

ARTICLE

Monitoring misuse of the WHO name and emblem in medicine promotion in India

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Abstract

The World Health Organisation has called for the ethical promotion of medicines. This study to monitor the misuse of the WHO name and emblem in medicine promotion in India found that the name or emblem of WHO has been used extensively for unethical promotion of drugs, nutritional supplements and consumer products in India. This unethical promotion is evident in advertisements, pharmaceutical indices and other publicity material.

It is commonly believed that doctors are aware of unethical practices and corruption in the medical profession but most of them prefer to keep quiet about it. Thus the general perception is that doctors are part of the conspiracy of silence and secrecy and most refuse to stick their necks out (1). Doctors must not forget that they have social obligations and must use their knowledge and skills to save society from medical exploitation. This includes unethical medicine promotion and propaganda. For, if doctors do not take a stand on such issues, then who will?

Indian dental and medical professional associations are busy endorsing consumer products as our cricketers do, and have come to be referred to as the Indian Colgate Association and the Indian Dettol Association. A recent editorial (that read more like an advertorial) of the *Journal of Indian Medical Association (JIMA)* commented: "IMA and Eureka Forbes Limited, a manufacturing company responsible to introduce the world class water filter and water purifier system in our country jointly take up the awareness programme across the country about the role and need of pure water..." (2)

We have been noticing the use of the World Health Organisation (WHO) name and its emblem in medicine promotion and thought of studying it further as a voluntary project. We searched the WHO-Health Action International drug promotion database www.drugpromo.info for studies on the misuse of the WHO name and emblem, but did not find any. However we did find a recent study commissioned and sponsored by the WHO-India office whose findings indicate the institutionalisation of blatantly unethical and illegal promotional practices by drug companies in Mumbai, India (3).

During a field exercise in a training course on promoting rational use of medicines in the community, conducted with WHO South East Asian Regional Office (March 1-8, 2006), participants were asked to bring to the class oral rehydration

solution (ORS) packs with the WHO name and emblem. The data were subsequently published (4).

Since WHO's ethical criteria for medicine promotion must be adopted, published and disseminated, and compliance with the criteria monitored on a continuous basis (5) we planned this study to monitor the misuse of the WHO name and emblem in medicine promotion in India.

Some of the initial findings of our study were presented at a WHO/UNICEF technical briefing seminar on essential medicines policies, at the WHO Headquarters, Geneva, Switzerland (September 18-22, 2006).

Promotional statements in the name of WHO

Many companies make statements quoting WHO. The references quoted in such promotions are grossly incomplete, making cross verification difficult. For example, Raptakos, Brett & Co Ltd, in its advertisement for *Hepatoglobine*, states that "Anemia is independently associated with increased mortality-WHO (World Health Organisation)." The reference for this statement has been given as "*Archives of Internal Medicine* Vol 165 No 19, October 2005 (6)". This does not disclose the names of the author(s) or the page numbers of the journal where it has been published.

Another company has been creating a fear psychosis by stating: "2010: India will have 100 million heart patients, 2015: Heart diseases will replace infectious diseases as a major killer, 2025: Nearly half of India's population will suffer from heart ailments" in the name of a WHO report, the reference for which is not given (7).

Can we deduce from these examples that the missing details vital for valid verification have been deliberately omitted?

In the name of WHO GMP certification

WHO does not give "good manufacturing practice" (GMP) certification to any unit but it recommends in its manual how a "WHO type" certificate should be given by a drug regulatory authority (8). The manual specifies that certificates should not bear the WHO emblem (para 4.1, page 89). It mentions that marketing authorisation may be suspended or revoked if the product is being promoted in an inappropriate or unethical manner (para VIII, page 32). Yet, in India, we see pharmaceutical

companies indulging in various unethical permutations and combinations such as:

- “WHO GMP/UK MHRA approved plants” (9, 10)
- “WHO-GMP certified” (11, 12, 13, 14)
- “WHO GMP certified” along with mention of “more than 100 WHO-GMP certified products” (15)
- “WHO GMP standards” (16)
- “WHO GMP (Revised Schedule ‘M’)” (17)
- “GMP certified schedule - M compliant unit adhering to WHO GMP norms” (18)
- Using a seal of “WHO Certified GMP” (19, 20)
- Using different seals of “WHO GMP Certified” (21), advertising nimesulide combination brands including kid tab and suspension (22) and advertising hepatoprotective nimesulide (23)
- Using a different seal of “Certificate of WHO-GMP and WHO-GMP Certification” together (24)
- Using yet another seal of “WHO GMP Approved, an ISO 9001-2000 certified company” (25, 26)
- Using emblem of WHO with words GMP (27, 28)

In some promotions, the claim of WHO GMP status has been made even before the plants became operational. It is like starting a new medical college with the claim that it is Medical Council of India (MCI) compliant!

Some examples:

- “WHO GMP compliance unit opening shortly!” (29)
- “Setting up state of art WHO-GMP compliance formulation plant” (30)
- “New ultra modern CGMP/WHO-GMP compliant manufacturing unit being set up at Rudrapur” and “third party pharma manufacturing - being set up in WHO-GMP and ISO 9001:2000 compliance” (31).

The certification mania has reached such proportions that those wanting to buy an operational pharmaceutical manufacturing plant are asking for a WHO GMP approved unit (32).

In advertising job openings, some companies have described themselves as being “A WHO-GMP company” below the company’s masthead (33). These advertisements have been carried in national dailies known for ethical journalism.

We did not come across a single advertisement in international journals claiming WHO GMP certification. It is obvious that WHO cannot have the GMP certification scheme for India alone.

Promoting medicines as having received WHO prequalification status

WHO has a scheme of prequalifying the medicines and commits that “a key lesson learned is that with technical input and guidance, manufacturers of generic medicines in developing countries are able to manufacture ARVs of proven quality and efficacy, as well as effective diagnostics”(34). What WHO has learnt does not seem to apply to India, for we can report use of

prequalification status in the advertising of a branded product - *Rabipur*. The joint advertisement by Sanofi Aventis and Chiron vaccines claims that their “PCEC vaccine is WHO-prequalified and recommended for purchase by UN agencies” (35).

In the name of WHO model list of essential medicines

Themis Medicare Ltd, Mumbai, promoted its antimalarial combination of lumefantrine with artemether, *Lumether*, as a “WHO recommended artemisinin combination therapy for malaria” and in its product flyer used the words “*Lumether* included in WHO Model list of Essential Medicines Core list (revised March 2005)”. The copywriters committed the blunder of magnifying para 6.5.3.1 of the Essential Medicines List relating to antimalarial medicines which says that “for curative treatment medicines for the treatment of P Falciparum malaria cases should be used in combination Armether + Lumefantrine.”

How WHO is played with on ORS products

The capacity of the pharmaceutical industry to counter any move towards rational therapy should not be underestimated. The industry introduced high price ORS packs after discovering the popular swing towards the rational therapy of diarrhoea(36). While the WHO-recommended ORS formula was adopted by the industry, it was not without commercial exploitation of WHO’s name. Due to the confusion in ORS formulations available in the market, even the literate find it difficult identifying what exactly is recommended by WHO, which composition is correct and most recent, and whether WHO recommends the orange/lemon flavours of ORS. Patients are routinely advised to dissolve the whole ORS pouch in one litre of water. If the patient buys a smaller pouch the end result can well be imagined. We found so many versions of the WHO name/emblem on ORS products in India that it was difficult for us to identify which one was correct. Given below are the company names and their claims (4). Try solving the riddle.

- Micron Pharmaceuticals - WHO formula
- FDC Limited - Based on W.H.O. Formula (WHO in bold) and WHO. ORS emblem in which “recommended” is not readable
- Merck Limited - New WHO recommended formula (written twice) and WHO ORS emblem
- Maan Pharmaceuticals Ltd - WHO recommended formula
- Unichem Laboratories Ltd - WHO/UNICEF recommended formula
- Wallace Pharmaceuticals Pvt Ltd - Emblem WHO ORS (recommended not readable)
- Shreya Life Sciences Pvt Ltd, Mumbai -This product corresponds to the formulation recommended by WHO and UNICEF with emblem of WHO recommended ORS

WHO in ORS advertisements and promotion

Since ORS is a big market segment, brands are heavily advertised. Given below are some advertisements relating to ORS:

- "Relyte safe sips. The WHO recommended low osmolarity ORS" (37).
- "One ORS for all the little ones-Now Electral based on W.H.O. formula" (38).
- "New WHO ORS recommendation. Now in leader brand" reads another ad of *Electral* (39).
- "The WHO based ORS formula" states the ad for *Electrokind* (40).
- The ad for *BioRS*, a combination of ORS and Synbiotic, is shocking. It has used the WHO emblem and markets the ORS-Synbiotic combination in the same pack and space with the statement that "a single body cut opens both the packs" (41).
- Terrible is a poster in Hindi allegedly issued by WHO ORS and Complete Home Diarrhea Management Programme (WHO should know if it was party to such a programme) brought out by nine Indian ORS brands (and not companies) viz *Electral*, *Electrobion*, *Neotral*, *Punarjal*, *Rebalanz*, *Relyte*, *Ttk ors*, *Vitalyte* and *Walyte*. They have used the WHO ORS emblem together with copy that says that the mother and father of Raju did not have the right knowledge of treatment of diarrhoea, hence Raju lagged behind Nandu. Accompanying the copy are pictures of two boys aged three years, in which Raju is shown as having stunted growth as compared to Nandu.

The 46th WHO Assembly in 1993 requested member states to "develop policy guidelines on the use and protection of international nonproprietary names (INN), and to discourage names derived from INNs, and particularly names including established INN stems as trade marks" (resolution WHA 46.19), as such use can frustrate the rational selection of further INNs for related substances, and it will ultimately compromise the safety of patients by promoting confusion in drug nomenclature. Thus drug regulating authorities have the authority to disallow a trade name on grounds that it is misleading (8). We found the promotion of ORS-LTM, an electrolyte energy drink with vitamin C in ready-to-serve tetra packs, which the manufacturer (<http://www.jagdale.com/juggat.html>) recommends for many conditions but not diarrhoea (42).

WHO name and emblem in vaccine promotion

ARV manufacturers have been in the forefront of using the WHO name. Earlier publications by Aventis and later Sanofi-Aventis relating to its brand *Rabipur* have been claiming "WHO recommended & US FDA approved Rabipur". Recently, Sanofi-Aventis distributed a table-top pen stand as promotional material, where the packing and the gift both mention "WHO recommended & US FDA approved Rabipur". While this study is not commenting on the status of US FDA approval, it certainly objects to the repetitive use of the phrase "WHO recommended Rabipur".

Ranbaxy Laboratories uses the WHO name in its flyers of *Verorab* and Bharat Serums & Vaccines Ltd, Mumbai, mentions "dosage and administration of *Rabglob* as recommended by WHO".

Another multinational GlaxoSmithKline, Mumbai, has been promoting its combination vaccine *Tritanrix HB + Hiberix* as "The only WHO approved pentavalent combination," and quotes the reference of www.who.int/vaccines-access/quality/un_prequalified (43). The obvious question is why should WHO recommend specific brands of vaccines?

Use of WHO in promotion of nutritional supplements

Biomiicron Pharmaceuticals, Chennai, has used the WHO emblem and below it the legend "WHO-GMP Schedule-M," in the advertisement of its orange flavoured combination product containing Calcium, Biotin, L-Glutamic Acid, Folic acid and Vitamin D3 (44).

Mother's Horlicks, a product of Glaxo Smith Kline, is promoted with the claim that it "complies to WHO guidelines providing 20% calories from proteins." There is no reference provided to substantiate the claim of the multinational. Half a dozen insertions of the same advertisement were found in one single issue (45) of a publication, indicating the massive budget for the promotion of this nutritional product.

WHO on consumer products

The consumer product industry cannot afford to miss making hay while the WHO sun shines and the darkness in monitoring medicine promotion prevails. A mosquito repellent liquid refill - *Tortoise Ninja* (manufactured by Bombay Chemicals Pvt Ltd, Batch No LS 0013, Mfg date: 01/2006, MRP INR 45.00) has the WHO emblem on its product pack with the words "WHO recommended" and in fine print "NAK 4455 recommended for adoption by WHO. Reference report No 741/2002," whatever that means.

Discussion

A WHO publication (46) has quoted the conclusion of others (47) that "most multinationals had improved considerably by the late 1980s. Local and domestic firms were now mainly responsible for inaccurate promotion. Silverman et al's books show a clear improvement over time in promotion in developing countries." We beg to differ with the learned authors. We found multinational giants indulging in such misrepresentations in India along with local and domestic firms. India is a developing country and if this is the state of "clear improvement" in medicine promotion, one wonders what could have been worse. There have been enough warnings that double standards might be adopted by pharmaceutical companies in following codes for medical advertising in developing countries (48).

But we do agree with the conclusion of Norris et al (46) that "publication of descriptions of deceptive promotion can lead to improvements." So we hope that the concerned will take note of our exhibits and sanitise the filth in medicine promotion.

It is not clear what our central and regional committees that were constituted to tackle unethical promotion of medicines, are doing (49) given the unregulated state of medicine

promotion in India. Nor has the pharmaceutical industry spared the WHO name and emblem from blatant exploitation.

The Food and Drug Administration of the United States launched an initiative to help consumers obtain accurate, up-to-date and scientific information about health consequences of foods and dietary supplements. It entered into an agreement with the Agency for Healthcare Research and Quality which reviews the claims before they appear on labels. Accordingly, an interim evidence based ranking system for scientific data has been introduced. The highest grade 'A' stands for significant scientific agreement about the health claim. 'B' is given to claims for which there is good scientific evidence supporting the claim but it is not entirely conclusive, 'C' for claims for which the evidence is limited and inconclusive and 'D' for claims with little scientific evidence (50). If such a scientific approach can be adopted for nutritional products, how much more so is it needed for medicines, which are more hazardous. If claims made for medicines in promotional material are screened first, before they are allowed to go public, it would surely check the deviants.

This is the output of more than two years of research and due to constraints of manpower and resources all the misuse has not been exposed. Here is what readers can do if they notice misuse of the WHO name/emblem:

- Catch the medicine promotion for errors of omission and commission.
- Scan the promotional material and save it. Procure hard copy evidence.
- Inform WHO authorities and active consumer organisations like CERC Ahmedabad, LOCOST Vadodara, VHAJ New Delhi, NetRUM Nagpur about it.
- Ask WHO to seek clarification from the concerned pharmaceutical company.
- Ask WHO to use the right to information (RTI) to get the details.
- Network and discuss in E-forums like E-drugs, IndPharm, NetRUM.
- Use personal media connectivity to counter the promotion.
- Lobby with politicians for effective legislative control of medicine promotion.
- Educate medical students and consumers about medicine promotion and train them in "ad-busting" (36).
- Insist that scientific journals to which you subscribe have, and practices, editorial policy of rejecting unethical medicine promotion.
- Create a watchdog body to monitor unethical medicine promotion.
- Organise to file public interest litigation.

Time to rewrite WHO ethical criteria

The WHO Ethical Criteria for Medicinal Promotion (WHO Geneva, 1988) was written decades ago and desperately needs to be updated. It is silent on such misuse of the WHO

emblem and name as detailed above. It has become obsolete and outdated. It needs to encompass a warning for misuse of WHO emblem/name and should explicitly warn of legal action in such cases. It must spell out what WHO will do if its name/emblem is misused for medicine promotion. It is a tragi-comedy when the name/emblem of an organisation that recommends ethical criteria is unethically used.

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WHO disclaimer: *We have been requested by WHO to insert the following disclaimer: "Although WHO takes the misuse of its name very seriously, WHO does not endorse the content of this publication and has had no involvement in the author's actions. Similarly, WHO has not verified the accuracy of any statements made in this publication."*

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Changes in the editorial boards of *IJME*

With 2009, the *IJME* editorial boards have undergone some changes. Some people have stepped down, others have joined, and still others have moved from one board to the other.

To those who have stepped down, we express our gratitude for their valuable support. Arun Bal from Mumbai, Sunita Bandewar from Pune, M D Gupte from Chennai, PK Sarkar from Kolkata, Somboon Kietinun from Thailand, M Janaka Munasinghe from Sri Lanka, Md Humayun Kabir Talukder from Bangladesh and Zulfqar Bhutta from Pakistan have contributed enormously to the journal's growth and development in the years that they have been part of the extended *IJME* team.

We welcome, to the editorial board, Prabha Chandra from Bangalore, Nobhojit Roy, formerly web editor, and Neha Madhiwalla, formerly editorial advisory board member. Anurag Bhargava joins the editorial advisory board from Bilaspur. Bashir Mamdani and Meenal Mamdani step down from the editorial board and join as members of the editorial advisory board from the US. Other new members of the international editorial advisory board are Angus Dawson from Canada, Aamir Jafarey from Pakistan and Sisira Siribaddana from Sri Lanka.

We hope that the new entrants will add to the richness of discussions in the journal and spur it to new heights in coming years.