WHO accused of stifling debate about infant feeding

Annabel Ferriman *BMJ*

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Infant feeding specialists who want the WHO to recommend exclusive breast feeding up to 6 months claim debate is stifled

International specialists in infant feeding have expressed concern that the World Health Organization's policy of establishing partnerships with private industry has gone too far, with the result that debate about the infant food industry's role in marketing breast milk substitutes is being stifled.

A group of specialists who want the WHO to recommend that babies should not be introduced to complementary feeding until about 6 months of age, claim that at a recent joint meeting of the WHO and Unicef in Geneva on infant feeding they were prevented from discussing the issue. In addition, several background papers, prepared for the week long meeting, were edited so that they were less critical of the infant food industry.

Dr Audrey Naylor, a paediatrician and executive director of Wellstart International, who was one of the consultants at the meeting, told the *BMJ*: "We felt discomfort at not being able to discuss the age at which complementary feeding should be introduced to infants." She said that 20 of the 28 consultants signed a statement saying that scientific evidence was now sufficient to warrant changing the WHO's recommendation to about 6 months, but no discussion was allowed.

The current WHO guidelines, which recommend the introduction of complementary feeding at age 4-6 months, lead to confusion and to babies being offered other things from the age of 3 months and sometimes even earlier, Dr Naylor said. "The literatures suggests that this leads to increased morbidity and mortality," she added.

Two members of the consultants group at the meeting, which included physicians, policymakers, nutritionists, and lawyers, have written to the WHO's director general, Dr Gro Harlem Brundtland, protesting at the way that their papers were changed.

Ms Ellen Sokol, a US lawyer who had been asked to write a paper on strengthening the international code of marketing of breast milk substitutes and who had said in her paper that the marketing practice of the manufacturers was an obstacle to that end, found all such references deleted. "The revised paper no longer reflected the assigned topic," she told Dr Brundtland.

Ms Judith Richter, a specialist in the politics of health from Tübingen, Germany, also complained to Dr Brundtland. She had been commissioned to write a paper on how globalisation affects infant feeding; in it she wrote that infant food manufacturers should not be involved in policymaking on infant feeding because of their conduct in relation to their marketing practices and international debates, and because of a conflict of interest between profit making and public policymaking. She found that the part of her paper outlining these arguments had been cut from her paper, and she protested to Dr Brundtland that her paper had been "censored."

A spokesman for the WHO said: "The agreed ground rules for the technical consultation in March explicitly excluded discussing the WHO's current recommendation on the duration of exclusive breast feeding (4-6 months) because WHO research is under way in this connection.

"As far as alleged censorship is concerned, the WHO is an international, intergovernmental organisation, and the WHO documents have to conform to a high standard of scientific objectivity and balance. By the time the consultation meeting convened, seven of the nine background papers had met this standard and two had not.

"With regard to the suggestion that the WHO is getting too chummy with industry, it is in fact the WHO's mandated role to bring all legitimate players together on a given public health issue. The food industry continues to play an important and constructive role in relation to infant feeding." □

Drug industry is unwilling to run trials in children

Zosia Kmietowicz *London*

Few drug companies are willing to undertake clinical trials in children voluntarily, according to a survey carried out by Britain's Consumers' Association. A change in the regulations governing drug licences may be the only option for ensuring that products used in children are safe and effective.

As part of its campaign to ensure that all drugs used in children are subject to the same regulatory procedures as those used in adults, the association wrote to all 79 members of the Association of the British Pharmaceutical Industry on 11 April asking them how they were addressing the issue. By the time the *BMJ* went to press earlier this week, only four companies had responded.

The low level of response suggests a general apathy in this area among the pharmaceutical industry, said a spokeswoman for the Consumers' Association.

"The pharmaceutical industry has a major contribution to make, and we are appalled at the level of response," said Louise Ansari, the association's press officer. "However, it is heartening to see that some companies are approaching the issue responsibly. Norgine Limited, Bristol-Myers Squibb, and Schering Plough have all recently completed trials in children or are in the process of conducting them."

Altogether 40% of drugs used to treat children are not licensed for that purpose, and a recent study found that across five European countries 67% of children in hospital receive unlicensed or "off label" drugs (8 January, pp 79-82).

Obtaining parental consent for sick children to enter a clinical trial can severely hamper progress, according to the companies who responded to the association's letter. They called for a financial incentive to be made available to them and quoted the scheme offered by the US Food and Drug Administration, which involves a six month extension to the drug patent.

Dr Ike Iheanacho, deputy editor of the *Drug and Therapeutics Bulletin*, dismissed the excuse of unwilling parents as "not necessarily true." "Parents need to be told the facts and encouraged to take part in trials so that we can gather more data on children—otherwise we will always be in the dark," he said.

Although an incentive scheme may encourage some companies to take action on licensing medicines for children it would always be voluntary and only presents an interim solution, said Dr Iheanacho. "Ultimately we would be arguing for some regulatory framework that requires all products destined for use in children to undergo rigorous trials," he added. □