where adequate medical care is absent.

(Courtesy Health Action International)

In Support of MARD's Strike.

We the Bombay Group of the Medico Friend Circle are disturbed and agitated at the stand taken by the civic

authorities on the KEM (MARD) doctors' strike. By threatening the doctors with disciplinary action the BMC and the representatives of political parties in the Standing Committee have shown utter disregard for all the norms of democratic functioning and the law. We wish to point out that: (1) The KEM doctor's agitation was not for demands for personal gain—they were not demanding wage increase, tenure etc or even better conditions for themselves. (2) The doctors have repeatedly stated that the objective was only to draw public attention to the atrocious conditions of the public hospitals, (3) The doctors did not abstain from duties even when they were on hunger strike.

The authorities have generally accepted these points-but have denied the lack of facilities, bad maintenance, lack of drug etc without producing even a single fact to support the denial. Not only that, the KEM doctors' point was aptly vindicated when the authorities were forced to close down an operating theatre following press disclosures of unhygienic conditions there.

What has in fact angered the civic authorities and the political parties in the standing committee is the unusual boldness and the high level of consciousness and social responsibility displayed by these doctors in this agitation. What has frightened them is that the KEM doctors have broken away from the power structure (in our society doctors are an integral part of the power structure) and have tried to directly appeal or educate the people about their rights- i.e., in the words of the authorities, 'violated the rules' of democratic game. The BMC authorities are not unaware that such actions by doctors can well act as catalysts in bringing together doctors and patients (people) who can demand accountability from civic institutions. This is precisely what has unnerved the civic authorities-only they call it 'inciting the patients'.

The KEM doctors have shown remarkably high standards of social responsibility. Any action against them by the civic authorities will be a gross violation of the most primary democratic rights of the Indian citizen. The doctors have committed no illegal act; they have used only non-violent and constitutional means of agitation; their only 'offense' is that they have chosen not to hide the conditions in the public institutions in which they work-conditions which directly affect thousands of people. In attempting to conceal these conditions the BMC is in fact, committing a grossly illegal act.

Amar Jessani

Padma Prakash

Dipyrone Hearing in Germany

On 19, October 1986 the German Federal Health Office held a hearing on dipyrone in Berlin to reevaluate the risk/benefit ratio of this old but in certain countries still much used painkiller.

The Health Office presented figures of the adverse reaction monitoring system. Although the data is rather incomplete due to underreporting there were 94 lethal cases after the intake of dipyrone in the FRG from July 81 to July 86 in the files. The Health Office evaluated only three of these cases as unrelated to dipyrone.

Haematological reactions (agranulocytosis) were the cause of death in 46 cases, allergic reactions (shock, skin) in 39 cases. This makes clear that other risks of dipyrone than agranulocytosis must be taken into account.

The controversial discussion of the Hoechst-sponsored Boston study on analgesics, agranulocytosis and aplastic anemia took a large amount of time in the hearing. The coordinator of the study, Dr. Samuel Shapiro had some difficulties to explain how they came to their final "excess risk estimate" of agranulocytosis of 1.1 per million for any intake of dipyrone during a week's period. Many of the invited scientists did not think that this was a very useful figure because it does not allow to quantifying the risk on a user/year basis.

Calculating with other figures in the study and a consumption estimate it was thought in the end that the risk is more likely to be in the range of 1 in 30,000 to 1 in 70,000 per user and year. The speaker of the FRG's Pharmacists Association concluded at the end of the hearing that it took him a long time to understand that the risk of agranulocytosis is as high as it was already estimated in the 1981 hearing of the Health Office on dipyrone.

The Deputy Health Senator of Bremen, Prof. Schonhofer pointed out, that only a ban of dipyrone can reduce the risks, as less dangerous alternatives are available. He also mentioned that dipyrone is a severe problem for the Third World, as much of it is used there and the possibilities to survive the adverse reactions is much lower than in industrialized countries. He made an appeal to the responsibility of the biggest dipyrone-producing country to act.

In two months the Federal Health Office will announce its decisions on dipyrone. As the president of the Office pointed out in his final statement everything

from making all forms of dipyrone prescription only and a ban of combination products, a further limitation of indications to a total ban is possible.

Source: Pharma Brief, W. Germany
Campaign Newsletter No.6.

CAP-Report: A fact-sheet on Analgin.

—Book Review.

The Consumer Association of Penang (CAP), Malaysia is an example of how a determined group in a Third World Country can rouse public opinion by publishing a series of study-reports on a number of important consumer-issues. The small book under review, 8th in the series of study-reports by CAP, has been published at an opportune time. The question of Analgin is being hotly discussed after the publication of the so-called Boston-study on the incidence of agranulocytosis due to *Ana/gin* and a few other anti-inflammatory agents. In such a context, this 'CAP-Report' on the details of the use, misuse and adverse effects of Aminophenazone and Dipyrone (Analgin) in Malaysia should be of valuable help for the activist groups not only in Malaysia but to some extent in other third-world countries also since it gives valuable information in consolidated form on the adverse effects of Aminophenazone and Analgin. Though aminophenazone has been banned in India, Analgin continues to be extensively used and misused and hence the small chapter on Dipyrone, which gives valuable information on adverse effects of dipyrone as reported from different countries, would be of great interest to Indian-readers. Chapter No. 4 on "regulations concerning aminophenazone and dipyrone in other countries" is also of general interest. It shows that dipyrone has been withdrawn or banned in a full dozen countries and is under prescription control in five countries.

The chapter on 'International marketing' exposes the double standards practised by multinational drug companies. Thus for example, though Dipyrone has been withdrawn from the U.S. from 1977, subsidiaries of American multinationals like Dupont, Foremost McKesson, Richardson-Merrel, Searle, Upjohn... etc. continue to market Dipyrone in Latin America. The indications for use also differed. For example, in 1974, Wintrop, another multinational, advocated "menstrual pain" as one of the indications for dipyrone whereas "in the U.S., F.D.A.-required druglabelling had warned women who were menstruating against using Dipyrone because of the possibility of severe haemorrhage."

In the remaining chapters, there is some systematic recording of the different brands available, misleading claims made, wrong information provided by drug companies to queries; over prescription by doctors in Malasia. Anybody wanting to do a similar study report in India would find this CAP-report as a good example of concrete documentation of nasty marketing practices of the drug companies. Four case-reports of adverse drug-reaction due to Amidopyrine, Aminophenazone and Dipyron have been given. These give an idea about the human agony involved in these lethal adverse drug-reactions. The Malasian cases, however, do not give the identification details as to the name of the patient, doctor or date, dispensary, place.....etc.....etc.

A couple of references have been repeated. Otherwise this is a well-written, quite readable report. We, in India, should aim at preparing similar report on some of the most hazardous drugs being sold in India.

Anant R.S.

(CAP-Report, No.8, Drugs and the Third World: Aminophenazone and Dipyron-hazards and marketing Practices, published by Consumer Association of Penang, 1986: 87, Cantonment Road. Penang, Malasia, pp. 132, Price : not given.)

SC flays continuance of banned drugs

The Supreme Court today (Nov 13) flayed the Union Government that it is "murder" to permit, under the stay orders of the High Courts the continuance of drugs banned by it in 1983. While hearing the cases on oestrogen-progesterone pregnancy drugs, the judge declared that they were surprised that the High Courts should have granted stay orders in such matters. There was no answer on behalf of the Union Government to the persistent query of both the judges as to why it had not sought transfer to the Supreme Court, of the cases pending in the various High Courts against the July 23, 1983 notification banning the 18 drug formulations as dangerous to public health and which according to the Union Government had been stayed by the High Courts of Bombay, Calcutta, Andhra Pradesh and Gujarat. Some of the 18 banned fixed dose combinations are of steroids, Amidopyrine, chloramphenicol, atropine in analgesic antipyretics, Analgin, tetracycline and Analgin with vitamin C, Phenacetin, chloramphenicol with streptomycin, penicillin with streptomycin and anti-histamines in antidiarrhoeals. In its reply to the Supreme Court petitions filed by the drug companies, the Union Government has stated "it is only a few companies, particularly the multinationals with vested interests who are opposing the Government's action."

The Supreme Court in its order came down heavily on the Union Ministry of Health, the Medical Council of India, and the Indian Medical Association for 'betraying' the cause of Public Health by non-action on the implementation of the notifications of July 23, 1983 banning the manufacture, sale and import of these 18 drugs.

The Drugs Controller of India has been directed to decide whether oestrogen-progesterone pregnancy tests should be banned because they are a danger to public health. This decision must be given within a maximum period of six months concerning *Menstrogen* injections and tablets, *Menstrogen forte* injections and *Organutin* tablets manufactured by Infar (India) Ltd. as also *E.P. Forte* manufactured by Uni-chem. The Judges directed the Drugs Controller of India to give notice of the inquiry to the two companies before them as also the Petitioner. The notice must also be published in two national papers of the Hindi and English languages plus one regional language newspaper. The Judges stated that these directions were being given because in matters concerning public health, the people likely to be affected should be given an opportunity of participating in the inquiry. The Drugs Controller of India has been directed to allow any consumer group or party who wishes to participate in the inquiry and they may be given such hearing as the Drugs Controller thinks fit. The two companies and the Petitioner will be entitled to be heard and present their evidence in the inquiry with both parties exchanging the evidence presented. The evidence will also be made available to the consumer groups participating in the inquiry. It will be open to the Drugs Controller to hold an inquiry, where necessary at places other than Delhi to suit the convenience of consumer groups and other persons participating in it.

Source: Hindustan Times 14-11-86

Letter to WHO & UNICEF

Dear Dr. Mahler / Mr. Grant

At a special WHO/UNICEF meeting in Geneva, from 17-18 December 1985, a group of experts concluded that transnational baby milk companies should stop donating milk supplies for newborn infants in maternities and other maternity situations.

This WHO/UNICEF meeting was the result of a request by delegates at the World Health Assembly in May 1985, who wanted clarification of the provisions of the WHO/UNICEF International Code on the Marketing of Breastmilk Substitutes. At this meeting member delegates had reported that transnational baby milk companies had violated the Code by providing excessive quantities of artificial milks to hospitals in order to create demand for the products.

Nine experts from eight countries together with WHO and UNICEF staff participated in the December 1985 meeting to provide clarification and guidelines to the Code's provisions on free breastmilk substitute supplies, to member states of the WHO. This meeting produced a report of its proceedings and recommendations, and also revised a background paper on physiological factors influencing breastfeeding.

This report was submitted to the 39th World Health Assembly in May 1986. However we read with great concern the news report published in the International Herald Tribune (IHT) Saturday-Sunday, May 10-11, 1986, that *one of the recommendations in the report had been omitted.*

The recommendation was that *'maternity wards and hospitals should not be recipients of free or subsidized supplies of breastmilk substitutes.*

The IHT reported that the above recommendation was omitted from the WHO/UNICEF guidelines because of pressure from the United States and the baby food manufacturers. We were upset to read this report because if it is true it would mean that the WHO and UNICEF have unfortunately been subjected to and succumbed to outside pressure in the performance of their duties.

We feel this is a serious matter because the recommendation that was omitted had been the result of careful deliberation. The experts at the WHO/ UNICEF meeting in December 1985 after carefully examining the medical grounds for providing breastmilk substitutes to newborns determined that the percentage of infants who need breastmilk substitutes is so small that donations by

companies cannot be justified, particularly given the dangerous promotional potential of such supplies donations. For the few babies that need them, hospitals can afford to purchase infant milk supplies, just as they buy supplies of other food, equipment and medicines.

The experts recognized possible social and economic situations in which infants may need breastmilk substitutes. They noted that infants in institutions such as orphanages and refugee camps may justifiably need free infant milk, through those institutions. In such cases, the donations should be provided for as long as the infants concerned are in need.

However for the majority of newborns where breast milk has been proven to be the best source of infant nutrition, free or subsidized supplies of breastmilk substitutes in maternity wards or hospitals would lead mothers to be dependent on these sources of nutrition for their newborn once they leave the care of the hospital.

In most of the Third World where mothers are poor and illiterate, and clean water supply is often nonexistent, the incidence of diarrhoea among infants being fed with contaminated water is very high. Poor families who cannot afford expensive infant milk formulas will stretch their meagre supplies of the latter. This will mean diluting the milk formula which will lead to malnutrition of infants. Diarrhoea and malnutrition can lead to fatalities and impairment of healthy growth among children.

It is for this reason that the WHO/UNICEF expert group had recommended that hospitals should not receive free or subsidized infant formula and other breastmilk substitutes. We regret that this crucial recommendation was omitted in the final WHO/ UNICEF guidelines. We are all the more concerned by the news report that this omission was caused by 'pressure from the United States and the baby food manufacturers'. If this report is correct, then it indicates that powerful vested interests have been able to exert undue influence on the WHO and UNICEF in a crucial matter related to the health of infants of the Third World. Such a development, you will agree, is most disturbing and will be objected to by everyone who has the interests of children at heart. Moreover, such manipulation of United Nations agencies by business companies and governments protecting such interests is deplorable.

We therefore would like to seek your clarification whether the report on the omission of the recommendation is accurate.

We also strongly appeal to your goodself as Director-General of WHO and Executive Director of UNICEF to use your offices to reinstate the original guidelines for the sake of infants and children in the Third World.

We seriously hope that you will consider our request as it comes from the peoples of the Third World. We would also appreciate a response from you at your earliest convenience. Best Wishes.

Sincerely,
S M Mohd Idris
Coordinator
Third World Network, 87, Cantonment Road,
Penang, Malaysia.

Bill to Restrict Ads on Breast Milk Substitutes

A bill to restrict the trade as well as production, supply and distribution of breast milk substitutes and

feeding bottles is to be introduced in the Winter Session of Parliament. It seeks to:

- * Ban all forms of advertisement suggesting that milk powder and milk related equipment are equivalent to mother's milk.
- * Make it mandatory to print a notice on every container that "breast milk is best for your baby" and insert a warning that breast milk substitute is not is the sole source of nourishment for an infant.

Labels on the container should indicate the hazards likely to occur if the milk is prepared inappropriately. Advertisements should not have words such as 'humanized' or materialized; nor should they carry photographs of 'fat' babies as part of the promotional gambit. The bill seeks to forbid all forms of incentives for the sale of breast milk substitutes. Inspectors will be empowered to enter and search buildings where clandestine trade of breast milk substitutes is being carried out. Under the proposed enactment the punishment for contravening various clauses includes imprisonment upto three years and a fine of Rs 5000/-

Source: Times of India, 3-11-1986.

XIII ANNUAL MEET OF THE MFC

Medico Friend Circle will hold its XIII Annual Meet at Seva Mandir Training Centre, Kaya (near Udaipur), Rajasthan, on the 26th and the 27th of January 1987. The theme chosen for discussion this time is "*Family Planning in India: Theoretical Assumptions, Implementation and Alternatives*".

We invite you to attend the Meet and share your views and experiences. The participants are as usual expected to pay for their own travel. Simple boarding and lodging facilities will be available at the venue, on a payment of Rs. 20/- per day per person. We charge a small registration fee to cover the cost of the cyclostyled background papers. Return reservation facilities are also available. If you wish to attend, please write to us at : *Medico Friend Circle, 1877, Joshi Galli, Nipani - 591 237*. We will then send you the venue details and background papers,

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