



Under-regulated Weight-Loss Supplements Threaten Consumer Safety in Low and Low-Middle Income Countries: A Call to Action

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Received date: 25 July, 2024, Manuscript No. IJGH-24-143220;

Editor assigned date: 27 July, 2024, PreQC No. IJGH-24-143220 (PQ);

Reviewed date: 12 August, 2024, QC No IJGH-24-143220;

Revised date: 19 August, 2024, Manuscript No IJGH-24-143220 (R);

Published date: 26 August, 2024, DOI: 10.4172/ijgh.1000194

countries (Ukraine, Tanzania, Zimbabwe and Uganda) reported that regulators do not monitor weight-loss supplements in their respective countries.

Keywords: Dietary supplements; Weight loss; Advertising; Regulation; Global health policy; Public health; Low and Low-Middle Income Countries (LMIC)

Introduction

A lack of government surveillance and regulations creates conditions where commercial actors profit from the sale of a range of harmful consumer products in Low- and Middle-Income Countries (LMICs) [1]. An example of this practice is the sale of milk products that contain dangerous chemicals such as melamine, formaline and detergents [2]. Given the history of industry predation in LMICs and the negligent manufacturing practices of over-the-counter Weight-Loss Dietary Supplements (WLS) industries, we are concerned that weak regulations around WLS may lead to inequitable health risks to consumers [3,4].

Many manufacturers adulterate WLS with dangerous ingredients, including phenolphthalein, sibutramine, sildenafil and orlistat, which can have serious health effects when consumed in high, unsupervised doses or by people with health problems [4]. Further, studies have illustrated that WLS can lead to severe medical events such as death and disability for children and youth [5]. WLS are distinct from prescription drugs or medications approved by regulatory agencies and their harms are well-documented in the epidemiological literature [3,4,6]. However, there is no consensus on the definition of WLS and a lack of regulatory frameworks to ensure consumer safety globally, particularly in LMICs [7,8].

Our research team recently conducted a global pilot policy scan of national regulation in 30 countries, documenting that only seven of the 30 reported legal frameworks and pre-market regulations relating to WLS [8]. Furthermore, only six countries reported limitations on advertising to children, with one country having a minimum legal age to purchase WLS [8]. Using data from our global policy scan, the present study focuses on national regulation in LMICs to assess the presence of WLS: (1) definitions, (2) regulatory limitations for advertising and (3) regulatory actions for monitoring. In doing so, we aim to inform efforts to strengthen governmental oversight for WLS in LMICs.

Materials and Methods

The present study focused on 21 LMICs, as classified by the World Bank at the time of data collection from among the 30 countries surveyed in our original [8]. The 21 LMICs were from all World Health Organization (WHO) regions: Africa (n=5), East Mediterranean (n=4), the Americas (n=2), South-East Asia (n=5), Europe (n=2) and Western Pacific (n=3) [9-10]. Upon consultation with the institution redacted Institutional Review Board, this study was deemed to not be human subjects research (Table 1).

Abstract

Objective: A recent global scan study on Weight-Loss Supplements (WLS) highlights the urgent need for strengthened government regulations due to its global health risks. This study aimed to provide insights that would strengthen governmental oversight of these supplements in LMICs.

Methods: We conducted a survey of WLS policy experts from 21 LMICs, representing various World Bank income classifications and World Health Organization regions. The survey, administered online, explored aspects such as legal frameworks, monitoring and enforcement. Descriptive statistics were utilized to determine the presence or absence of regulatory measures.

Results: The 21 LMICs surveyed in this study, there were only four countries, namely, China, Morocco, Pakistan and India, where experts reported the presence of a definition for weight-loss supplements used by their governing body. Experts from 13 countries reported the presence of non-registered or non-licensed products in their countries' markets. Experts from four

Questions	Names of Countries
Definition for weight-loss supplements	
Yes	China, Morocco, Pakistan, India
No	Botswana, Nigeria, Sri Lanka, Indonesia, Malaysia
Don't Know	Bangladesh, Lebanon, Tanzania
Missing Data	Iran, Philippines, Ukraine, Zimbabwe, Uganda, Ecuador, Thailand, Turkey
Minimum legal age for purchase of WLS	
Yes	Nigeria
No	Uganda, Bangladesh, Indonesia, Iran, Lebanon, Pakistan, Philippines, Sri Lanka, Ukraine, Tanzania, Botswana, Brazil, China, Ecuador, Malaysia, Thailand, Turkey
Don't Know	Zimbabwe, Morocco, Bangladesh
Missing Data	India
Limitations on advertisements that apply to media outlets	
Compliance of registered or licensed products with regulations	Nigeria, Pakistan, Philippines, Bangladesh, India, Morocco, Indonesia, Brazil, China, Malaysia, Thailand
Presence of non-registered or non-licensed products on the market	Lebanon, Nigeria, Pakistan, Philippines, Bangladesh, India, Morocco, Indonesia, China, Ecuador, Malaysia, Thailand, Turkey
Compliance of online sales and purchases with regulations	Bangladesh, India, Morocco, Indonesia, China, Malaysia
Regulator(s) does not monitor weight-loss supplements	Ukraine, Tanzania, Zimbabwe, Uganda
Regulator monitors product post-market surveillance	Indonesia
Not active limitations	Botswana
Don't know	Sri Lanka
Missing Data	Iran
Monitor advertising by government	
TV and Cinema	Philippines, Morocco, Bangladesh, Nigeria, Pakistan, China, Malaysia, Thailand
Billboards and Banners	Philippines, Morocco, Bangladesh, Nigeria, Pakistan, China, Malaysia, Thailand
Printed Media	Philippines, Bangladesh, Nigeria, Pakistan, China, Malaysia, Thailand
Radio	Philippines, Morocco, Bangladesh, Nigeria, Pakistan, China, Malaysia, Thailand
Internet	Bangladesh, Nigeria, Pakistan, China, Malaysia, Thailand
No limitations	India, Botswana, Brazil
Don't Know	Sri Lanka, Tanzania, Ecuador
Missing Data	Iran, Lebanon, Ukraine, Zimbabwe, Uganda, Turkey
Other	Indonesia: Regulator will monitor advertising post-market surveillance only, China: All advertisements need to be approved by authorities.
Limitations on advertising to children	
Yes	Morocco, China
No	Nigeria, Pakistan, Philippines, Indonesia
Don't Know	Bangladesh, Sri Lanka, Tanzania, Ecuador

Missing Data	Uganda, Botswana, Brazil, Turkey
Other	India: Advertisements need to declare dangers to children, Malaysia: All product advertisements must follow the requirements as in the Medicines (Advertisement & Sale) Act 1956 and the Medicine Advertisements Board Regulation 1976. Claim and dosage of a product will follow the approved registered claim and dosage of the product. There are no supplements that are approved for weight loss in children; Thailand: "Children should not take this product" is a mandatory warning on food supplements such as WLS.

Table 1: Description of regulatory frameworks of low- and low-middle-income countries on Weight-Loss Supplements (WLS): Definitions, limitations on advertisements and monitoring for supplements intended specifically for weight loss (N=21 countries).

Sampling and data collection

Non-random purposive sampling was employed to select five countries from each WHO region with varying world bank country-level income statuses (Table 1) [9,10]. Drug and dietary supplements regulation experts from each country were identified from various scientific writings, websites of regulatory bodies and the professional network of the authors.

We invited identified experts to participate in the study through emails that included the study purpose and the survey link. Incomplete responses with less than 75% progress and more than a month of inactivity were closed to allow other experts to be contacted. When multiple individuals from a country responded to the survey, we selected the response from a regulatory agency employee in the relevant department. Data collection was completed when we obtained complete survey responses from one expert in each of the 30 countries. For a full description of our sample and data collection method, please refer to Okoya, et al. [8].

Survey design

The survey was administered *via* Qualtrics in English, with a French translation available upon request. Questions were presented in multiple-choice format, along with open-text responses for additional information. All questions included a "Don't Know" response option. We defined WLS as "any dietary supplement promoted for weight loss." Claims were defined as statements made about a product's content or effects (i.e., health, nutritional, or functional). An adverse event was defined as any undesirable experience associated with using a product by a patient or consumer.

Measures

Survey questions related to WLS regulation within six domains, including legal frameworks, pre-market requirements, claims, labeling and advertisements, product availability, adverse events and monitoring and enforcement. For the present study focused on LMICs, we explored expert responses to the following survey questions:

- Does the legislation in your country have a definition for supplements intended specifically for weight loss? ("Yes and if the answer is yes, please provide the definition that applies in your country for weight-loss supplements;" "No;" "Don't Know;" "Other (please explain)")
- Do limitations on advertisements apply to any of the following media outlets? Select all that apply. ("TV and cinema;" "Internet (social networks, blogs, etc);" "Billboards and banners;" "Printed media (newspapers, pamphlets, magazines, etc.);" "Radio;" "Other (please explain)").

- Which of the following does the regulator(s) in your country monitor regarding weight-loss supplements? Select all that apply. ("Presence of non-registered or non-licensed products on the market;" "Compliance of registered or licensed products with regulations;" "Compliance of online sales and purchases with regulations;" "Regulator(s) does not monitor weight-loss supplements;" "Other (please explain)")
- Is there a minimum legal age to buy supplements for weight loss in your country? ("Yes;" "No;" "Don't Know")
- Are there any limitations on advertising for weight-loss supplements to children in your country? For example, is advertising these products allowed in youth magazines or in TV programs for children, etc.? ("Yes;" "No;" "Don't Know;" "Other (please explain)")

Analysis

We derived descriptive statistics by tallying response options. Qualitative responses were analyzed by two independent coders and then re-categorized as a "Yes," "No," or "Don't Know" response.

Results

Table 1 lists each of the 21 LMICs by WHO region, World Bank income category in 2021 and the profession of the expert who responded to the survey. Of the 21 included countries, in only four countries (China, Morocco, Pakistan and India) did experts report that there was a definition for WLS used by their governing body. Experts from Botswana, Malaysia, Nigeria, Sri Lanka and Indonesia reported that there were no formal definitions in place for WLS in their respective countries, while experts from three countries reported "Don't Know," and experts from eight countries did not answer the question. Only the expert from Nigeria reported a minimum legal age (18 years old) for WLS purchase (Table 2). However, experts from Morocco, China, Thailand and India reported that their countries had restrictions on the content of their advertisements, such as the requirement to mention the dangers of WLS to children.

Experts from thirteen countries (Lebanon, Nigeria, Pakistan, Philippines, Bangladesh, India, Morocco, Indonesia, China, Ecuador, Malaysia, Thailand and Turkey) reported the presence of non-registered or non-licensed products in their countries' markets. Experts from Ukraine, Tanzania, Zimbabwe, Uganda reported that regulators do not monitor WLS. In the Philippines, Morocco, Bangladesh, Nigeria, Pakistan, China, Malaysia and Thailand experts reported that government-imposed limitations on advertisements on TV and cinema, billboards and banners and radio. In addition, experts from Bangladesh, Nigeria, Pakistan, China, Malaysia and Thailand reported that limitations exist on internet sales of WLS products (Table 2).

WHO Region1		
Country Name	World Bank Income Category-2	Expert Credentials
Africa		
Botswana	Upper-Middle Income	Regulator, administrator, pharmacist, healthcare professional, public health professional, researcher
Nigeria	Lower-Middle Income	Regulator, administrator
Tanzania	Lower-Middle Income	Pharmacist, researcher
Zimbabwe	Lower-Middle Income	Researcher
Uganda	Low Income	Regulator, administrator
Americas		
Brazil	Upper-Middle Income	Researcher
Ecuador	Upper-Middle Income	Healthcare Professional
South-East Asia		
Sri Lanka	Lower-Middle Income	Student at the Ministry of Health
Bangladesh	Lower-Middle Income	Researcher
India	Lower-Middle Income	Food Safety regulator, nutritionist
Indonesia	Lower-Middle Income	Pharmacist
Thailand	Upper-Middle Income	Pharmacist
Europe		
Ukraine	Lower-Middle Income	Public health professional
Turkey	Upper-Middle Income	Government professional, physician
Western Pacific		
China	Upper-Middle Income	Regulator
Malaysia	Upper-Middle Income	Regulator, administrator
Philippines	Lower-Middle Income	Pharmacist
Eastern Mediterranean		
Morocco	Lower-Middle Income	Public health professional
Pakistan	Lower-Middle Income	Regulator, administrator, pharmacist
Lebanon	Lower-Middle Income	Healthcare professional
Iran	Lower-Middle Income	Government researcher

Table 2: Surveyed low- and low-middle-income countries by World Health Organization (WHO) region, World Bank income category in 2021 and the credentials of the expert that provided responses to the survey (N=21 countries).

Discussion

A history of multinational dietary supplements industry, as well as smaller scale within-country companies, selling harmful consumer products in LMICs is an urgent cause for concern, only compounded by the widespread problem of global and dangerous adulteration of WLS in nearly the absence of proper regulation. Our study findings highlight important gaps in WLS in child-related regulation by national governments across LMICs. Our study has some limitations. Given

that only 21 LMICs were included, the generalizability of our findings is limited. As our survey was available in only English and French, we limited participants to only those who were proficient in one of the two languages. Since regulatory terms and definitions vary across LMICs and across languages, it is possible that participants differed in their interpretation of the meaning of some of the terminology used. Our study findings provide further support for calls in the field for stronger national regulation on WLS to protect children and consumers of all ages in LMICs [7,11]. Promising policy recommendations include the

establishment of pre-market requirements for rigorous scientific evidence of safety and prohibitions on unsubstantiated weight-loss claims [12]. In addition, the Global Nutrition Policy Review, conducted every seven years by the WHO, should enhance its protocol for comprehensive assessments of national policies to include regulation of dietary supplements and specifically WLS [8]. Leadership from international health agencies, such as the WHO, on this growing global health threat for LMICs will be essential to ensure the adoption of robust policy assessments and effective regulation of WLS sold to consumers in LMICs.

Conclusion

This work highlights important gaps in WLS regulation by national governments across LMICs. Stronger national regulations around WLS are imperative to safeguard consumers of all ages in these countries. Leadership from international health agencies is essential to implement thorough policy evaluations and efficient regulation for weight-loss supplements sold to consumers in LMICs.

The under-regulation of weight-loss supplements poses a significant threat to consumer safety, particularly in low and low-middle income countries where regulatory frameworks are often weaker or less enforced. The rising popularity of these products, driven by aggressive marketing and the pursuit of quick fixes, places vulnerable populations at risk of severe health consequences. It is imperative for international health organizations, governments and regulatory bodies to collaborate in strengthening oversight and implementing stricter regulations to safeguard consumers. Education and awareness campaigns are also essential to inform individuals about the potential dangers of unregulated supplements. By taking decisive action now, we can protect public health and ensure that individuals in these regions are not exposed to undue harm in their quest for effective and safe weight management solutions.

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