

submissions

From: submissions
Subject: FW: Submission on application A1097 - Late Acknowledgement

From: Brian Sandle [REDACTED]
Sent: Monday, 16 February 2015 9:22 AM
To: submissions; [REDACTED]
Subject: Re: Submission on application A1097 - Acknowledgement [SEC=UNCLASSIFIED]

Hi, too late I suppose, but here is back up for my steroid point. Brian

I paste text but the article is at: <http://newint.org/features/1983/11/01/hunger/>
New Internationalist

DUMPING [image, unknown] *Protecting children from dangerous drugs*

[image, unknown]

Hunger and the wonder drug
Some are born ill, some acquire illness and some have illness thrust upon them. In the last group are countless hungry children of the underdeveloped world who have suffered the side-effects of anabolic steroids. *Dexter Tiranti* reports on the disturbing findings of an international consumer survey* just released.

THE Dutch-based international pharmaceutical company. Organon, is actively promoting its anabolic steroid drugs for the treatment of malnourished children in the Third World. The side-effects of these drugs can include irreversible masculinizing effects in girls and the stunting of children's growth. This is one of the findings of a survey carried out by more than 17 consumer associations and correspondents in 12 countries whose results have just been released.

In India, where malnourishment affects 30 per cent of children, Organon's anabolic steroid 'Fertabolin' is promoted in medical journals as 'helping (the child) to gain full weight and height' and 'ensures optimal assimilation of food'. In the Philippines where nearly a third of the children have moderate to severe malnutrition (according to the Philippines Nutrition Program 1978-82). Fertabolin is also promoted for children's use. Advertising copy includes phrases like: 'a delicious syrup flavour children love /.../ a remarkable appetite stimulant and builds body tissue.'

Such promotion in poor countries has been described by Dr Andrew Herxheimer, a senior lecturer in clinical pharmacology at Britain's Charing Cross Hospital Medical School, London, as 'absurd and evil because /food/ is what is needed. These drugs should not be used for that purpose... It is a blatant example of cynical marketing of an unnecessary, harmful and undesirable drug in countries with too weak a control system to defend their population.'

[image, unknown]

FERTABOLIN ADVERT to the Indian Medical Profession

According to Herxheimer, senior lecturer in clinical pharmacology, London, 'Improves the bloody picture' is the only thing acceptable in

this advert, but even here it should be restricted to very narrow indications like serious bone marrow disease. To stimulate appetite is irrelevant because the cause of the decrease appetite has to be treated. And these drugs are far too dangerous to be used as symptomatic treatment.... it's using them like an appetiser. As for 'helps gain normal weight and height' this is just not true. Giving children anabolic steroids like this will increase their growth in the first place, but also lead to premature cessation of growth in the long bones of the limbs, so the size of the limbs will be smaller in the end than it would be if the child grew more slowly and naturally.'

The drug itself is totally banned from use for children in the United Kingdom. And in all other Western countries it is strictly controlled.

One of the main manufacturers of anabolic steroids is Organon, subsidiary of the Dutch multinational company AKZO *- 77th largest company in the world. Organon sells these drugs in 29 countries, holding an unconfirmed 40 per cent of the world market.

The company's two main competitors in anabolic steroids are the US pharmaceutical giant Winthrop and the Swiss drug firm Ciba-Geigy.

It was in the mid-1960s that these drugs first made the headlines when East European and Russian women athletes were found to be using it for their muscular development. The unfortunate side effects of 'virilization', irreversible masculinizing characteristics like the enlarging of the clitoris, deepening voice and growing of hair on the chest were the reason for the non-appearance of the outstanding Soviet athlete Tamara Press from the Mexico City Olympics in 1968 and the beginning of the sports sex tests.

Anabolic steroids are synthetic derivatives of the male hormone testosterone. This hormone is responsible for the male aspects in human beings including the genitalia, hair on the chest and baldness. The hormone also enhances anabolism, the overall process of building up body tissue. But this only happens effectively when the 'building stones' of good food are already provided.

The drug is used, according to Dr Herxheimer, 'in very resistant cases of anaemia to stimulate blood formation by the bone marrow - where the marrow has ceased to function properly. However, their effectiveness is not certain.' In other words, where there is no established cure for a potentially fatal disease then it's worth taking a chance.

As for the bodybuilding functions the American Medical Association Drug Evaluations firmly condemns their use saying 'there is an added risk of liver damage and interference with the testicular function.' Adds the British National Formulary: 'the use of anabolic steroids as tonics is quite unjustified.' Yet this is precisely what Organon is doing with the promotion of its drugs in the Third World.

In the Third World drugs such as anabolic steroids are marketed for a whole host of trivial or even wrong symptoms. And the problems of side-effects can be compounded because many save on doctor's fees by going straight to the pharmacy for advice and medicine. Often this is provided by unqualified shop assistants whose only knowledge of their stock comes from sales representatives of the drug companies. Prescriptions are not required. Conditions are ripe for overdosing and consequent adverse effects.

Particularly grave side-effects are possible from anabolic steroids given to children. According to the British National Formulary the drug can accelerate their growth initially. But this can also lead to the premature closing of the epiphyses. the joints between the growing ends of the bones and the main part of the long bones. So the limbs eventually end up smaller than if the child had grown more slowly and

more naturally.

The consumer survey, however, found:

. Organon's anabolic steroids consistently promoted for children, in countries where conditions for overdosing are prevalent.

. Winthrop's anabolic steroids being advocated for malnutrition and a host of trivial complaints.

Of the three drug giants involved in the promotion of anabolic steroids to the poor world, only Organon has concentrated on the children's market. They have done so with promotional literature which emphasises a raspberry-flavoured syrup version of the drug the spoonful of sugar that helps the medicine go down. Indeed because of their promotion of Orabolin for the use of malnourished children in Bangladesh in 1981. the company has already been attacked in its home country of Holland by the lively medical action group WEMOS, who raised the issue with the Dutch government and press. OXFAM also contacted Organon about their Bangladeshi promotional literature. The company's reply was eminently reasonable: "It is obligatory for local (Organon) companies to have all material used for doctors' information approved by headquarters. Unfortunately sometimes the system does not work and something slips through. The printed material you refer to, ... had not yet arrived (in Holland) and consequently had not been approved by Organon International. /*. */ As a result of your information we have taken corrective measures with respect to Bangladesh and other countries where this may have occurred." The same defence, an isolated one-off case, has been maintained in subsequent press releases by Organon when replying to WEMOS criticisms.

Much of the promotional material of Organon in Third World countries carries highly misleading claims of the efficacy of anabolic steroids for underweight children. True, malnutrition is no longer mentioned but that's hairsplitting. The message is still clear. Indeed with the Philippines the same giraffe image is used to convey the idea of children shooting up as was used in the Bangladesh advert withdrawn in 1981. Is it a coincidence that the Organon subsidiary in the Philippines should have virtually the same advertisement we were assured was withdrawn from the Bangladesh market "and other countries where this may have occurred"?

One thing is certain, the promotion of anabolic steroids as a "cure" for undernourished children is still going on.

Furthermore, the labelling of anabolic steroids and information on the accompanying literature show a clear double standard between the drugs sold in the West and those promoted in the Third World. Members of the consumer's survey found when buying Winstrol, a product of Winthrop, in New York and Penang (Malaysia) extraordinary differences on the package inserts. In the US leaflet there is only one carefully circumscribed indication (symptom when the drug should be used). In the Malaysian version the drug proves useful for /ten/ conditions from burns to dwarfism, malnutrition due to alcoholism to brittle bones in old age.

The same double standard is used by Organon. On the company's anabolic steroid labels used in Canada, they mention:

"Side effects (occurring in some patients seldom, others more frequently); these side effects should always be mentioned as information to patients and prescribing doctors . men/boys: phallic enlargement, increased frequency of erections (in pre of mammary gland). . women/girls: masculine hair, deepening of voice, clitoral enlargement; these phenomena are irreversible. . in both sexes: water and salt retention, nausea, changed libido, acne, agitation, insomnia, danger from haemorrhage when combined with anti-coagulants, growth in height

stops prematurely, tumours of the liver.â€™ Organonâ€™s labels from the Third World list few if any side-effects.

When asked about this double standard in labelling, the drug companies have plausible answers. They cite differences in medical opinion on anabolic steroidsâ€™ safety and regulations for use from one country to another. So whilst in the United Kingdom anabolic steroids cannot be prescribed for children, in Holland they can. This allows the companies to play ping pong with the responsibility for their own drugs labels and literature ,bouncing the ball safely back over the net to the Third World governments. They say that it is up to relevant Health Ministries to decide what medicines to allow onto the market and make sure they are used safely. Yet they are fully aware that Third World regulatory authorities donâ€™t have independent testing centres to research their drugs. Instead they rely on manufacturers for information on which to base their decisions. So the drug can be promoted as a cure-all with little or no mention of dangerous side-effects.

Standardization of drug labels is obviously essential. Winthrop is looking into this. When the US consumer survey agent made enquiries the company was helpful, providing samples of its Winstrol labels from different countries including Latin America. And there was significant standardization. Asked if the company was prepared to recommend its anabolic steroids for the treatment of malnourished children, Winthropâ€™s director of international public affairs, Mr Robert Schaffer, replied firmly â€˜No way... we never anywhere today recommend it to... say increase appetite or in any sense be taken as a tonic.â€™ Yet every Winstrol label apart from that used in the US carried the words, â€˜In nearly all chronic serious illnesses where there is a general state of /malnutrition/ (our emphasis) with impairment of appetite and food assimilation.

Winstrol facilitates proper utilisation of ingested protein.â€™ True they do not mention malnourished children directly. But nearly every starving child is likely to be chronically and seriously ill into the bargain. So whilst Mr Schaffer is technically correct, these fine points of semantics are not likely to be understood in a Latin American farmacia where an anxious parent wants a medicine for her sickly infant.

Pharmaceuticals are big business today. Lack of regulatory controls in poor countries mean that drug companies can virtually say - or omit *-* what they like about their products to increase sales. However, when dealing with medicines which have such a direct bearing on the life or death of poor world consumers, the international community has a right to demand irreproachable business ethics.

/*Copies of the full report, â€˜An International Study on the Availability and Marketing of Anabolic Steroids. December 1982/ *-*/ March 1983â€™ are available. Price US\$25.00 including airmail postage from: International Organization of Consumers Unions, Regional Office for Asia & the Pacific, P0 Box 1045, Penang, Malaysia./

*Double Standards
... on anabolic steroids*

. The major anabolic steroid manufacturer promotes a version of this drug as a raspberry-flavoured syrup for children in the Third World. This syrup is not found on sale in the West. according to a consumersâ€™ survey. In fact the drug is banned for childrenâ€™s use in the UK and heavily restricted elsewhere.

. Anabolic steroids are promoted in the Third World for a wide range of symptoms from kidney disease to arthritis. post-operative wound-healing to bums, convalescence to malnutrition. In the West they can only be used in a few resistant cases of anaemia and in some countries (not in the UK, USA or Canada) for pituitary dwarfism.

. Few or no side-effects of the drug are listed on the medical literature which accompanies the Third World drug packages. Accompanying literature in the West gives an exhaustive list of the sometimes very serious side-effects.