

Suitability of Deworming Medicine (Albendazole) and Multi-Micronutrient Supplement for Tawana School Girls*

By

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The following subject summary may facilitate the members of the Expert Committee to resolve the issue of suitability of Albendazole and Multi-Micronutrient Supplements for Tawana Primary School Girls.

1.0 Procurement of Albendazole and Multi-Micronutrient Tablets (MMN)

1.1 The Aga Khan University (AKU) being Technical Advisor of Tawana Pakistan Project (TPP) recommended the prescription plan and selected foreign brands of Albendazole and Multi-Micronutrient tablets (MMN).

1.2 The National Implementation Unit (NIU) of the project imported the above medicine /MMN through UNICEF, costing Rs 9.25 million out of allocated funds of Rs 387 million from the following countries.

- a. Albendazole (400 mg chewable) 280,000 tablets from Cyprus
- b. Multi-Micronutrient (MMN) non-chewable 12.32 million tablets (contain 15 vitamins and minerals, primarily formulated for pregnant women – Annex 1) from Denmark.

1.3 Dosage

Albendazole: One tablet twice yearly to be administered before the start of feeding.

MMN: One tablet twice a week.

1.4 **Stock Position:** The bulk of the stock have been stored in sub-optimal conditions at district level for the last 15 months because of their non-utilization due to sub-standard quality and side effects.

Albendazole: A total of 280,000 tablets are available to meet the initial dose requirement (one tablet before the start of feeding) for 280,000 girls (53% of the total beneficiaries) and must be used before August 2007. There is still shortfall of 250,000 tablets to meet the first dose requirement of 530,000 girls.

MMN: Adequate stock of 12.32 million tablets are available to meet the requirement of 530,000 girls (100% of the beneficiaries) for one academic quarter of 11.7 weeks. These tablets will be expired in January 2006.

* (Presented in the Meeting of Technical Committee of MoWD on Administration of Multi-Micronutrient and Albendazole held on 23rd June 2004)

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2.0 Distribution, storage and administration of tablets: Issues

2.1 Distribution and storage of tablet was affected through Pakistan Bait-ul-Mal. Transferred to 20 districts in February –March 2003. The religious community particularly in NWFP and Balochistan provinces voiced their apprehensions against the use of these tablets, may affect the fertility of girls. Due to their side effects of nausea, vomiting, abdominal discomfort, diarrhea, headache, unconsciousness etc possibly due to wrong instruction of administration, reported in 100 girls out of 1800 girls (6%) in some schools of Pakpattan, the Director General Health Punjab province, issued orders not to administer these tablets in the TPP districts of Punjab. Subsequently in May 2003, the administration of Albendazole and MMN were stopped in all TPP schools. Since then the medicine/MMN have been stored in sub optimal conditions at district level for the last 15 months. Long storage under harsh conditions of high temperature and humidity, sunlight exposure etc, may have further deteriorated the quality of the tablets due to various chemical interactions, producing unpleasant smell and may have affected the safety of tablets. There is a need to improve the storage conditions of the present stock as suggested repeatedly to the concerned project stakeholders. The MMN are known to interact with each other and influence their bioavailability. There is a lack of consensus on the need for MMN. The MMN tablets were primarily formulated for pregnant women and their side effects could be due to high doses for young primary school girls. About 87% of the micronutrients in tablets had 125-300% higher dosage levels (annex 1) than RDA of girls (5-12 years). Such high doses may be difficult to tolerate and to retain fully and can be dangerous. The highest areas for investigation of MMN formulated for pregnant women should be the efficacy and safety of these tablets for young primary school girls. UNICEF also confirmed the usage of these MMN for pregnant women and could not produce any evidence of its use for primary school children in any part of the world. It may be pointed out that recently more than 30 Indian children died due to over doses of vitamin A. Similarly 2000 cases of iron poisoning in children due to ingestion of iron-supplements formulated for adults have been reported in USA.

3.0. Laboratory Analysis

3.1 According to chemical analyses of these tablets the quality of Albendazole tablets was sub-standard as declared by NIH and only five vitamins out of fifteen vitamins and minerals in MMN tablets, claimed by Danish Supplier were identified by TGA laboratory in Australia.

4.0 Recommendations (National/International)

4.1 The UNICEF, WHO and UNU recommended a composition of a Multi-Micronutrient supplement (Annex 1) to be used in pilot programmes among pregnant women in developing countries (vide workshop held at UNICEF head quarters, New York, July 9, 1999). The same Multi-Micronutrient supplement was recommended by The Aga Khan University for young primary school girls under Tawana Pakistan Project.

4.2 A pilot administration of imported Albendazole and one instead of two tablets of MMN, revision of prescription plan, reducing dosage and procuring locally produced

deworming medicine and micronutrient tablets have been recommended in two meetings of Technical Committees of MoWD.

4.3 Based on their field experience and physical condition of medicine and MMN tablets stored under unfavorable conditions (temp above 45 degree centigrade) for a long time, the representatives of AKU and heads of eleven NGO team partners recommended that these tablets may not be suitable for human consumption and should not be used in project districts. (Vide Meeting of NIU with AKU /NGO team partners on 24th May 2004 held at Islamabad)

4.4 National policies for addressing micronutrient deficiencies have been widely adopted in 28 developing countries including Pakistan for control of vitamin A, iodine and iron deficiencies. A four in one package (deworming every six months with vitamin A capsule, iron tablet weekly and iodized salt) being more economical and effective, has been used for better improvements in health and nutritional status. In India, 40 million primary school children have been receiving deworming tablets, iron tablets, vitamin A capsule and iodized salt (three micronutrients only) along with midday noon meal since 1995. This was found highly cost effective and efficient measure to improve educational and nutritional status of children after one year. The programme under Nutrition Mission headed by the Prime Minister of India is expected to reach 250 million children by 2007. We may follow the successful Indian experience. Regarding the annual cost of deworming medicine and micronutrients (4-in-1 package) is Rs 30 per child in India as compared to Rs 53 per child in Tawana Pakistan Project.

5.0 Actions required by MoWD/Ministry of Health

In the light of the foregoing, the Technical Committee may decide

- 5.1** Re-administration of imported Albendazole and multi-micronutrient tablets only after their clearance of the following tests by the Ministry of Health
- a. Efficacy and safety (toxicity risk etc) of MMN tablets
 - b. A pilot field administration of Albendazole and MMN tablets to school girls by EDO (Health) and to monitor any potential adverse effects during supplementation trial.
- 5.2** The cost of these imported tablets may be claimed from the supplier, in case the Ministry of Health finds these tablets unfit for human consumption.
- 5.3** Procurement of locally produced four-in-one package (deworming medicine, vitamin A capsule, iron tablet and iodized salt) as an alternative, which is also in line with the national policy to eliminate vitamin A, iodine and iron deficiencies among the school girls for the rest of the project implementation period may be considered.

**Comparison of dosage of Imported Multi- Micronutrients with RDA
for Pregnant Women and girls (5-12 years)**

Ingredients	Multi-Micronutrients		Pregnant Women	Girls (5-12 years)	Over Dosage (% of RDA)
	Dose per tablet		RDA*	RDA**	
Vitamin A (µg)	800		800	600	133
Vitamin D (µg)	5		10	5	100
Vitamin E (mg)	10		10	11	90 (under)
Vitamin C (mg)	70		70	45	167
Vitamin K (µg)	---		---	60	--- (Missing)
Thiamine (mg)	1.4		1.5	0.9	156
Riboflavin (mg)	1.4		1.6	0.9	156
Vitamin B6 (mg)	1.9		2.2	1.0	190
Niacin (mg)	18		17	12	150
Folate (µg)	400		400	300	133
Vitamin B12 (µg)	2.6		2.2	1.8	144
Iron (mg)	30		30	10	300 (Very High)
Zinc (mg)	15		15	8	188
Copper (mg)	2		2	0.7	286
Selenium (µg)	65		65	40	163
Iodine (µg)	150		175	120	125

* Based on DRI, US Food and Nutrition Board, Washington D.C: National Academy Press. 2001 (Vide Bienz et al. Adequate dosing of micronutrients for different age groups in the life cycle. Food and Nutrition Bulletin. 24(3); 57; 2003. The United Nations University.)

* Recommended Daily Allowance for USA

** Recommended Daily Allowance for Developing Countries.