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QUALITY MEDICINES FOR EVERYONE

PREQUALIFICATION OF
MEDICINES PROGRAMME
A UNITED NATIONS PROGRAMME
MANAGED BY WHO



World Health
Organization

WHY IS THERE GLOBAL CONCERN ABOUT DIARRHOEAL DISEASES?

Diarrhoeal diseases are a leading cause of childhood morbidity and mortality in developing countries, and a major cause of malnutrition. In 2003, an estimated 1.87 million children below 5 years of age died from diarrhoea, with 8 out of 10 of these deaths occurring during the first two years of life. In developing countries, children below 3 years of age experience around an average of three episodes of diarrhoea every year.

Mortality due to diarrhoea among children under 5 years of age, by WHO region

WHO Region	Diarrhoea as a cause of death among children aged < 5 years (%)
South East Asian Region	19.5
Eastern Mediterranean Region	16.7
African Region	16.3
European Region	14
Region of the Americas	12.7
Western Pacific Region	12

In WHO's Eastern Mediterranean region, over 200, 0000 deaths due to diarrhoeal diseases still occur annually in children under five years of age.

WHAT IS THE RECOMMENDED TREATMENT FOR ACUTE DIARRHOEA AND ITS DEVELOPMENT STAGES?

Efforts to tackle childhood diarrhoea are longstanding. In 1978, the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) adopted ORT using oral re-hydration salts (ORS) solution as the primary tool to fight dehydration due to diarrhoea. As a result, the number of deaths due to acute diarrhoea in children under the age of five fell from 4.5 million to 1.5 million deaths annually. Nevertheless, acute diarrhoea remained a leading cause of mortality among children in developing countries. In 2004, WHO and UNICEF released revised recommendations for managing diarrhoeal disease aimed at dramatically cutting the number of deaths due to diarrhoea. The recommendations took treatment advances into account: a new formulation for ORS containing lower concentrations of glucose and salt, and success in using zinc supplementation as an adjunct to ORS.

WHY IS ZINC TREATMENT RECOMMENDED FOR TREATING ACUTE DIARRHOEA?

The rationale for using zinc to treat acute diarrhoea is based on its effects on immune function, on intestinal structure or function, and on the epithelial recovery process during diarrhoea. (Zinc deficiency has been found to be widespread among children in developing countries, and occurs in most of Latin America, Africa, the Middle East and South Asia.) Zinc has been identified as playing a critical role in metallo-enzymes, polyribosome, the cell membrane, and cellular function, suggesting that it also plays a central role in cellular growth and immune system functioning. It has also been shown that intestinal zinc losses during diarrhoea aggravate pre-existing zinc deficiency. Convincing evidence for the clinical importance of zinc has come from randomized controlled trials that evaluated the impact of zinc supplementation during acute and persistent diarrhoea. These trials have shown that zinc supplementation reduces the duration and severity of a diarrhoea episode, and lowers the incidence of diarrhoea in the following 2–3 months,



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AS A PHARMACEUTICAL MANUFACTURER WHAT ROLE CAN I PLAY?

Industry can help ensure that the WHO–UNICEF recommendations are implemented by preparing quality-assured zinc formulations for which zinc is the only active ingredient. Products should be formulated so that the strong metallic aftertaste of zinc is masked, to make them more acceptable to children. The invitation to zinc-sulfate manufacturers to submit an expression of interest (EOI) for product evaluation to the WHO Prequalification of Medicines Programme can be found at: http://apps.who.int/prequal/info_applicants/eoi/EOI_Zinc-V1.pdf. This EOI relates to the following: zinc sulfate products: dispersible tablets 10 mg, 20 mg; oral liquid: 10 mg per unit of dosage forms; and tablets: 10 mg, 20 mg.

References:

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