

**A Survey of Alcohol-Based Hand Sanitizers in Nairobi: Packaging, Labelling and Regulatory Compliance**NASSER N. NYAMWEYA<sup>1\*</sup> AND KENNEDY O. ABUGA<sup>2</sup><sup>1</sup>*Pharma Manufacturing Solutions Ltd, P.O. Box 21297- 00505, Nairobi, Kenya.*<sup>2</sup>*Department of Pharmaceutical Chemistry, School of Pharmacy, P.O. Box 19676- 00202, Nairobi, Kenya.*

**Alcohol based hand sanitizers are currently recommended for routine use in curbing the spread of the COVID-19 global pandemic. The present survey examined hand sanitizers marketed in Nairobi County with regards to product appearance, packaging, labelling and declared composition. Seventy-six samples were collected from five sites within the Nairobi metropolis - Central Business District, Kibera, Kilimani/Karen, Ngong and Thika. A wide range of non-conformities were observed for the criteria applied. Many samples had incomplete or missing label information, ingredient lists, cautionary warnings, Kenya Bureau of Standards (KEBS) standardization marks and permit numbers. Glycerin, fragrances and carbomers were the most common added ingredients. Poor formulation indicators such as haziness and phase separation were encountered in some products. The median price of the products was KES 250 (USD 2.36) per 100 ml although there was considerable variation in pricing of samples. None of the samples evaluated fully met all the standards for the parameters evaluated. Strict adherence to regulatory standards by producers of hand sanitizers is required to ensure that only compliant products are available on the market.**

**Keywords:** Hand sanitizer, alcohol, labelling, coronavirus, product quality

**INTRODUCTION**

Hand sanitizers (hand rubs) are liquid or gel formulations applied as germicides to improve hand hygiene for the control of infectious diseases. Although a variety of antimicrobial agents may be used in hand sanitizers, the SARS-CoV-2 pandemic which broke out in 2019 specifically led to the global widespread use of alcohol-based hand sanitizers (ABHS). The virucidal effects of alcohols result from the alcohol-induced denaturation of membrane proteins in enveloped viruses. Ethyl alcohol (ethanol), isopropyl alcohol and n-propanol have been shown to be effective against coronaviruses at alcohol levels of 60 - 95% (v/v) [1, 2]. Some products incorporate additional ingredients such as humectants, thickening agents, pH adjusting agents, denaturants and fragrances.

Locally, the Kenya Bureau of Standards (KEBS) is the competent authority mandated with regulation of ABHS according to the 'instant hand sanitizers specification' (KS EAS 789:2013) [3, 4]. The specific requirements include appearance, labelling, packaging and product quality tests.

Labelling requirements for consumer products address three objectives namely, declaration of identity, quantity and responsibility. Identity and quantity should be placed prominently and conspicuously without misleading or deceptive claims, while the name and full address of the responsible manufacturer/distributor should be appropriately imprinted [5]. The label consists of two components: the principal display panel (PDP) and product facts label (PFL). For ABHS, the PDP holds the alcohol concentration, formulation type, purpose of the product and pack

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contents, while the PFL contains the active ingredient(s), use(s), warnings, directions and inactive ingredients [6]. In addition, the manufacturing date (MD), expiry date (ED) and batch number (BN) should be indicated.

Previous studies have demonstrated the existence of poor-quality hand rubs in the market. Ochwodo et al. found that 50% of alcoholic hand rubs in the Kenyan market did not meet efficacy standards [7]. Additionally, during a spike in demand, some vendors may exploit rapid market growth by selling sub-standard or counterfeit ABHS products. Such products are likely to be ineffective for the specified purpose which undermines disease control measures instituted by government agencies. Thus, evaluation of ABHS products in circulation against KEBS requirements presents a rapid means of identifying counterfeit and sub-standard products.

There is a dearth of studies in the literature that have addressed quality aspects of ABHS. Therefore, the aim of this study was to evaluate the quality of locally available ABHS, with regards to compliance with regulatory requirements.

## **MATERIALS AND METHODS**

### **Study sites and sampling**

Sampling was conducted over a period of two weeks covering the second half of April 2020. During that period, the Nairobi metropolis was under movement curfew, occasioned by the COVID-19 pandemic. Five sites namely: the Nairobi Central Business District (CBD), Kibera, Karen and Kilimani (upmarket areas), and the metropolitan towns of Ngong and Thika were selected for the study. The Nairobi CBD targeted the on-transit population while the other sites covered upper, middle and lower classes in the socio-economic strata.

The target samples were the smallest available packs of ABHS brands encountered. These were chosen as the typical pack sizes for personal use products for the general population. The points of sale chosen for sampling were randomly selected supermarkets, pharmacies, shops, kiosks and hawkers. A total of 76 samples were obtained,

comprising of 66 unique products because some brands were collected in two locations. Sample information was entered into a Microsoft Excel spreadsheet (Microsoft Corporation, Redmond, WA, USA) for data analysis.

## **RESULTS AND DISCUSSION**

The samples were subjected to evaluation for appearance, packaging, label information completeness, cautionary warnings and KEBS standardization mark (S-mark) conformity with reference to the KEBS specification for hand sanitizers [4]. The compliance status with KEBS requirements is summarized in Figure 1. The results have been expressed as percentage of the total number of samples evaluated irrespective of multiplicity for some brands.

### **Appearance**

The KEBS specification states that “the sanitizer shall be clear, colorless and in the form of liquid or gel.” Gels, being more viscous, provide the advantage of reduced spillage and run-off when applied onto the hands compared to liquid formulations. While all the products in this study could be described as liquids or gels, many of them were not clear and some were colored. A quarter (25%) of the products appeared hazy, which suggests incomplete dissolution of one or more of the components or phase separation. A small proportion (5%) of the products had a definite color or tint. One sample showed distinct phase separation of the contents into two layers.

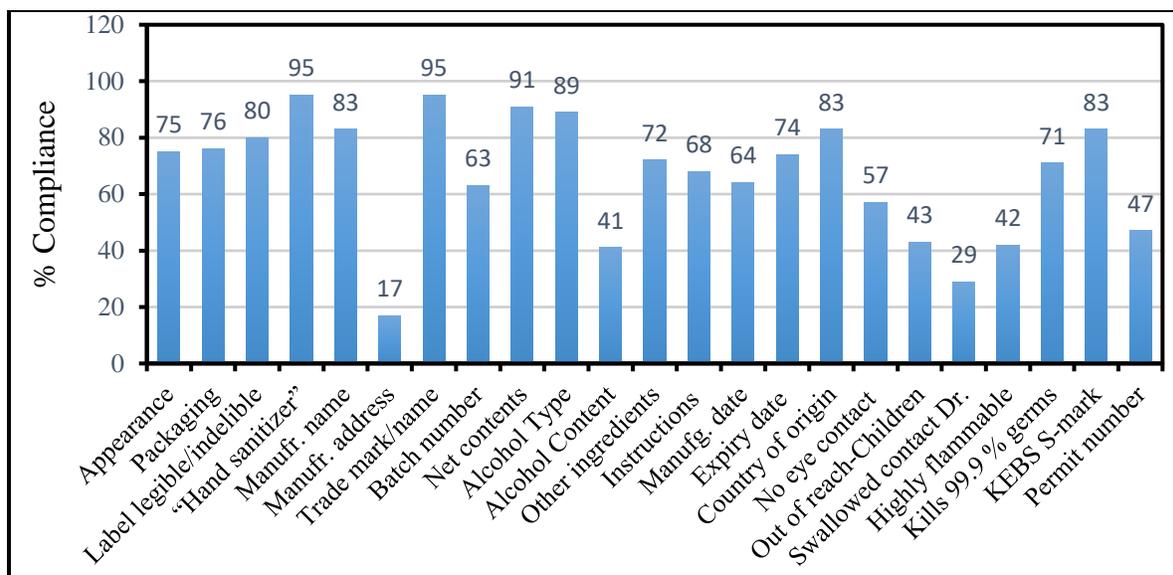
A range of viscosities were observed with some products flowing within 5 seconds of container inversion while others flowed very slowly or not at all in the same time-interval. Some products labelled as gels were free flowing liquids contrary to claims.

### **Packaging**

Most sample containers were made of clear polyethylene terephthalate (PET) as determined from the stamped recyclable-plastic code numbers. One sample had a container made of opaque high-density polyethylene (HDPE). The fill volumes ranged from 29 - 400 ml, although the majority of products were filled to 50, 60 or 100 ml. Four samples did not bear the net contents while three had non-matching label and

fill volumes. The majority of the closures encountered were flip top caps (76%) or disc top caps (18%).

Three (4%) of the products were sprays which had spray pump closures.



**Figure 1: Compliance status of samples evaluated.**

The figures represent the percentage of products having or complying with the indicated KEBS standard criterion. Manufr – manufacturer, Manufg – manufacturing, Dr - Doctor

## Labeling

Figure 1 shows compliance levels for the labelling aspects considered. The labelling issues observed included obscured labels, cutoff portions of print, poor inking, hand written data, faint illustrations, overlaid label prints or entirely missing labels. Ten samples had the manufacturing/expiration date and batch numbers stamped over the label print thus obscuring important information. The usage instructions were either written in English or infographics. About 4% of the samples listed foreign manufacturers from China, India or the United Kingdom. Twenty-two samples (29%) did not have any precautions at all while 15 (20%) were fully compliant. One sample carried the warning, 'for adult use only'

Proper labelling is integral to quality requirements since the label confers product identity and elicits consumer confidence in the product. Label contents enable customers to better understand the product and make informed choices. Information about actives, other ingredients, instructions, use and precautions

provides reassurance on perceived benefit. The alcohol content of ABHS for instance is key in quality perception of the product while use of emollients/moisturizers improves cosmetic appeal.

## Composition

Alcohol is the active ingredient in ABHS while water is required to promote protein denaturation [8]. The most common additional ingredients for the samples were glycerin, polymers and fragrances. One third (33%) of samples did not list the ingredients used in the ABHS. Some ingredient information was incomplete, abbreviated or used trade names. A full list of ingredients should be provided on the label for consumer information since certain individuals may have allergies to specific ingredients or could have personal reasons for not using them.

## Alcohol Type and Content

Although most products (89%) indicated that 'alcohol' was an ingredient, the majority of them (62%) did not state the specific alcohol used. Specifying the constituent alcohol is useful for

management of accidental or intentional product ingestion. Where the alcohol content was stated, the alcohol content ranged from 60% to 80%. Three samples had labeling inconsistencies for the alcohol type (2) and alcohol content (1) indicated on the PDP and PFL.

### **Other Ingredients**

Many ABHS contain thickening agents which are typically polymers. Depending on the type and concentration of polymer used, the viscosity of the liquid can vary considerably. The most widely used polymer used was carbomer, as listed in 25% of products.

Humectants are added to ABHS formulations to counteract the drying effects of alcohols. The most widely used humectant is glycerin which was listed in 51% of the products. Additional ingredients included, pH adjusting agents such as triethanolamine (17%), perfumes/fragrances (37%), aloe (13%) and coloring agents. As carbomers require neutralization to achieve maximum viscosity, a pH adjusting agent is necessary to facilitate gelation and adjust the thickness of the formulation. Although, some products listed denatured alcohol as an active ingredient, none of them specified the denaturants used.

### **Regulatory aspects**

Samples without KEBS permit numbers, may be categorized as counterfeits. The results showed that Kibera (54%) and Nairobi CBD (54%) had the highest counterfeit levels followed by Thika (36%), Ngong (33%) and the upmarket areas (25%). Twenty-four samples bearing the KEBS S-mark lacked accompanying permit numbers. This represents products falsely depicted as having the requisite market authorization to unsuspecting consumers. Conversely, three out of 13 of the samples without the S-mark had valid permit numbers.

Most samples had label claims with regard to the percentage microbial kill. The figures printed on the products were 99%, 99.9% or 99.99%. Use of any of these specific figures however, if not supported by actual experimental data is questionable and may give consumers a false sense of security. Prior studies have also demonstrated variable efficacy in ABHS

attributable to viscosity, in addition to the level of alcohol [7].

Two key players in the product (in this case ABHS) marketplace are the manufacturer/vendor and regulator. They perform an interplay of roles to ensure quality, safety and efficacy of the product which requires perpetual concordance with legal requirements. Both parties bear the risk and uncertainty attendant to product entry and persistence in the market. The regulatory authority holds the responsibility of controlling the ABHS market, since the end users have no means of testing the quality of the products.

### **Pricing**

The normalized prices of the samples ranged from Kenya Shillings (KES) 75 to 517 per 100 ml with a median price of KES 250 (USD 2.36). When categorized by location the median prices per 100 ml were KES 231, 237, 256, 300 and 300 for CBD, Kibera, Karen/Kilimani, Ngong and Thika, respectively. Samples without a KEBS S-mark had a median price of KES 208 while samples with the S-mark had a median price of KES 256 per 100 ml. These prices indicate that within the Nairobi metropolis, there is regional and possibly quality-based pricing differentiation. The sample prices were comparable to those found in prior studies [9 - 11].

### **User implications**

The results of this study demonstrate that some unsuspecting customers may be purchasing illegal hand sanitizer products of unknown origins, which may be counterfeit and/or substandard. Furthermore, these products did not meet the appearance, labelling and ingredient declaration requirements. Fake and ineffective products pose serious danger to individual users and undermine government efforts towards containing the COVID-19 pandemic.

### **Recommendations**

Label audits are necessary for consistent compliance and traceability of products. Manufacturers need to employ appropriate checklists to review conformity of their products with regulatory requirements. Ingredients should be identified by common or chemical names instead of abbreviations or trade names for ease

of identification. In the current era of consumerism, the regulatory authority needs to institute a vigilance scheme with a functional verification and reporting mechanisms in order to detect questionable products in the market. The need for improved regulation and customer awareness on ABHS products has also been noted by other authors [12].

## CONCLUSIONS

The study found substandard and counterfeit ABHS products in the Nairobi metropolis during the COVID-19 outbreak when demand greatly escalated. Since the city is a microcosm of the market trends in Kenya, the results are likely to reflect quality issues with these products

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countrywide. Consumer education and functional reporting mechanisms are necessary to curb circulation of illegal products in the Kenyan market. Developments in the information and communications technology framework could support such initiatives for an effective regulatory regime. Notably, none of the samples completely fulfilled all the regulatory and labelling requirements evaluated.

## DECLARATION

The authors wish to state that further analytical work is underway to determine the alcoholic composition and impurity profile of the samples covered in this study.

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