

Market analysis of the ORS and zinc markets in Kenya

Commissioned by PSI/Kenya

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Abbreviation list

APHIA:	AIDS, Population and Health Integrated Assistance
CDD:	Control of Diarrhoea Disease
CIFF:	The Children's Investment Fund Foundation
DHS:	Demographic Health Survey
DTK:	Diarrhoea Treatment Kit
EDL:	Essential Drug List
GoK:	Government of Kenya
HIV:	Human Immunodeficiency Virus
IMCI:	Integrated Management of Childhood Illnesses
KEMSA:	Kenya Medical Supplies Agency
MoH:	Ministry of Health
NGO:	Non-Governmental Organization
ORS:	Oral Rehydration Salts
ORT:	Oral Rehydration Therapy
PMTCT:	Prevention of Mother to Child Transmission of HIV
UNICEF:	United Nation Children's Fund
USAID:	United States Agency for International Development
WHO:	World Health Organization

Key Findings

The new WHO (World Health Organization) guidelines for the treatment of diarrhoea in children under 5 years old include the use of low osmolarity ORS (Oral Rehydrating Salts) and a 10 to 14 day treatment of zinc.

However, whilst the DHS (Demographic Health Survey) survey 98 reported that only 9.5% of children with diarrhoea had not received any treatment, in 2003, this percentage went up to 31.8%. Knowledge and use of ORS have gone down especially amongst young caregivers due to a reduction in the public health focus on diarrhoea treatment.

This loss of focus on oral rehydration treatment (ORT) has had a major impact in three main areas:

- 1- Caregivers reduced knowledge about the benefits of ORS and zinc as well as lack of self-efficacy;
- 2- Limited availability of zinc and ORS through the public and private sectors caused by a reduction in the demand;
- 3- Inadequate health professionals' recommendation and counselling on ORT.

To influence in these three main areas there are various possible interventions including:

- launching of an ORS and zinc communications campaign aimed at increasing demand
- developing a public-private partnership with ORS manufacturers to increase the availability of zinc in the market
- launching a socially marketed diarrhoea treatment kit to rapidly address lack of availability of products
- focusing on the training of health providers to increase demand at health centre level.

Introduction

PSI/Kenya commissioned this report to inform the programmatic strategies relevant to the reduction of under 5 years old morbidity and mortality in Kenya through the increased use of ORS and zinc as per WHO recommendations.

The data was collected in a period of two weeks through 15 face to face in-depth interviews with pharmaceutical manufacturers, distributors, UNICEF, WHO and other stakeholders as well as visits to the trade in and around Nairobi (see Annex 1).

This report will start by describing the current limitations in the use of ORS and zinc, and the challenges to increasing this. We will then analyse both the ORS and zinc markets dynamics as well as the existing marketing mix. We will also look at current regulatory limitations. This analysis will then discuss a range of potential interventions.

Background

In May 2004 WHO and UNICEF signed a joint policy agreement for the treatment of diarrhoea in children. The new disease management guidelines include the liberal use of the new low-osmolarity

ORS and home fluids to correct and prevent dehydration, zinc supplementation for 10-14 days to shorten the duration and severity of diarrhoea and continued feeding including breastfeeding.

The benefits of the new ORS include improved efficacy, decreased need for intravenous therapy and decreased stool output by 20%. Zinc supplementation decreases the duration and severity of a diarrhoea episode. Zinc also prevents repeat episodes of diarrhoea and opportunistic pneumonia in the 2-3 months following the initial bout. It also enhances growth and improves appetite.

Although the use of ORT (oral rehydration therapy) has been proven to be one of the most cost effective ways to treat diarrhoea, the analysis of the DHS 2003 shows that Kenya experienced a 32% decline in ORT use between the most recent DHS surveys (1998 and 2003). The DHS also suggests that knowledge about ORS has gone down, particularly amongst caregivers between 15 and 19 years old (61.1% in 1998 vs. 48.5% in 2003) as well as 20 to 24 years old (71.6% in 1998 vs. 65.1% in 2003).

The reduction in the knowledge and use of ORS is believed to be the result of the reduced focus on diarrhoea treatment brought by the change in public health strategies in 2001 from a vertical disease management "Control of Diarrhoea Disease" (CDD) to a more integrated one. The IMCI (Integrated Management of Childhood Illnesses) launched by WHO, is an integrated approach to child health that focuses on the well-being of the child. Although this approach ensures the combined treatment of the major childhood illnesses, emphasizing prevention of disease through immunization and improved nutrition taking into account the variety of factors that put children at serious risk, the focus on certain diseases appears to have lost some momentum.

While a few years ago ORT Corners were available in many health centres (funded by UNICEF), they have now been replaced by other services often created to deal with the HIV/AIDS pandemic such as PMTCT (Prevention of Mother to Child Transmission of HIV). The loss of focus on ORT has resulted in a reduction in the amount of communication and information provided to caregivers and health workers. This has had a major effect and in conjunction with some other factors has led to a reduction in demand for ORS. Further, whilst ORS were easily available through the public and commercial sectors a when ORT was extensively promoted in the 1980s and 1990s, a limited choice is only now available through pharmacies and health centres. This has restricted access to the treatment modality for many especially in the rural areas where it is needed the most.

In 2007, following WHO recommendations, zinc was fast tracked at policy level in Kenya to become part of the Essential Drug List (EDL). Although zinc was integrated in the diarrhoea treatment guidelines, only 24% of health providers have been trained so far because IMCI training is more resource intensive and it is particularly expensive to implement (up to \$30,000 per district).

With such background the GoK together with many of its health partners (such as UNICEF, WHO) have decided to make the increased use of ORS and zinc a priority for 2009.

The ORS and zinc markets

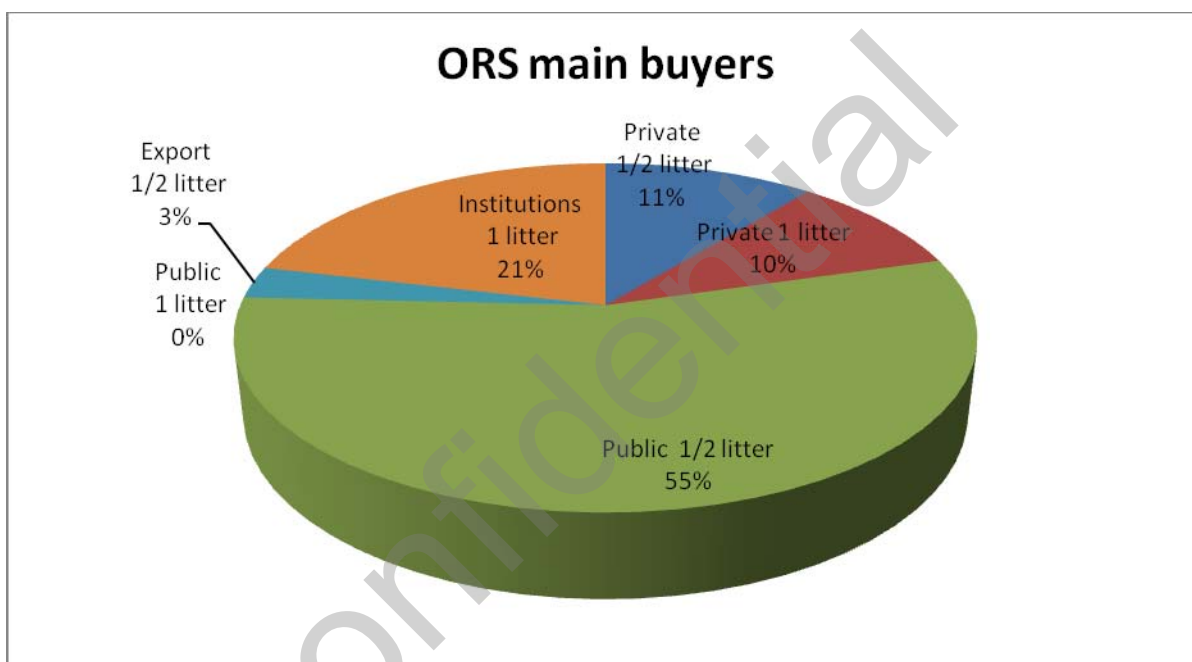
ORS market

Market analysis

There is a high level of rivalry in the ORS market in Kenya mainly due to the fact that the bulk of the demand is concentrated in the public sector (see Annex 2). The lack of product differentiation also

contributes towards the high level of rivalry because all ORS has to be made following WHO formulation to be able to compete for a GoK contract. This situation dictates dynamics such as high price sensitivity as well as the lack of industry’s willingness to invest further in the market unless public demand dictates so by changing its requirements.

The following chart shows an estimated breakdown of the ORS market by the different buyers. These figures have been calculated using data gathered through interviews. After interviewing the main ORS manufacturers in Kenya, we have an approximate understanding of the amount of sachets sold through the private sector. However, we were unable to find out how much of the ORS sold to distributors is sold to NGOs/Institutions or to wholesalers in other countries. We also found that the volume sold to the public sector was in the majority of the cases over estimated when compared to the information the Kenya Medical Supplies Agency (KEMSA) had shared with us for on the volume of ORS bought in 2008.



The limited involvement of private sector distribution channels and the power of the public sector as the main buyer has driven the ORS market to be very price sensitive and generic. In these circumstances, manufacturers are reluctant to invest any money in communication which has compounded the negative effect on the private sector demand. There are however some manufacturers not selling to the GoK because the payments are not guaranteed. Those organizations rely more heavily on the export market.

Current Demand

Public Sector

ORS is available through the public sector financed by the GoK (80%) and UNICEF (20%). The product is currently part of the “Kit” (see Annex 3) of drugs distributed to all the lower levels public facilities such as the health centres, dispensaries, and clinics under the “Push” system. Under this system, public health facilities get a kit containing a pre-determined number of drugs from the EDL (Essential Drug List) on a quarterly basis. This also means that as the content of the kit is fixed, some facilities may run out of product while others have ORS expiring on the shelves. In fact, KEMSA believes that there is 30% wastage of medicines under this system.

KEMSA is currently changing its procurement system to a “Pull” system in which each facility will be able to order the products that they require out of a fixed budget. The advantage of this system is that it will reduce wastage and stock-outs; however, facilities may not decide to prioritise ORS in their budgets reducing the availability of the product in public sector health centres even further. The system is currently being rolled out in the North Eastern and Coast Provinces and is expected to be fully implemented in the next couple of years although hospitals are already under this new system.

The Government of Kenya (GoK), through KEMSA, is the main buyer of ORS in the country. It launches a tender every year to buy all its health product needs.

The public sector calls for a tender once a year and tends to favour manufacturers that can provide more than one product. This is a challenging process as it has to be finished within 12 months (within the financial year that ends in June) and manufacturers only sign one off contracts. By June, the budget needs to have been spent meaning that in a very limited amount of time, the manufacturer will be notified of the order and it will have to order the raw materials, manufacture and deliver the full quantity of product required.

These one off contracts also mean that manufacturers, not knowing if they will be able to win the tender the following year, are not able to make considerable medium and long-term investments in the business.

There are a minimum number of sachets that will be distributed through the public sector as part of the kit within the “Push” system. The number of sachets is predetermined in each kit and varies depending on the type of facility (i.e.: a dispensary or a health centre). In 2008, KEMSA procured and distributed through the public sector 3.8 million ½ litre sachets of ORS. A breakdown of this number can be seen in the following table.

Table1: Approximate number of sachets available through the public sector:

½ litre ORS sachets in KIT	Number of facilities	½ Sachets /kit	Per quarter	In 2008
Dispensaries	1,537	400	614,800	2,459,200
Health Centres	503	500	251,500	1,006,000
Other (e.g.: facilities in “Pull” system, hospitals)	109	n/a		334,800
TOTAL distributed through the public sector				3,800,000

(Source KEMSA; The second Kenya National Health Sector Strategic Plan (NHSSP II) 2004-2010)

Private Sector

The availability of ORS through the private sector in Kenya is limited. Some of the interviewees mentioned that this has changed from a few years ago when ORS was much more widely available through the private sector, even being found at Duka (kiosk) level. The main reason for this is the lack of consumer demand.

Although the incidence of diarrhoea remains high, with 16% of children under 5 years old sampled, having experienced diarrhoea in the two weeks preceding the survey - DHS 2003), only 29% of children with diarrhoea were given a solution made from ORS packets (DHS 2003). The reduction in

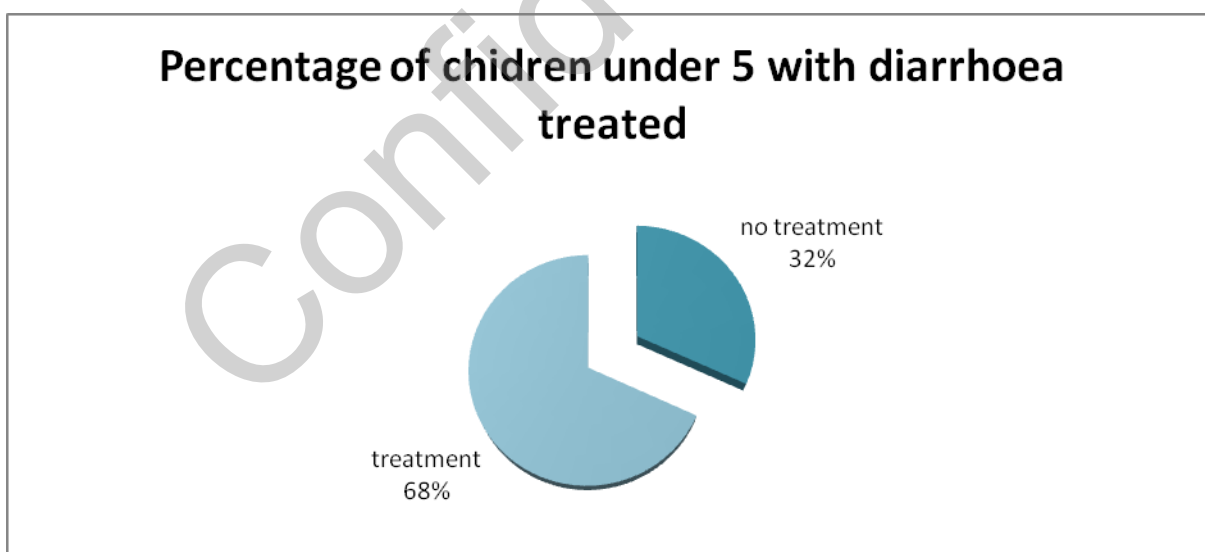
the demand of ORS is somewhat explained by the reduction in knowledge between the older generation of caregivers and the new generation

The reduced demand can also be explained by what is currently happening at health centre level. The results of a study on “Community case management of childhood diarrhoea in Asembo and Kibera” were published towards the end of 2008 shedding some light on the reasons why the use of ORT may be declining in Kenya. This report highlighted that although the knowledge about the importance of treating diarrhoea was present, the use of ORS was limited. This was believed to be due to the inconsistent treatment of diarrhoea by health workers reaffirming the belief that ORS is a medication making caregivers reliant on health workers guidance.

Anecdotally, some of the interviewees believed that with limited amount of time, health workers struggle to properly counsel caregivers. They appear to believe that antimicrobial agents kill the viruses that cause diarrhoea and in wanting to provide a “solution” (i.e.: stopping diarrhoea) to the child’s illness (some of which may have spent considerable time and money getting to the health centre), tend to prescribe antimicrobial and antimotility agents even in cases of non severe dehydration (contrary to WHO guidelines which recommend ORS). The practicalities around the use of oral medication instead of ORS for non-severe cases of dehydration, needs to be researched further.

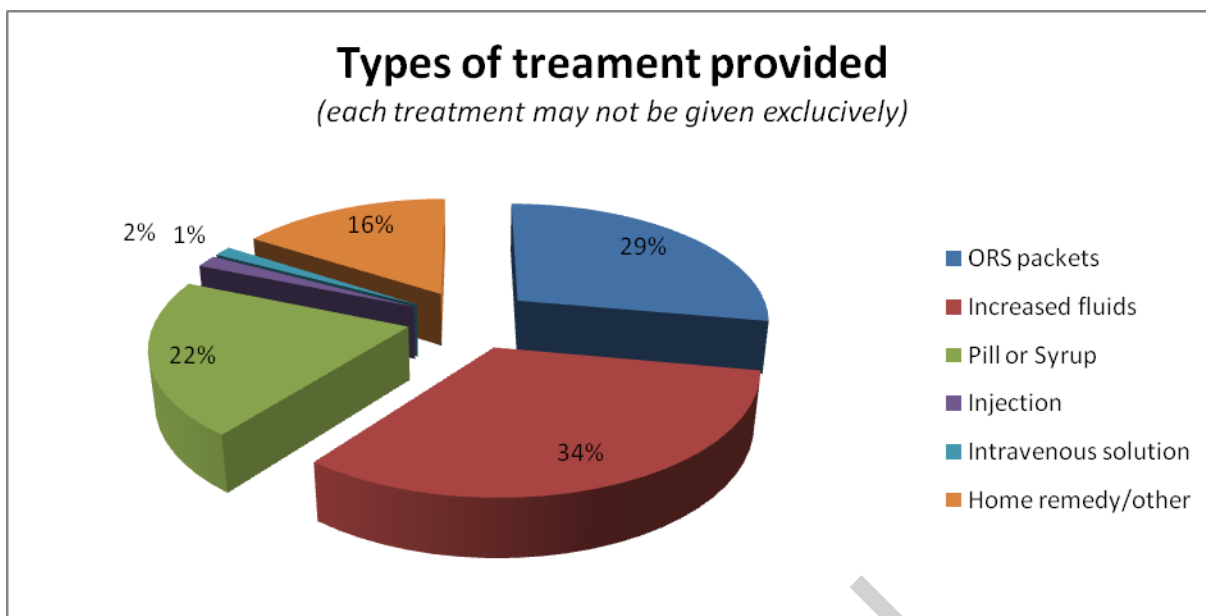
Existing demand vs. Potential

Given that Kenya has an under 5 years old population of 6,161,000¹ and that when the DHS survey was conducted, 16% of this cohort had experienced diarrhoea in the previous two weeks, one could estimate that the number of episodes of diarrhoea in Kenya in one year is roughly **26 million**².



¹ UNICEF Statistics 2006

² DHS 2003. We are assuming that 16% of all under 5 children get diarrhoea every two week period (26*16%= 4.2 episodes per year)



The above charts show data from the DHS estimating the number of episodes that are treated and untreated, and breaking down the types of treatment that are used in Kenya. As there is no detailed information in the DHS on difference in treatment depending on the severity of the episode, we will assume that the treatment given was appropriate (although research has shown that certain non-severe episodes are treated inappropriately with medication, injection or intravenous solutions). We know however, that 32% of episodes were untreated and of those that were treated, 29%, received ORS. Taking the currently untreated population and those that currently receive ORS as being the total potential opportunity for ORS, we can estimate that the number of episodes that could be treated with ORS could be roughly 15.6 million (Number of episodes per year untreated 8,150,264 + Number of episodes treated with ORS 7,483,890).

Assuming that each episode is treated with on average with 3 ½ litre sachets (although there is no information available on the actual amount of ORS given to a child per episode. Ideally, each child should receive 2 litres of ORS, however anecdotal evidence suggests that not all patients receive the full amount) the potential need for ORS in Kenya is 46,902,461 sachets. From information provided by KEMSA we know that 3.8m sachets were procured in 2008 for the public sector. We also know from manufacturers that they sold roughly 4.9 million half litre sachets (or their equivalents) and that institutions provided roughly 6.9 million ½ litre sachets. Therefore, we can estimate that 15.5m ½ litre sachets per annum are currently available in Kenya (this may be an overestimate as it is believed that some of the private sector supply is exported). This leaves a gap of approximately **31 million ½ litre sachets** (623.813 DALYS averted).

Current supply

Although there is a limited demand for ORS, there are more and more manufacturers of the product. This is because Kenyan manufacturer see the opportunity of becoming exporters of ORS to countries like Sudan and Somaliland. They also see potential in the institutions (such as NGOs) market.

We identified six main players in the Kenyan market:

- Laboratory and Allied Ltd.
- Elys Chemical Industries Ltd

- Universal Corporation Ltd.
- Sphinx Pharmaceutical Ltd.
- COSMOS
- Biodeal Laboratories Ltd.

The total capacity of these manufacturers is approximately **165 million sachets** per year. Many of them are not currently running at full capacity (only running the production line in 8 hour shifts) but they all mentioned the possibility of scaling up production in a relatively short amount of time (max. 3 months).

Marketing Mix analysis

Product

There is a variety of brands available in the Kenyan market, many of which are manufactured in country (see Annex 4). All the ORS products found in the market, were made following the most recent WHO recommended formulation with low-osmolarity. The most common flavour is orange although Laboratory and Allied's *O.R.S.* is unflavoured (to keep its cost as low as possible). In the high end of the market a lime/lemon or orange flavoured ORS, *PEDITRAL* made by Searle is also available.

ORS is available in sachets containing 14.00gr preparations to make ½ litre or 20.56gr preparations to make one litre. The most popular size is the ½-litre preparation as this is the size most commonly available through the public sector. NGOs however tend to prefer one litre preparations.

Price

Price to consumer

The price of ORS is similar across the market varying between Kesh 10 (\$0.125) and Kesh 15 (\$0.1875) for a pack of 14.00gr for ½ litre preparation.

In the high end side of the market there is also *PEDITRAL* (made by Searl in Pakistan) sold at Kesh 50 (\$0.625) for a 1 litre preparation.

Price to trade

The price to trade will vary depending on the volume sold however manufacturers quoted prices between kesh3 (\$0.0375) and kesh4.5 (\$0.05625) for ½ litre sachets.

1 litre preparations were priced between kesh5 (\$0.0625) and kesh7 (\$0.0875) (apart from *PEDITRAL* which is sold at kesh36.6 -\$ 0.4575 for 1 litre preparation).

These prices were higher than those from other non-Kenyan manufacturers such as Erica Pharma (\$0.0456 for 1m 1 litre sachets) and ShTrifecta (\$0.0273 for 1m 1 litre sachets).

Unfortunately, information on the costs of ½ litre sachets from non-Kenyan manufacturers did not arrive on time to be included in this report).

Distribution

Although it seems that a few years ago ORS were widely available even through Dukas (kiosks), nowadays the product is mainly available in pharmacies and health facilities.

The mark ups on ORS tend to be standard across the industry, distributors and wholesalers add between 20-25% whilst retail adds 33% to the wholesale price.

Communication

Public sector demand creation

The public sector demand creation has been limited. The MoH with the assistance of UNICEF, WHO and other partners runs the “Malezi Bora” campaigns (meaning Good Nurturing in Key Swahili) twice a year in May and November. In November 2008, the campaign was developed around the prevention of diarrhoea. This is the latest communication that took place on the issues of diarrhoea treatment. It was however, limited to the public sector health centres and the number of materials available was insufficient in the mind of some of our interviewees.

Private sector demand creation

Demand creation at private sector level is inadequate. We were unable to find any point of sale materials and often the product was not easily accessible at outlet level.

As per previous comments, manufacturers are not investing in communication and there is little product differentiation.

Potential product improvements

Starch based ORS

When interviewing the industry on their perception of rice-based ORS very few interviewees were aware of its existence. Some had heard about a similar product being tested in Bangladesh. Although many were interested in finding out more, manufacturers made it clear that WHO’s recommendation on any new ORS formulation would be a prerequisite to start manufacturing it. Also changing the formula would mean re-registering the product which will cost time and money

Based merely on WHO guidelines and the UNICEF/WHO Recommendations from 2004, there is not a recommendation on rice-based ORS. This is probably due to the lack of suppliers, concerns about stability of the product and the lack of consensus on the level of increased effectiveness that rice-based ORS offers for non-acute diarrhoea. As UNICEF / WHO are promoting low-osmolarity ORS and zinc, the need for rice-based ORS may not be as important. Zinc may offer benefits that take the place of the benefits i.e. reduced severity, that rice-based ORS offers

Biological flavouring:

None of the interviewees had heard about biological flavourings or about any issues surrounding the use of artificial ones. The main concern was to offer a flavour that was suitable for children.

There was the feeling that there is no need currently to deal with new types of ORS but that it is more important to make sure that the current product is widely used.

Current interventions

USAID is currently funding the APHIA II project through PATH, an international NGO, to work in the Eastern, Western and Nyanza provinces. The activities funded under this RFA are expected to improve and expand facility and community based HIV/AIDS and Tuberculosis (TB) prevention, treatment, care and support and to a lesser extent, reproductive health/family planning (RH/PF), malaria, and maternal and child health (MCH) services.

Also funded under this RFA are selected training and operations research activities that contribute to improved service delivery that will be gradually introduced and increased over the course of the project.

We understand from a meeting with PATH in Nairobi that the training curriculum on diarrhoea treatment for health workers has been revised and updated and a certain number of training sessions for health worker trainers have taken place in four districts of the Western Province.

It was also mentioned that some BCC materials have been developed and tested although they have not been printed yet.

Under this project, the plan was that the private sector would also be trained, although this seems to have been delayed.

Zinc market

Market Analysis

The Zinc Sulphate (in dispersable tablets of 20mg) market is currently quite limited in Kenya. The market dynamics show an underdeveloped market where a limited demand has attracted only a small number of players (Annex 5). The supplier power could be an issue as it seems that access to good quality raw materials at a reasonable price is limited.

Current Demand

Public sector

The WHO recommends the addition of Zinc Sulphate to the treatment of diarrhoea, and therefore the product was fast tracked to be made part of the EDL. Although the product is procured by KEMSA for the public health care facilities, it is unclear if it was included in the kit itself. Although some interviewees believed that this was the case, KEMSA explained that zinc is treated as a “supplement” and therefore is procured and ordered separately.

The first procurement of zinc of the product Zincfant (by Nutriset) was carried out directly by UNICEF although the distribution was managed by KEMSA. Since then, the GoK has procured its own zinc, mainly from COSMOS. Since 2008, the total amount of zinc distributed and procured by KEMSA has been 6,723,400 tablets.

Private sector

The benefits of zinc in the treatment of diarrhoea are not well known amongst consumers and even amongst health care providers. This really limits the demand for the product through the private sector which is currently driven by doctors’ prescriptions.

Existing demand vs. Potential

Following on the previous calculations that assume under 26 million episodes of diarrhoea per year and that 15.6 million is the number of potential episodes that could be treated with ORS and zinc (these are episodes already treated with ORS or not treated at all) 156 million tablets would be necessary (each episode being treated with 10 tablets of Zinc Sulphate). With current availability through the public sector being 6.7 million tablets, this rough calculation suggests that there may be a **gap of 150 million tablets in the market or of approximately 15 million treatments** (231.189 DALYS averted).

Current Supply

There is only a limited number of Zinc Sulphate, 20mg products registered in Kenya:

- ZDT 20 Tablets (Square Pharmaceuticals Ltd., Bangladesh)

- ZinCos (COSMOS Ltd., Kenya)
- DisZinc (Sai Mirra Innopharm PVT. Ltd., India)
- Zinc Sulphate Tablets (Alkem Laboratories Ltd., India)

We were not able to gather information about the amount of Zinc Sulphate sold through the private sector although we believe that the amount is very limited.

COSMOS mentioned a manufacturing capacity of 550 million tablets per year however the manufacturing capacity of the other companies remains unclear although we were told that “capacity would not be a problem” by those that were approached for a quote.

Marketing Mix analysis

Product

There are clear guidelines from WHO on the type of zinc needed to treat diarrhoea. This need to be Zinc Sulphate, in dispersable tablets of 20mg or oral solution. Many vitamin products are available commercially, however is it uncommon for these products to have the recommended dosage of zinc. The product also needs to be formulated in such a way as to mask the strong metallic aftertaste of zinc to enhance acceptability to children.

With only four brands (see Annex 6) registered the choice of product is limited. DT-Z 20mg is the brand that is more widely available in pharmacies and fulfils WHO guidelines. Due to its “P” classification, zinc is not available in supermarkets or other outlets. We found it however present at the “supplement” aisle in Nakumatt (main supermarket chain in Kenya) although they had other strengths:

- | | |
|--|--|
| - Gluconate 70mg (manuf.: Health Aids) | Kesh 960 (\$12)/90 tablets |
| - Zinc 15mg (manuf.: Pharmacy Exclusive) | Kesh 249 (\$3.11)/50 tablets |
| - Zinc 15mg (manuf.: Natrodale) | Kesh 630/175 (\$7.87) tablets or Kesh 345(\$4.32)/75 tablets |
| - Zinc-C (manuf.: Vega9) | Kesh 1140 (\$14.25) / 30 tablets |

It is also worth highlighting that although the PPB affirms that zinc is classified as a “P” product, COSMOS maintains that ZinCos, its zinc branded product has already been re-classified as a “GSL”. This was not confirmed by the PPB. ZinCos is not currently available through the private sector.

Currently none of these products are WHO pre-qualified although one manufacturer COSMOS has submitted applications for WHO prequalification in for their ARV products and are in the process of submitting applications for ACT anti-malarials (Artemether/Lumefantrine combinations), suggesting that they may have the capability and experience to seek prequalification for Zinc Sulphate.

Price

Price to consumer

At pharmacy level, Zinc Sulphate in dispersable tablets of 20mg are sold by the tablet for Kesh10 (\$0.125) (mainly the brand ZDT 20). Consumer demand for the product is very low and pharmacists mentioned selling it mainly only when prescribed by a doctor.

Price to trade

The price per tablet to the distributors varied between kesh2 (\$0.025) and kesh5 (\$0.0625) per tablet although these prices will vary depending on the volume ordered. ZDT (kesh2,08) and ZinCos (kesh3) prices were comparable with Nutriset's Zincfant (\$0.024 per tablet).

Distribution

Zinc's classification as a "P" medicine means that it is currently only legally available through pharmacies and health centres (although the product was also found in the supplement aisle of a major supermarket as previously mentioned).

Communication

Communication on the importance of giving zinc together with ORS in the treatment of diarrhoea was limited to the public sector through the work done by the MoH (with the support of UNICEF and WHO). No other communication has been done and many health providers (e.g.: pharmacists) were unaware of the benefits of prescribing zinc together with ORS. We were unable to see any point of sale material.

Knowledge and attitudes

Caregivers

Mothers are the primary decision makers with regard to home treatment and care seeking.

"The Community case management of childhood diarrhoea in Asembo and Kibera, Kenya 2007" together with 2005 DHS highlight the following insights:

- 71.1% of mothers know about ORS although knowledge was lower amongst the younger generation (15-29y 48.5% and 20-24y 65.1%) and there was a clear difference in knowledge between urban (78.8%) and rural mothers (69.1%)
- Accessing trained health workers appears to determine ORS use
- Caregivers generally do not feel confident treating diarrhoea in the home setting and many believe that ORS needs to be prescribed by a health provider
- Caregivers have extreme faith in the knowledge and expertise of trained healthcare workers
- Most people obtain ORS in health facilities where:
 - ORS is free of charge and recommended/prescribed by health providers
 - The general assumption is that ORS is only available in a health centre
- During a diarrhoea episode the priority is to stop diarrhoea quickly
 - Oral medications are known to achieve stopping the diarrhoea
 - Most caregivers do not believe that ORS/ORT stops diarrhoea
 - ORS is perceived to be medication
 - ORS is considered superior to homemade solution because:
 - It is made by experts and therefore safer and more effective
 - It is easy to prepare and administer
 - It tastes better
 - It costs less

Health workers professionals

- ORS is specifically recommended by only 30% of health workers and another 25% recommend other types of treatment such as antimicrobial agents

- Community health workers are an underutilized resource. Herbalists and traditional healers do not recommend ORS or ORT and 20% of caregivers in Asembo sought care from them

Current classification status

Oral Rehydration Salts

It is still unclear what the classification of ORS is in Kenya; however, there is a precedent of ORS being available through commercial outlets such as kiosks.

Zinc Sulphate

The WHO guidelines³ recommend that to make sure that zinc is more widely available the product be made an over the counter product. However, in Kenya zinc is still classified as a “P” product (Pharmacy only product) which means that it can only be available through pharmacies. The main reason for this is the fact that Kenya follows the British Pharmacopeia.

Way forward

The reclassification of zinc as a GSL (General Sales List) or OTC product should be made a priority to increase access to it. For this change to take place, the manufacturer itself will need to explain the reasons why the product needs to be reclassified. The support from WHO, UNICEF, the MOH and other stakeholders will speed the process, as would providing examples of other countries where the product is classified at GSL.

Registration

Registration of a modified product

If the modification is minor (e.g.: modification of one excipient) the PPB will need to be notified and the manufacturer will need to show a comparison between the old and the new products. The manufacturer will also need to run a pilot study for 3 months to show stability. The product will then be registered with the PPB in around 3-4 weeks for \$200.

If the modification is major however (e.g.: launch of a starch based ORS) a new application will need to be submitted to the PPB. The process of registration will take between 6months and one year and will cost \$1,000 if the product is manufactured abroad or \$500 if it is made locally. If the manufacturer has not been previously visited, the PPB will need to inspect the manufacturing site for GMP (Good Manufacturing Practices) accreditation. This costs an additional \$4,000. This process takes between 3-12 months.

Re-branding

To rebrand a product, PSI will need to present a non-objection letter from the manufacturer. A new application will need to be filed incurring the same costs as if a new medicine was being registered.

Over-branding

In this situation, the PPB needs to be informed and a letter of non-objection will need to be presented by the manufacturer. The content of the packaging of the drug can not be modified.

*Implementing the New Recommendations on the Clinical Management of Diarrhoea*³, World Health Organization 2006

Conclusions

1. There is limited demand for ORS and zinc due to lack of information from caregivers as well as from health providers.
2. On the supply side, there is a considerable selection of ORS products and increasing the volumes currently manufactured does not seem to be an issue.
3. The majority of the products available in the market comply with the WHO formulation guidelines.
4. The choice of zinc products available is more limited as there are only four registered products.
5. Existing pharmaceutical manufacturers could easily start making Zinc Sulphate in 20mg dispersible tablets. However, about 2 years would be required to develop the right formulation and to register the new product.
6. Cost wise, the price of ORS that was quoted to us by Kenyan manufacturers was slightly higher than those quoted by foreign manufacturers however we understand that there should be some room to negotiate them down based on volume.
7. Only two of the Kenyan manufacturers interviewed were in the process of getting WHO pre-qualification for ARVS/ACTS (COSMOS and UNIVERSAL). COSMOS, the only one currently making zinc had yet to consider the pre-qualification of ZinCos. On the other hand, already WHO pre-qualified zinc products such as Zincofent, are not registered in Kenya.
8. Some development partners highlighted their preference to build capacity in country favouring procurement from Kenyan manufacturers.

Recommendations

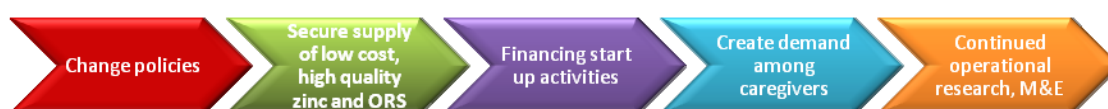
Intervention options

Having analysed the dynamics surrounding oral diarrhoea treatment in Kenya, and with the goal of reducing morbidity and mortality amongst children under 5 years old through increased consistent use of ORS and zinc there seem to be three key intervention areas:

- 4- Increase knowledge and self-efficacy amongst caregivers
- 5- Increase availability of zinc and ORS through the public and private sector
- 6- Increase health professionals' recommendation of ORS and zinc

The following table shows the different areas where interventions could be targeted (CIFF's areas for opportunity in acceleration concept), and identifies the issues within these areas and possible approaches to address them.

Table 2: Potential intervention areas



Issues		Reclassification of zinc and clarification of classification of ORS	Increase availability of ORS and zinc through public and private sectors	Lack of WHO pre-qualified zinc in the country.	<ul style="list-style-type: none"> • Need to increase knowledge and self-efficacy amongst caregivers. • Need to increase health professionals' (private and public) recommendation of ORS and zinc 	<ul style="list-style-type: none"> • Lack of in-depth understanding of caregivers' and health professionals barriers to use • Need for baseline data
Potential Interventions	<i>Increase knowledge and self-efficacy amongst caregivers</i>				Inform and educate caregivers on the benefits of ORT (incl. ORS and zinc)	Gain a better understanding of caregivers' barriers to use ORS and zinc: TRAC survey on ORS and zinc
					Launch of a generic BBC campaign on ORS and zinc	Qualitative research FOQUs like to gain a good understanding of caregivers challenges
	<i>Increase availability of zinc and ORS through the public and private sector</i>	Advocacy work by MoH partners (WHO, UNICEF) at PPB level	Engage and incentivise pharmaceutical manufacturers to make zinc sulphate dispersable tablets	Provide manufacturers with the support (financial and technical) to get zinc pre-qualified by WHO		MAP survey to gather baseline information on product availability
			Finance increased procurement of zinc through public sector			
			Incentive private sector retailers especially in the rural areas to stock and sell ORS and zinc			
			Provide ORS manufacturers with subsidised zinc to be bundled with ORS			
			Launch of a Socially Marketed DTK		Launch of a branded campaign on new a Social Marketed Diarrhoea Treatment Kit	

				(DTK)	
<i>Increase health professionals' recommendation of ORS and zinc</i>		Increase community mobilisation through CHWs by including Zinc in CHWs product portfolio		Engage and train traditional healers such as herbalists to sale and recommend ORS and zinc	Gain a better understanding of health professionals barriers to prescribing ORS and zinc
				Funding of rapid roll out of training on the benefits of zinc and ORS for all health provider (private and public)	

There are many possible intervention combinations. This is only a selection of potential interventions based on level of commitment necessary:

Option 1

To develop and launch a 1 year intensive, behaviour change communication (BCC) campaign during the rainy season using mass media as well as mid media (including TV, radio and print advertising together with drama groups and wall paintings) targeting the most at risk population and more specifically young caregivers (15-24 year old) whose knowledge about ORT is lower. To support the campaign, posters, leaflets and a video (to be shown during road shows or at the clinic) could be developed to communicate the importance of ORT, highlight the perceived positive benefits of ORS (e.g.: rehydrates my child), the less well know new benefits of zinc and ORS (e.g.: low-osmolarity ORS actually reduces stool output by 20%). Merchandising such as t-shirts, plastic spoons and pens would also be available. Research would be necessary to gain a better insight into caregivers' knowledge, attitudes and practices surrounding the treatment of diarrhoea and its challenges. The research would help in the selection of the barriers needing to be overcome and of the most appealing benefits of the DTK.

Costs:

Between \$1 million and \$1.2m (see Annex 7 for estimated detailed communication costs)

Research: \$200,000

Impact

- Increase percentage of mothers who know about ORS packets and the benefits of zinc.
- Increase demand of ORS and zinc through the public and private sectors. The increased demand would be measured by higher sales of ORS and zinc through the private sector and the levels of stock in the public sector.
- Reduction in the percentage of children not receiving any treatment (currently at 32%)

Pros

Such a campaign would revive the interest in ORS and create demand for zinc whilst teaching young mothers about the importance of starting ORT at home.

Seeing the increase in ORS/zinc demand, the private sector will also be incentivised to invest in the differentiation of their ORS products and more manufacturers would be interested in making zinc.

Cons

The availability of ORS and zinc are limited. It will take manufacturers up to two years to have a zinc product in the market. This means that there will only be four products available in the market to start with.

Zinc and ORS would be sold separately as they are at present, making the use of the full 10-day treatment course of zinc less likely and its cost potentially higher.

Considerations

In the short term, with a limited supply of ORS through the public sector dictated by the “push” system to a certain number of ORS sachets per quarter, the majority of the increase in demand would need to be fulfilled by the private sector.

The private and the public sectors would need to be engaged before the campaign is launched to make sure that they are aware and prepared for an increased demand.

The private sector may require some assistance with the rapid scale-up of the distribution of ORS and zinc to the rural areas.

Option 2

Together with Option 1, PSI could work with the private sector to facilitate the bundling of ORS with zinc by ORS manufacturers. They could be supplied with fully subsidised zinc sulphate tablets for a limited amount of time (e.g.: two years). This would give them enough time and financial resources to develop their own zinc product. The increased contribution generated by selling the DTK at a slightly higher price than the ORS sachets would be re-invested into the development of their own zinc and diarrhoea treatment kit. This would facilitate the quick availability of DTKs in the market and would encourage manufacturers to invest in the development of a zinc sulphate product. An appropriate insert would be developed to be included in all the DTKs giving caregivers directions on how to administer the product correctly.

Costs

- Option 1: approx \$1m
- In year 1: if 1m DTKs (treating 7% of the 15.6m potential episodes that could be treated with ORS and Zinc) were sold and in year 2: 2m were sold (13% of potential market), there would be a need to procure 30m tablets at a cost of \$0.025/tablet, \$750,000.
- Artwork and printing cost of Insert: \$100,000

Impact

Health impact would be 227.866 DALYS averted compared to 181.510 DALYS averted if only the same amount of ORS were sold without zinc.

The volume of ORS should also increase thanks to demand creation driven by the generic campaign.

Pros

This would be a market wide approach, which would allow for the use of zinc to be ramped-up quickly and would provide all manufacturers interested in the distribution of zinc with the same opportunity.

This option will also provide the donor with an exit strategy after two years.

Cons

This is effectively an indirect subsidy and there is a degree of uncertainty as to how effective it will be in increasing the use of ORS with zinc. There is no certainty of the outcome.

This would involve dealing with various manufacturers, which would be a complex and time consuming managerial task.

Considerations

Manufacturers will have to invest in an increase in packaging costs (i.e. manual packing of DTK as well as extra packaging to bundle both products.).

The transition after year two will be a challenge where working capital will need to be taken into consideration.

Option 3

In conjunction with Option 1, PSI could work with a local manufacturer to launch a social marketed DTK which would include the development of supporting materials and an attractive packaging to make it as user friendly as possible. A branded campaign would create brand awareness whilst a generic campaign would focus on the general demand creation of ORS and zinc.

This would give the project the flexibility to change suppliers if other manufacturers can provide less expensive or better quality products. PSI would be able to change suppliers raising again the market standards.

The training of private providers would be part of the sales force's task to create demand and encourage the prescription of ORS and zinc.

Research would be used to develop the packaging and supporting materials as well as to define consumers' willingness to pay. A TRaC would also provide the project with information on caregivers' attitudes, knowledge and practices to be used in the development of the supporting materials. A MAP survey would provide a baseline as well as monitoring data on the availability of the DTK, ORS and zinc in the market.

Costs

- Option 1: \$1m
- Branded advertising campaign \$1.5
- Development and production of DTK packaging and insert(\$0.60 per unit for 1.05m units of which 50,000 would be for promotions and free sampling) \$630,000
- Procurement of ORS and zinc approx \$1.6m (for 1.05m DTK units)
- Research\$200,000

Impact

Increase in the use of ORS together with zinc as well as ORS on its own by the target audience.

Increase of caregivers' knowledge and self-efficacy.

Medium term halo effect, by which other DTKs and zinc products will be launched to respond to the new competition.

According to a separate financial model (Annex 8) the project would be cost recoverable starting in year 6 as long as the price of the product was increased by at least inflation every year.

Pros

The launch of a new product, ORS bundled with zinc, will raise the market standards creating competition and incentivising local manufacturers to compete by developing similar products.

A Socially Marketed DTK would be available in the market faster than with option 2 even in the rural areas as PSI's existing distribution channels would be utilised. This option would also build local capacity whilst PSI could keep control over the finished product making sure that the product and consumer price are acceptable for the target audience.

The newly developed brand could eventually be licensed-out to create an exit strategy for the donor.

Cons

The funding commitment would be for around 5 years although product income would be re-invested in the project.

Considerations

With changes in the prices of materials it could be challenging to make the product fully cost recoverable (level 4) whilst still affordable to the target audience.

Currently one ½ litre sachet of ORS is sold at approximately kesh 10 whilst each tablet of zinc is sold for Kesh 7 to kesh 10. This means that the price of the DTK (which will include four sachets of ORS and 10 tablets of zinc) should not be higher than kesh140, although research will need to be carried out making sure that this price is acceptable. If the price was too high the target audience would not be able to afford it, however if the price was too low, questions around the quality of the product would be raised and the potential for the packs to be open at retail level and sold by the unit would be higher.

Option 4

To work with public sector training health professionals at all levels. Understanding that caregivers mainly trust the health workers' advice, demand for a DTK would be created driven by their advice.

Public and private health workers would need to be trained in the benefits and need to use ORS and zinc in the treatment of diarrhoea.

Costs

\$30,000 is the average cost of an IMCI training per district, the level of investment will dictate the number of districts that could be covered (there are 150 districts in Kenya).

The printing of materials would also be necessary not only for health professionals but also for students at college/university level.

Impact

Increase in the use of ORS and zinc through the health provider recommendation.

Pros

This is a more focused intervention. The necessary curriculum has already been developed by the MoH together with partners like PATH and some trainings have already taken place. The investment

required would be mainly for the financing of the rapid roll out of IMCI trainings and printing of materials.

This would be a time limited intervention.

Cons

This is a high cost intervention with results that will only be felt in the medium, long terms.

This will be a process requiring continuous and lengthily exchanges with the MoH and other partners.

Health providers' time is limited and they might not have time to properly council caregivers.

There is a high turnover of health professionals making it almost impossible to train everyone.

Training would have to be properly coordinated to make sure that staff is not spending too much time outside of the health facility.

Considerations

There will be some need to provide the public sector with commodities to make sure that it is able to fulfil the demand generated.

The training of the private sector as well as the traditional health professional will also be very important.

Research will be necessary to better understand what is currently stopping trained health workers from systematically prescribing ORS.

This intervention will need to be highly coordinated with the MoH as well as with some of its partners currently working in this area.

Annexes

- **Annex 1:** Contact details of interviewees
- **Annex 2:** Porter's 5 forces – ORS industry analysis
- **Annex 3:** Kit content
- **Annex 4:** List of ORS products in the Kenyan market
- **Annex 5:** Porter's 5 forces – Zinc industry analysis
- **Annex 6:** List of Zinc products in the Kenyan market
- **Annex 7:** Estimated communication costs
- **Annex 8:** DTK projections
- **Annex 9:** Packaging estimated costs

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