Stochastic Modelling and Computational Sciences

MARKETPLACE SAFETY: ADULTERATED AND COUNTERFEIT MALE ENHANCEMENT DIETARY SUPPLEMENTS

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ABSTRACT

The global male enhancement dietary supplements market has unfortunately witnessed an increase in the proliferation of fakes, substandard products that contain PDE-5Is, including sildenafil, tadalafil, and vardenafil. These unregulated supplements that are commonly sold in the U.S. as natural remedies to erectile dysfunction represent a real danger to consumer health, given the fact that their formulations contain pharmaceutical-grade compounds. Lack of regulation and supervision, admixing it with banned substances, and the convenience that comes with ordering these products online and sponsoring adverts have led to fake ED products in the world. This article considers what has caused the proliferation of tainted male enhancement supplements with an emphasis on this literature's analysis of discovering and confirming the presence of PDE-5 inhibitors within these products. HPTLC, HPLC, GC-MS, and LC-MS/MS are the analytical tools described that have been used to identify synthetic PDE-5Is in dietary supplements. The article also recognizes some of the issues these regulatory bodies face in an attempt to reign in the distribution of such products and the constant fight against counterfeits. The research shows that better regulation, early signaling techniques, and increased awareness should be pursued to protect consumers of male enhancement supplements. The increasing adoption of advanced tools for analysis and collaboration with other countries is also vital in protecting people's health and ensuring that bad products do not reach the market. Solving these problems is impossible without joint global efforts to improve the quality control of dietary supplement products and protect the population from hazardous substances.

Keywords*; Adulterated supplements, Counterfeit male enhancement products, PDE-5 inhibitors, Erectile dysfunction supplements, Pharmaceutical adulterants, Chromatography for detection, Mass spectrometry in supplement analysis, Sildenafil adulterants, Online pharmacies and counterfeit drugs, Nutraceutical regulation***.**

INTRODUCTION

The global market for male enhancement dietary supplements has already developed relatively fast within the past couple of years due to the growing demand for products that can improve male sexual functions. Although proper supplements can have a specific profit, the boosting trend has significantly increased piracy goods. These inferior supplements, flavored as safe and natural, are potentially hazardous to consumers since their ingredients are uncontrolled, supplements contain hidden substances, and many supplements are spiked with dangerous contaminants. Fake and substandard male enhancement products can be packaged with pharmaceutical-grade substances, including phosphodiesterase type 5 inhibitors (PDE-5 inhibitors), used in Viagra and Cialis. When taken without the prescription of a medical practitioner, these drugs can lead to very serious side effects when they interact with other medications or other health conditions. It is rather to what extent these products are sold on the markets and used by consumers as they pose a threat to health, hence the rising incidences of adverse health events associated with the supplement industry.

These fake drugs are readily available due to such factors as access to online drug outlets, direct marketing techniques, and International business opportunities in the Internet markets. Coupled with this problem, most consumers are ignorant of the dangers of buying supplements from unauthorized or unauthorized sellers. In addition, the lack of proper enforcement of simple laws in some parts of the globe permits counterfeit products to circulate within the markets. These agencies find it difficult to safeguard people's health. This article is intended to raise awareness of marketplace risks for male enhancement dietary supplements that are adulterated or labeled as counterfeit, highlighting the factors that led to their proliferation. It will expand on the framework of nutraceuticals, products defined as an interface between food and pharmaceuticals regulated as such, and its

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different approaches in distinct global regions. Further, the article will discuss the most frequently reported admixtures in male enhancement products with a focus on PDE-5 inhibitors and approaches for their identification. This article will also provide a pass-through to jot down the global activities and attempts to curb counterfeits and protect consumers' lives in the markets.

2. NUTRACEUTICALS: THE TRANSITIONAL STATE BETWEEN FOOD, SUPPLEMENTS, AND DRUGS

Dr Stephen DeFelice coined the term nutraceuticals in 1989. A nutraceutical is a substance obtained from food that is beneficial for health apart from being nutritive (Dillard & German 2000). Nutraceuticals fall between food, food supplements, and pharmacological products; thus, their classification and regulation are quite a topic of debate. As a class of food products, nutraceuticals are fairly diverse, and the term can refer to functional foods, dietary supplements, and even single bioactive ingredients for consumption for their health benefits. In the most fundamental sense, food can be any material taken into the body for nourishment, for example, to supply energy and necessary nutrients and keep bodily functions going. This includes fruits, vegetables, grains, and proteins (Nyati, 2018).

These food products are, in most cases, rated as safe and healthy when properly taken in appropriate proportions and are covered under food laws. On the other hand, dietary supplements are foods that are taken in addition to other foods to ensure that the body gets adequate amounts of some compounds that it may not get in sufficient quantity from the regular diet. Supplements can be in different forms, such as tablets or capsules, powders, syrups, or liquids (Jenings et al. 2008). Some might include vitamins, minerals, herbs, amino acids, enzymes, or other substances believed to play a vital role in maintaining health or achieving some specific health goal. Still, in contrast with food supplements, it is not intended to serve as a complete source of necessary nutrients in the body but as an addition. The usage of dietary supplements is quite liberal in most nations, with most markets permitting their sale without the threat of strict control, specifically compared to drugs.

Drugs are substances formulated for use in diagnosing, preventing, treating, or alleviating diseases or medical conditions. Medications pass various clinical trials and requirements from the regulating government before they are released into the market. The Food and Drug Administration or European Medicines Agency in different countries is the official authorities that control drugs (Groenleer, 2014). After regulatory agencies have evaluated them, physicians dispense them to treat certain diseases, and their production and advertisement are closely regulated. Nutraceuticals fall between these categories. They are foods advertised as having certain health benefits, such as the ability to lower cholesterol levels, strengthen the immune system, or enhance cerebral activity. However, unlike drugs, nutraceuticals are not as tightly controlled and thus do not require as much rigorous testing and trials before going to market. This lack of harmonization leaves consumers without full assurance of the safety, efficacy, or quality of their products. One critical basis for the differentiation of nutraceuticals is the existence of bioactive compounds, naturally occurring substances in food with health impacts on the human body. Some of them include antioxidants, flavonoids, and omega-3 fatty acids. These compounds are being isolated and sold as concentrated supplements in liquid forms with various claims as chronic disease prevention or management remedies, including high cholesterol or inflammation.

Nutraceuticals are not restricted in the same way across different territories. In the United States, they are primarily classified as dietary supplements as provided under the Dietary Supplement Health and Education Act (DSHEA) of 1994, whereby the burden of safety is on the producer. Still, no approval is needed before putting a new product on the market, with no requirement for efficacy trials. Foods with medical and health claims in Europe are regulated by the European Food Safety Authority (EFSA) (Duttaroy, 2019). Still, many of the nutraceutical foods on the EU market do not undergo rigorous clinical testing. This study still found that nutraceuticals belong to a promising and expanding industry in the middle ground between food, supplements, and drugs. This is because consumers constantly search for healthy products to enhance their well-being instead of the usual over-the-counter drugs. However, this shift also poses a problem since there are fewer barriers to entry and weaker codes of communication: there is an increasing need for more comprehensive rules defining product safety and quality to assist people in making correct decisions for their health.

Figure 1: Nutraceuticals

3. NUTRACEUTICALS AND DIETARY SUPPLEMENTS INCREASED POPULARITY

Over the last decade, the marketplace for nutraceuticals and nutrient supplements has experienced growth and evolution due to the nutritional revolution (Nyati, 2018). People are changing their perception of the necessity of using male enhancement products, and the products have found applications based on ideas related to self-care, training, and prophylactics. Customers are expanding the usage of these commodities to treat diseases, boost performance, and sustain general fitness without relying on drugs. The improvement in the sales of horny goat weed supplements can therefore be attributed to the following factors:

- Population factor
- Increased awareness of natural products
- Increased access to the internet, among others

The increased consumption of nutraceuticals and dietary supplements is mainly attributed to the global aging population. With this enhanced life expectancy, it becomes important for most people to retain their strength and youth in later years. Too many men, male enhancement supplements that help them boost their sexual health and sexual performance are as welcomed as they approach middle-aged men and above (Hoberman, 2005). ED and other sexual problems are usual in elderly males, and the fact that some of the new products are promoted as nonprescription for the treatment of erectile dysfunction is encouraging. This kind of product states that these can enhance libido, endurance, and sexual health without the necessity to utilize drugs such as sildenafil, the one behind Viagra. To this end, there has also been increased demand for natural, noninvasive products like ginseng, maca root, and Yohimbe, which are often advertised for their effects on sexual health.

Three major threats include: first, the world's population is slowly aging; Second, people are becoming increasingly conscious of natural and reliable alternative measures towards health. Some consumers consider nutraceuticals safer, natural products that are an improvement over regular druggable medicines. This has promoted a healthy lifestyle culture that focuses on measures to prevent diseases and illnesses. In particular, nutraceuticals – food products containing compounds that positively affect the individual's health or demonstrate a preventive function regarding certain diseases, are considered one of the most effective preventive measures. While medicines are still commonly linked to effective therapies for particular disorders, consumers perceive nutraceuticals primarily as health maintenance products, which can give people a feeling of being in charge of their health. This contributes to why dietary supplements have become much more popular since they are readily

accessible online. E-commerce has helped to increase the rate at which consumers can easily order male enhancement products and other nutraceuticals from the comfort of their homes (Mahammadh, 2015). Today, with the help of home computers and the Internet, consumers can go from online retailers like Amazon to specially designed websites to choose a particular product and its brand, compare prices with other shops, and read other people's opinions on the product's quality. This convenience, coupled with the prospect of shopping online, makes it easy for men, especially, to buy medications used to treat erectile dysfunction in the privacy of their homes, away from the scrutiny of their partners. In addition, due to promoting these products through social media and endorsement by popular personalities, the market has been considered legitimate by potential consumers.

The growth in popularity has not arrived without its problems. The global nutraceutical market has been growing very fast, and this has been accompanied by the rise of other related products that are substandard and counterfeit due to poor regulation. This is even more dangerous when it comes to man-enhancement products, most of which have not undergone enough research to be proven to work (Roduit et al. 2014). This lack of rules on these products has flooded the market with substandard or even poisonous products. More information should be provided to consumers, and tougher legislation should be enacted on such products. Therefore, the consumer trend of purchasing nutraceuticals and dietary supplements, especially for male enhancement products, can be attributed to the following factors: demography, knowledge, and attitude towards natural enhancement products, and, most importantly, the comfort of buying from an online store. Thus, there is growth in the production of food supplements, but this has to be done carefully with extra precautions to protect the consumers and the quality of their products.

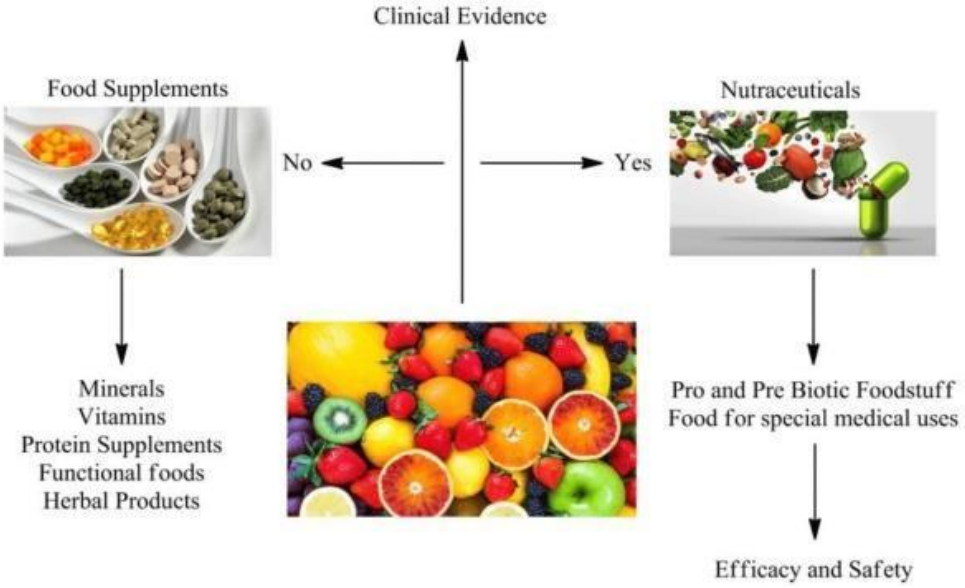

Figure 2: Dietary Supplements

4.0 REGISTRATION PROCESSES OF DRUGS AND DIETARY SUPPLEMENTS

Drug and dietary supplement registration are characterized by two separate procedures, which may depend on the effective regulations in one country or another (Gill, 2018). Such procedures must be in place because they act as preventive measures that safeguard consumers, retain quality, and defend against counterfeit and dangerous products. The health minister noted that drugs are well-tested, examined, and scrutinized before approval, while dietary supplements do not receive similar treatment. The following sections discuss the registration for medicines and nutritional supplements in the most developed countries, namely the USA and Europe.

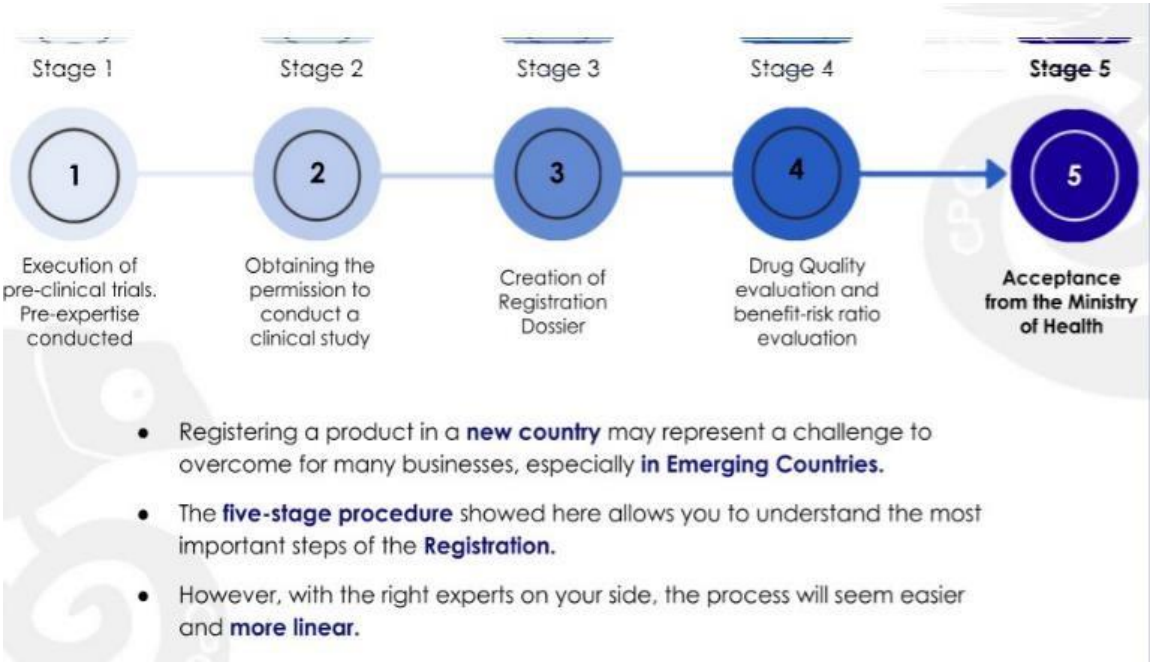

Figure 3: Registration Process

4.1 USA

The Food and Drug Administration (FDA) regulates the regulation and registration of drugs and dietary supplements in the United States. Nonetheless, the two categories' regulation possibilities are already significantly different.

Drugs

Drugs in the USA are approved under the Federal Food, Drug, and Cosmetic Act of 1938, which, as a legal requirement, requires companies to go through the pre-market approval process. This process starts with a clinical trial to evaluate the drug's safety and efficiency. The process involves three phases:

- Phase I seeks to determine the safety and dosage of the selected compound, either in its pure form or in a formulated product.
- Phase II determines whether the drug works in treating the condition or not.
- Phase III includes wide studies to establish the advantages of the drug to reveal negative consequences.

Once the side effect is successfully tested on humans, the drug company compiles all information from the clinical trials with the new drug, the proposed labeling and manufacturing processes, and then files for a New Drug Application (NDA) with the FDA. The FDA closely scrutinizes this application to ascertain that the drug bound to be developed is safe and efficient and that it is manufactured under standard practices before it is approved (Eaglstein, 2019). Once approved, the drug is cleared to be marketed by the company; the FDA has mechanisms, however, to continue to oversee post – the post-market safety of the drug through pharmacovigilance systems.

Dietary Supplements

Dietary supplements, on the other hand, do not require premarketing approval. They are governed by the Dietary Supplement Health and Education Act (DSHEA) of 1994. DSHEA demands that the manufacturer take full responsibility for the safety and labeling of the product (Dodge, 2016). Yet, there is no need to prove the safety and efficacy of the food supplement before it is marketed. Supplements are categorized under food products and thus must meet the GMPs; this means supplements must be free from contaminants and made under clean

processes. However, there is one major difference between drugs and dietary supplements, and that is that the former go through clinical trials. Despite the FDA's ability to ban supplements, risky supplements remain legal and are available on shelves until they are reported and withdrawn after people die. In the case of labeling, the FDA has set standards that the information on supplements should not be misleading, including instructions, a list of ingredients, and claims that have been proven.

4.2 Europe

In Europe, as in the United States, drugs and dietary supplements are regulated through different measures, mainly by the EMA for drugs and the EFSA for dietary supplements.

Drugs

The regulation of drugs in Europe is comparable to that of the United States, with steep approval measures from the European Union's pharmaceutical legislation. A clinical trial is also done similarly to the drugs approved in Europe, and the results are forwarded to the European Medicines Agency (EMA) (Vreman et al. 2020). An authorization procedure is applied centrally, so once the EMA has authorized the drug, it can be marketed in any EU member state of the individual's choosing. Before passing the drug through approval, the EMA undertakes a comprehensive examination of the drug regarding its quality, safety, and efficacy. Once a drug is authorized, it is most often followed up on in terms of safety, and the manufacturers are supposed to report any adverse effects through pharmacovigilance.

Dietary Supplements

In the EU, dietary supplements are classified under food products, though the Food Information to Consumers Regulation (EU FIC) encompasses heavier rules governing the use of supplements. As distinguished from drugs, dietary supplements do not need pre-marketing approval. However, manufacturers must inform the EFSA if they intend to introduce a new supplement to the EU market that includes any new ingredients. The EFSA can analyze the safety of these new ingredients, and if the former poses a health risk, the use of the ingredient can be prohibited or restricted. Also, dietary supplements have labeling requirements such as correct stating of ingredients, servings, and claims on the health boost that the supplements provide (Brody, 2016). These claims are restricted by EU health claim regulations, which require manufacturers to support any health-related claim they make with scientific evidence. While in the USA and Europe, drugs are regulated before they enter the market and also monitored continuously, dietary supplements, however, are not. Hence, it is advisable to give consumers some health checkups when buying supplements, particularly male enhancement products that can be fake or spiked.

5.0 FACTORS LEADING TO THE PROLIFERATION OF ADULTERATED AND COUNTERFEIT MALE ENHANCEMENT NUTRACEUTICALS AND DIETARY SUPPLEMENTS

Asant Uno & Wiemer stated many factors have led to the current situation where many male enhancement nutraceuticals and dietary supplements contain contaminants and counterfeits. Such factors are driven mostly by global demands, lack of regulation, and a tendency towards increasing reliance on online sales networks. Below are the primary factors contributing to the spread of these unsafe products (Kumar, 2019).

5.1 Internet Pharmacy and Online Pharmacies

The growth of internet-based businesses, especially the online pharmacy store, has fueled the distribution of fake male enhancement substances. The lack of rules and precautions makes it possible to find male enhancement supplements on the Internet without going to regular drugstores and even consulting with doctors (Chiang et al. 2017). This convenience has forced many consumers to order online, especially when it comes to products that offer a quick and instant solution to erectile dysfunction and poor sexual performance. This relative lack of a public face has made it possible for counterfeit manufacturers to take advantage of the relatively easy abilities of online shopping. As a result of ease of operation and poor regulation in most areas, internet-based markets are packed with fake goods. Even though there are regulations in the USA and Europe, enforcement like the FDA's Drug Approval process and filling EMA guidelines online are practically impossible. These fakes are often run by

counterfeiters who use the cover of fake websites or unregulated online pharmacies selling so-called cheap generics to widely acknowledged treatments like sildenafil (Viagra), tadalafil (Cialis), or other PDE-5 inhibitors.

Regional Differences in Online Sales

USA and Europe: In these areas, rogue online outlets without legal oversight are on the rise. Most fake supplements can be obtained without a prescription through anonymous outlets for persons seeking these products. However, the influx of the supply chain, the availability of many online platforms, and many international shipping channels make the governments of the two regions lack the capability and flexibility to apply anti-counterfeit measures.

Egypt and the Middle East: The operation of uncontrolled online pharmacies is even more prevalent for some countries in the Middle East & North African (MENA) region, where purchasing such medications may not be controlled as strictly as in most other developed countries. As is the case with Egypt, for example, the increased use of the internet in acquiring health products has led to increased circulation of fake supplements. There are also very few campaigns educating consumers about the risks posed by these products, hence contributing to the problem.

5.2 Tele-advertisements and Direct-to-Consumer Advertising (DTC)

Direct-to-consumer, or DTC advertising, is another equally influential reason why counterfeit male enhancement nutraceuticals are on the rise. Oy, ads for male enhancement products are lurking around virtually every corner of today's society, from social media to search engines, television, to radio (Rosenzweig, 2011). Such advertisements are generally misleading and flashy and provide a 180-degree turnaround in the target patient's condition without minimal or little-mentioned side effects. Nine out of ten of these products do not have proper scientific backup to support the claims, and most of them are sold in the market as risk-free and highly effective cures for ED. Counterfeiters and rogue manufacturers market fake products through television infomercials, social media influencers, and paid online advertisements. Most of these adverts are aimed at disadvantaged members of society and promise a magic solution to ED and sexual dysfunction with impunity to the public. These persuasive ad campaigns force consumers to believe in a product even without scientific recovery of the product's efficacy.

Dangers of DTC Advertising

USA and Europe: In countries with more developed regulations, DTC advertising is under a lot of pressure. However, today, many Web 2.0 sites (social networks, blogs, video-sharing sites, etc.) still have insufficient control. This has led to an increased number of adverts placed on products purporting to enhance male performance and that do not go through typical screening and approval by regulatory bodies.

Egypt and the Middle East: DTC advertising in some regions of the MENA more often consists of big promotions on social networks like Facebook or Instagram. These ads primarily affect audiences in countries with relatively less restriction on content on the Internet, hence a suitable environment for deceptive advertisement and the selling of counterfeit supplements.

5.3 Lack of Consumer Education and Awareness

This, however, has been made easier by the fact that the market is mostly flooded with half-awkward educated clientele due to a lack of adequate information as regards the content of the supposed male enhancement products. Many of these consumers do not know the dangers of using these products, especially if the producers neatly package the products with influential real-life success stories (Lindstrom, 2012). The problem of low consumer knowledge about the distinction between safe dietary supplements and potentially risky adulterated products results in incorrect choices. Consumers believe in labels and marketing collaterals since a product sold in approved online outlets or advertised on social media platforms is harmless. This false sense of security facilitates the process through which counterfeiters compromise the target audience. Due to the pump-and-pride nature of male sexual health problems, most consumers are embarrassed to look for professional advice and end up getting the products from shops.

5.4 Regulatory Gaps and Enforcement Challenges

Although there are raising fears about the safety of nutraceuticals and dietary supplements in the market today, many countries have weak laws that cannot help to stop counterfeits from flooding the market. This again poses a problem when differentiating between Dietary supplements and program Drugs since the latter are subject to rigorous tests while most nutraceuticals are not. Government and non-government agencies like the FDA and EFSA supervise the supplement market. Still, they are almost always overworked because of inadequate resources and the overwhelming number of products launched into the market. However, enforcement is challenged by the supply chain as fake products can be produced in any country and exported to other countries; hence, it is difficult for the agencies to monitor them. This has created a problematic atmosphere where any product can be produced and sold in the nutraceutical market without repercussions.

Table 1: Factors Contributing to the Proliferation of Counterfeit Male Enhancement Supplements

Factor	Description	Regional Differences
Internet Pharmacy & Online Pharmacies	Growth of online pharmacies enables easy distribution of counterfeit supplements without regulation or medical consultation.	**USA/Europe**: Increasing number of rogue outlets with minimal legal oversight. **MENA (e.g., Egypt)**: Unregulated online pharmacies widespread, leading to high circulation of fake products.
Tele-advertisements & DTC Advertising	Direct-to-consumer advertising, especially on social media and TV, promotes misleading and unregulated products.	**USA/Europe**: More regulation, but some online platforms still lack control. **MENA**: More widespread, especially on social media like Facebook and Instagram with fewer restrictions.
Lack of Consumer Education & Awareness	Consumers are often unaware of risks associated with counterfeit products, relying on misleading marketing and labels.	**Global**: Generally poor consumer knowledge, especially in markets with fewer regulations or education campaigns on the dangers of counterfeit products.
Regulatory Gaps & Enforcement Challenges	Weak laws and enforcement challenges make it difficult to control counterfeit products entering the market, especially with the global nature of online sales.	**Global**: Weak laws, overworked regulatory bodies (FDA, EFSA), and difficulty monitoring global supply chains contribute to widespread issues.

6.0 NUTRACEUTICALS AND DIETARY SUPPLEMENTS FOR ERECTILE DYSFUNCTION

Erectile dysfunction (ED), the inability of a male to attain or sustain an erection adequate for intercourse, is common in millions of men globally, especially in the aging fraternity (HN, 2017). Though therapies like phosphodiesterase-5 inhibitors (PDE-5 inhibitors) are usually prescribed for erectile dysfunction, many people look forward to seeking a cure through nutraceuticals and dietary supplements. As a result, substances like natural herbs, amino acids, and other plant derivatives are being sold as safer means of treating ED. However, very often, the effectiveness and safety of such supplements are not certain, and certain supplements have been found to contain "hidden" pharmaceutical substances, which can be harmful to consumers' health.

Figure 4: Nutraceutical Dysfunction

6.1 Natural Ingredients Commonly Appearing on Products

Many natural ingredients are used in dietary supplements for enhanced erectile function. Most of these ingredients are added due to their supposed blood flow boosting, nitric oxide boosting, or hormone balancing properties – all critical to achieving and sustaining an erection.

Panax Ginseng: Better known as the herbal Viagra, this is one of the most popular Asian herbs for treating erectile dysfunction (Ho & Tan 2011). They have found that it could be useful for erectile function by enhancing the formation of nitric oxide that leads to dilation of the vessels in the erectile organ to facilitate better blood supply. According to research, its efficacy has been confirmed in some cases; however, researchers aim to ensure minimal benefits.

Figure 5: Panax Ginseng plant

Yohimbine: Yohimbine is an alkaloid obtained from the African Yohimbe tree that is believed to have properties that can act as both a vasodilator and a stimulator of nerve activity (Hai et al. 2013). It is prescribed for the treatment of erectile dysfunction, especially when mental disorders are present. Visually, yohimbine has serious side effects, including increased blood pressure, anxiety, and dizziness, among others, which render it unfit for use by specific persons.

Figure 6: Yohimbine Extract

L-arginine: L-arginine is an amino acid that appears to function as a critically important precursor to the synthesis of nitric oxide, which acts as a vasodilator and a blood vessel dilator (Cziráki et al. 2020). Several investigations showed that the use of L-arginine could restore erectile function in men with mild to moderate forms of the condition. However, the use of FSDP is often disputed, and use may not always be effective for most people, particularly those with exacerbated ED or pathogens such as diabetes.

Figure 7: L-arginine

Tribulus Terrestris: It is well known that this plant extract is used in some male enhancement supplements as a natural testosterone increaser (Qureshi et al. 2014). Despite that, there are only a few works that show that it may have the ability to improve certain aspects of male sexual activity and can be beneficial for the treatment of erectile dysfunction. However, a lot of them suggest that it is effective for increasing libido levels rather than acting as an ED remedy directly.

Figure 8: Tribulus Terrestris

Horny Goat Weed (Epimedium): Originally, it was used in Chinese medicine to enhance circulation and, therefore, sexual capabilities (Ma et al. 2011). It is believed to have an IC50 value of itself to a certain degree, being similar to sildenafil, the active ingredient for Viagra. They have some basis in clinical uses, but their empirical evidence is weak, and their risks are poorly understood.

Figure 9: Horny Goat Weed

Maca Root: Maca root, which is regarded as one of the most effective natural stimulants for the sexual system, is usually found in the preparations used for sexual dysfunction therapy (Malviya et al. 2016). While some research indicates that it may enhance sexual drive and energy, there is not enough proof that maca can influence erectile capacity.

Figure 10: Maca Root

6.2 Color and Shape of the Final Nutraceutical Products and Customer Perception

It is, therefore, important for nutraceutical companies to understand that product packaging and appearance strongly impact consumers' buying decisions. This is perhaps due to color, shape, and packaging since they create a perception of how the male enhancement products will work. For example, products with bright colors look colorful; while ducts with shape capsules shaped capsules and action pills enjoy more reliability, utility, and trustworthiness. According to research, consumers tend to relate certain colors to other characteristics. Red and yellow have often been used in marketing male enhancement products since they connote energy/power/vigor

Shape: The shape of the supplement is also very vital. Alternatively, products that resemble familiar medicines (for example, the shape of Viagra) may be trusted by consumers on a subconscious level because they can be associated with doctor-recommended treatments. Some manufacturers even make the candy look like small, legitimate pharmaceutical-grade tablets. They are not, however, what they are.

Customer Perception and Branding: In addition to the above considerations, the overall branding, which consists of the name, logo, and the statement inscribed on the pack, affects customers' trust. Products that promise to be "natural" or "herbal" are perceived better by consumers, who increasingly turn to complementary medicine. However, this might be misleading as many of these products include synthetic and damaging ingredients. As for the natural ingredients listed above, there is hope, but nutraceuticals ' effectiveness in curing ED is not guaranteed (Nowak, 2010). It is also important to bear in mind that some supplements may contain or are laced with unlisted pharmaceutical substances like PDE-5 inhibitors, which have dangerous contra-indications or interactions with other prescribed substances. Furthermore, those supplements have their efficacy, depending on the individual, and their safety in the long term is still inconclusive. Therefore, anyone who is seeking to use nutraceuticals for erectile dysfunction should do so under prescription from a health care expert as they may suit certain individuals and not others.

7.0 PHOSPHODIESTERASE 5 INHIBITORS AS A TREATMENT AND ADULTERANT

PDE-5 inhibitors are prescription medications commonly used in the treatment of erectile dysfunction (ED). These drugs help effectively in the treatment because they prevent the breaking down of a material known as cGMP, which causes the relaxation of smooth muscles of the penis, thus fostering an enhancement of blood flow and erection. Some of the more popular drugs in the PDE-5 inhibitors family are sildenafil, commonly referred to as Viagra, tadalafil or Cialis, and vardenafil, referred to as Levitra. The effectiveness of these medications has been certified and recommended for the treatment of ED by several institutions, including the FDA and EMA. However, in today's male enhancement supplements, PDE-5 inhibitors also present as impurities in products that claim to be natural or herbal. This unlawful deployment of PDE-5 inhibitors presents a principal danger to consumers, who might not realize that those products contain drugs. Almost all of these supplements are over-the-counter, and most can be bought over the Internet or at other non-licensed outlets, thus escaping rigorous regulatory auditing. In many supplements marketed for erectile dysfunction, PDE-5 inhibitors are present (Reeuwijk et al. 2013). Yet, they are not labeled, and the actual quantity used might be much higher, raising the prospect of the accidental consumption of dangerous doses.

The most common type of drugs used as PDE-5 inhibitors are particularly dangerous when taken as pollutants because they interact with other medications, especially nitrates for heart diseases. Altogether, they cause dangerously low blood pressure that may lead to fainting, stroke, or sudden heart attack. Furthermore, many people, especially those with chronic diseases like cardiovascular diseases or kidney or liver affections, can be severely harmed when using these falsified products. Indeed, the incorporation of PDE-5 inhibitors in male enhancement products poses a blot on both the regular agencies' and consumers' trust. Even though these medications can be used efficiently as erectile dysfunction medication under the prescription, the application of these substances as supplement ingredients is unsafe for consumers. In this regard, regulatory authorities are raising efforts to identify and confiscate such fake products through various analytical tools and enhancing the regulatory frameworks against the online marketing of dietary supplements.

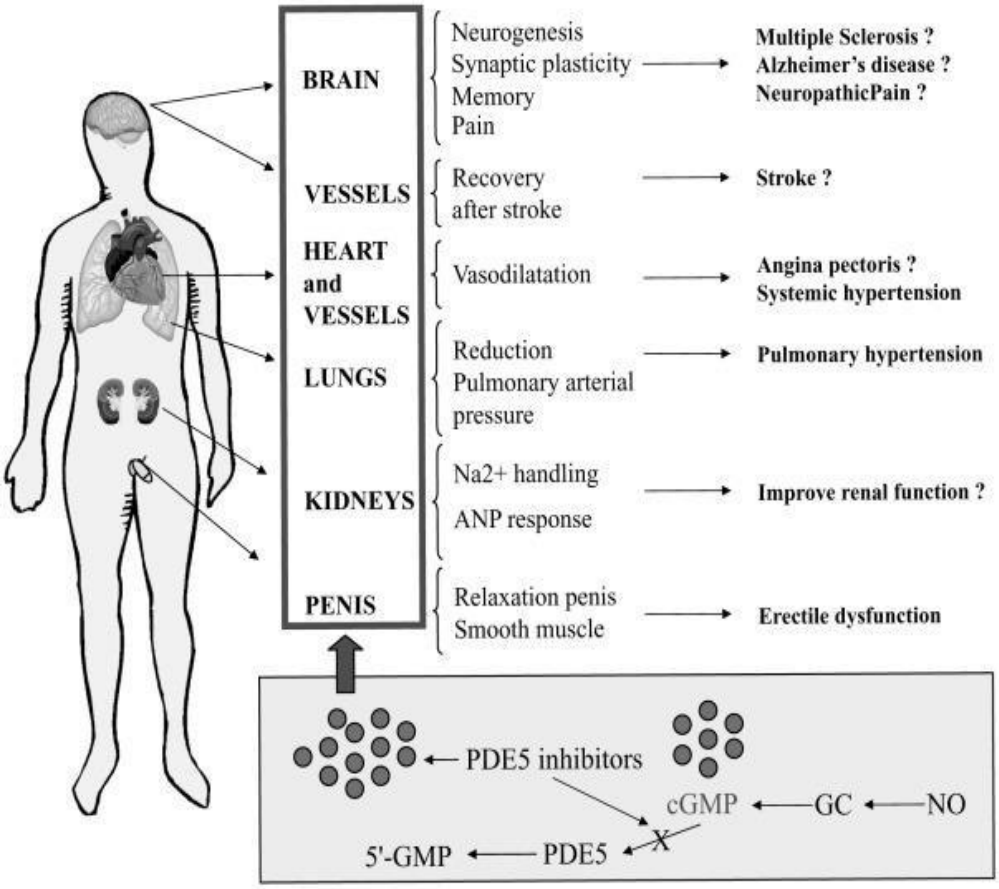

Figure 11: Therapeutic use of PDE5 Inhibitors

8. PHOSPHODIESTERASE-5 INHIBITORS ARE COMMON ADULTERANTS IN NUTRACEUTICALS AND DIETARY SUPPLEMENTS

PDE-5 inhibitors were originally prescribed to patients with erectile dysfunction, and their use in nutraceuticals and dietary supplements is a relatively new concern in the field of public health. PDE-5 inhibitors are pharmaceutical agents known to work effectively; nonetheless, they are dangerous when taken without medical authorization, as is the case with products masquerading as natural supplements that contain them as pollutants. Many of these chemicals are incorporated into male enhancement products in an attempt to boost the asserted performance. Still, using such ingredients has severe side effects for people who do not know they are there.

PDE-5 Inhibitors in Medical Treatment

Sildenafil, tadalafil, and vardenafil are PDE-5 inhibitors that address erectile dysfunction by enhancing the efficacy of the nitric oxide responsible for the widening of penile blood vessels. This opens the arteries and thus leads to an erection when one is sexually inclined. These drugs range are often recommended for patients after consultation with a health care provider, and their use is controlled because these combine with other drugs, particularly nitrates, which are used in the treatment of heart complications. Consuming PDE-5 inhibitors in supplements intended for male enhancement either intentionally or as a result of poor quality control makes such substances dangerous for one's health.

The Role of PDE-5 Inhibitors as Adulterants

Even though these drugs are used as prescription medicine to treat erectile dysfunction, they have not been accredited as OTC nutritional supplements. However, many male enhancement products, especially the so-called natural or herbal supplements, are laced with these drugs, and users are unaware of this fact. These manufacturers

may add PDE-5 inhibitors to the formulation to achieve the desired result faster and create a sense of Desire in the populace, hence selling more of the product. These products are often bought online, from sources that are not standard, or through direct marketing, where these products avoid standardization control. This is bad for health because the supplements contain PDE-5 inhibitors, which lead to various health problems. People may accidentally ingest these substances, which may have very serious unwanted side effects if the patient is also suffering from certain diseases, including cardiovascular disease, hypertension, or diabetes. Because the consumer is made unaware of the drug inclusion, they may not be aware of the dangers until a reaction happens. Moreover, the effects of these PDE-5 inhibitors in fake products may be higher or lower potency or contain other toxic substances that will increase risks.

Detection of PDE-5 Inhibitors (PDE-5I) as an Adulterant in ED Products

Sildenafil, tadalafil, and vardenafil belong to phosphodiesterase type 5 inhibitors (PDE-5Is) and are the most popular treatment for erectile dysfunction (ED). These compounds, despite being approved for use by individuals with erectile dysfunction, have also become popular adulterants in male enhancement dietary supplements. Given the fact that most of these products contain PDE-5Is that are marketed as "natural" male enhancement products, the fact that their formulations are not regulated, and the fact that they can cause interactions with other medications are major health concerns with the use of these products. Therefore, determining these pollutants in dietary supplements is of paramount importance with regard to the consumer's health. Chromatography, mass spectrometry, or spectroscopy has been used to quantify PDE-5Is in substances that contain counterfeit products. This section will review the approaches employed in identifying PDE-5 inhibitors in ED products; chromatographic and mass spectrometry methods will be discussed in detail.

Chromatographic Techniques for Detection

Chromatography is one of the most frequent identification methods for PDE-5Is in dietary supplements. HPTLC has been used to identify these compounds in a mixture accompanying a rich and efficient separation technique by HPLC and GC.

HPTLC, which stands for high-performance thin-layer chromatography, is a useful tool in HPLC that aims to identify PDE-5 inhibitors in herbal and pharmaceutical products. Densitometry was employed with HPTLC to identified sildenafil content in the pharmaceutical and aphrodisiac plants (Abourashed et al., 2005). This method is fast and inexpensive and is extremely useful when screening for one or more pollutants at a time. It entails placing the streaked sample in contact with the silica gel plate to separate and identify the known compounds in a solvent mixture. The separated components tend to appear under ultraviolet (UV) light, which helps identify substances like sildenafil, tadalafil, or vardenafil that belong to PDE-5 inhibitors.

High-Performance Liquid Chromatography (HPLC) is another common method used to identify PDE-5Is in dietary supplements. Other researchers also employed HPLC to analyze sildenafil citrate and its by-products on commercial products (Daraghmeh et al. 2001). The process occurs by applying the separation principle based on the compounds' distribution between a liquid mobile and stationary phase. This renders the method highly sensitive and specific, making it easier to detect and quantify PDE-5 inhibitors even in aqueous solutions. Specifically, besides sildenafil, HPLC can detect structurally related synthetic PDE-5Is and their analogs, which can be found in fake natural compounds (Lee et al., 2013).

GC, especially with mass spectrometry, was suitable for identifying PDE-5Is in matrices such as health supplements. The GC-MS analysis was used to quantify sildenafil, tadalafil, and vardenafil (Man et al. 2009). In the study, GC separates various products in a sample depending on their characteristic of vaporization. Mass spectrometry is a very sensitive and selective method for identifying PDE-5Is since the mass spectrometer will determine the molecular identity of the contaminants present in impurities.

Mass Spectrometry: A Powerful Tool for Detection

MS is now a vital analytical technique in the detection of synthetic analogs, such as PDE-5 inhibitors, in blends in supplements. When used with liquid chromatography, it produces LC-MS or LC-ESI-MS and provides even higher sensitivity and selectivity, allowing for the identification of multiple adulterants in one run. The method most suitable for identifying PDE-5 inhibitors in these supplements is Liquid Chromatography-Electrospray Ionization Mass Spectrometry (LC-ESI-MS). LC-ESI-MS is a hybrid technique that meets the separation capabilities of liquid chromatography and the ionization ability of mass spectrometry. The use of LC-ESI-MS to detect synthetic PDE-5 inhibitors in dietary supplements and herbal matrices has been applied in other researches (Gratz et al. 2004). This technique can offer analysis for even the smallest concentration of contaminants and can be used to prove whether the product contained PDE-5Is such as sildenafil or tadalafil. The LC step isolates the compounds, and the mass spectrometer then identifies these molecules through their distinct fragments.

Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) can be used in multi-target screening, increasing the chances of identifying different PDE-5 inhibitors. LC-MS/MS has been used to screen sildenafil, tadalafil, vardenafil, and their derivatives in the illegitimate products used as male performance boosters (Lee et al., 2013). It is sensitive and can provide qualitative and quantitative data, which is essential for deciding the regulatory results.

Other spectroscopic techniques include:-

Thus, chromatography and mass spectrometric analysis are the most common techniques used in PDE-5 inhibitor detection in dietary supplements, and NIR is described as the rapid screening method. NIR has been used to identify sildenafil analogs in plant-derived products (Said et al. 2014). Using NIR, obtaining the results of material quality characterization and controlling the quality of final products without carrying out time-consuming sample preparation is possible. However, it is comparably less sensitive than chromatography and spectrometry and must often be used as a screening method before the latter techniques are used. The identification of PDE-5 inhibitors as undeclared components in male enhancement dietary supplements is, therefore, very important for the safety of consumers. Some conventional and advanced analytical methods like HPTLC, HPLC, GC-MS, LC-ESI-MS, and LC-MS/MS are applied due to their higher sensitivity and specificity. These approaches allow for determining and measuring PDE-5Is and the fight against counterfeit products, preventing consumers from using unsafe materials globally. Since the current fakes are more enhanced compared to a few years ago, there will be a need to develop new and enhanced measures to counter the manufacture of such substandard products for the good of the population.*Risks and Health Implications*

This is because some nutraceuticals contain PDE-5 inhibitors, and this bears various health risks, especially to people who do not need to use such drugs. Potential health complications include:

Cardiovascular Effects: PDE-5 inhibitors also can cause mild to moderate fluctuations in blood pressure, and the combination of these medications with other drugs, particularly nitrates or alpha-blockers used in hypertension, may cause hypotension and fainting.

Drug Interactions: People, especially those who use antidiabetic, antihypertensive, or cardiovascular medications, may experience fatal effects from consuming a product with undeclared PDE-5 inhibitors. Such interactions may either increase the severity of adverse effects or decrease the effectiveness of critical therapies.

Unregulated Dosing: The level of PDE-5 inhibitor in a supplement may substantially differ, and nobody controls the quality or homogeneity of these preparations. Consumers may take an overdose of the drug and experience prolonged erection, priapism, or other complications.

Lack of Consumer Knowledge: A majority of male enhancement supplement consumers are unaware of the existence of PDE-5 inhibitors. This is a great worry as many customers buy these products based on the mention of ‘natural’ or ‘herbal,’ not knowing they contain real pharmaceuticals.

The dilution of male enhancement dietary supplements with PDE-5 inhibitors is thus a real danger to public health. Despite these drugs being approved treatments for erectile dysfunction, when present, unregulated

supplements pose a lot of hazards to the health of a consumer, especially when taken without the supervision of a doctor. These dangerous pollutants can, therefore, only be controlled through the development of better detection approaches and improved regulatory control. Education on the potential dangers for consumers and healthcare professionals is also an important consideration so that people would not accidentally take PDE-5 inhibitors when consuming those supplements.

Table 2: Risks, Detection, and Health Implications of PDE-5 Inhibitors in Dietary Supplements

Category	Details
What are PDE-5 Inhibitors?	Originally prescribed for erectile dysfunction (ED), including sildenafil, tadalafil, and vardenafil.
Use in Medical Treatment	Enhance nitric oxide effects to widen blood vessels and help erections. Prescribed with caution due to potential interactions with other drugs like nitrates used for heart problems.
Role as Adulterants	Added to "natural" male enhancement products to boost performance claims. Often in unregulated supplements, causing health risks, especially for individuals with existing health conditions.
Detection Methods	**Chromatography** (HPTLC, HPLC) and **Mass Spectrometry** (GC-MS, LC-ESI-MS, LC-MS/MS) used to detect PDE-5 inhibitors in supplements. These methods help identify contamination in products not properly regulated.
Risks & Health Implications	- **Cardiovascular Effects**: Blood pressure fluctuations, especially with other drugs like nitrates. - **Drug Interactions**: Dangerous with diabetes, hypertension, or cardiovascular meds. -**Unregulated Dosing**: Risk of overdose. - **Lack of Consumer Knowledge**: Many unaware of PDE-5 content.
Detection Challenges	PDE-5 inhibitors in supplements can vary in potency. Detection methods are critical for safety, but unregulated supplements still pose risks.
Health Risks of Contamination	Unregulated products may cause adverse effects like priapism (prolonged erection), hypotension, and interactions with other medications, leading to potential health emergencies.
Consumer Awareness	Many consumers unaware that "natural" supplements may contain PDE-5 inhibitors, leading to accidental use and health issues.
Conclusion	Better detection methods and regulatory control are necessary to prevent harm from adulterated supplements. Education for consumers and healthcare professionals is essential to avoid unintended PDE-5 inhibitor intake.

9.0 ADULTERATED AND COUNTERFEIT PRODUCTS IN THE MIDDLE EAST

The Middle East has transformed into a key region for falsified and substandard male enhancement dietary supplements, imperfect control over which contributes to counterfeit products' penetration into the market, stimulated by the increased demand for solutions to sexual health problems. These products sold as natural/ traditional products are sometimes counterfeit and contain banned substances, including pharmaceutical-grade products such as phosphodiesterase type 5 inhibitors (PDE 5 inhibitors) used in genuine FDA-approved erectile dysfunction drugs like Viagra and Cialis (Spitz, 2018). Some of the reported reasons include low observance of the current regulation proviso and the increased sales of fake male enhancement products in the Middle East. While current governments like the UAE and Saudi Arabia have accelerated efforts to improve the rules

governing pharmaceutical products, several nations within the region continue to exhibit a weak commitment to and flawed enforcement of quality standards. Two important classes concerned with this problem are online pharmacies and the grey market. Such points of sale enable the products in question to be introduced into the market without numerous inspections. People purchase such products from unauthorized and uncontrolled websites without regard to the credibility of the supplement in question.

In the Middle East region, and especially in recent years, the sale of counterfeit supplements has skyrocketed, according to the International Institute for Science and Technology (IIST). Counterfeit products are usually marketed in local markets, through pharmacies, and particularly through the Internet, and these have packaging that resembles genuine brand names (Davison, 2011). For instance, these FDA fake commodities are often labeled and packaged as 'herbal' or 'all-natural,' therefore; the users are unaware that they contain dangerous chemicals and substances that are worse than the drugs. This problem worsens due to ignorance and poor consumer awareness and knowledge. In some subfields, the effectiveness of these products is boosted by the vigorous marketing and increased use of Generational Marketing celebrities and social media that makes male enhancement supplements so effective. However, these advertisements give vague and overstated information that may solve the problem in only a few days, leading the consumer to use the product without knowing the potential hazard. Moreover, the Middle Eastern market is sensitive to conventional medicine; programs endorsing the use of other products that have no or little evidence or are not regulated can be popularized.

The authorities in the region have woken up to the vice and started taking action against counterfeit male enhancement supplements. The UAE's Ministry of Health and Prevention continues to alert consumers of unregistered products and perform raids on ports and markets to seize counterfeit products. Nevertheless, enforcement is still a major problem. For instance, substandard products containing PDE-5 inhibitors or other hazardous compounds can be imported from less restrictive countries, preferably in Southeast Asia. With the increasing market demand for male enhancement products, the Middle East could use improved legislation and consumer awareness. As some of the countries attempt to escalate the control of impurity, the circulation of substandard and fake supplements remains a clear pointer to the need to employ a combination of strategies that may entail creating awareness among the consumer, enforcement of the law, and multi-jurisdictional approaches to protecting the consumers.

10.0 GLOBAL EFFORTS TO COMBAT FALSIFIED AND ADULTERATED MALE ENHANCEMENT DIETARY SUPPLEMENTS

Counterfeit and substandard male enhancement dietary supplements are currently a global menace since they carry negative health implications to consumers, erode consumer confidence, and complicate regulatory actions. Since these products naturally have nasty ingredients, such as unapproved pharmaceutical drugs, including phosphodiesterase-5 inhibitors (PDE-5Is), governments and international organizations have embarked on several endeavors to tackle them. These include national legislation and international cooperation to prevent the sale and distribution of fake goods and increase consumer protection.

10.1 National Efforts

United States

In America, the primary governing body is the FDA—the Food and Drug Administration, which oversees the consumption of diet supplements so that its products are safe for human use. However, the FDA claims less authority over supplements than over other products, namely pharmaceuticals. While the FDA acts under the provisions of the Dietary Supplement Health and Education Act (DSHEA) of 1994, the agency does not review most supplements before they are sold in the market; therefore, consumers are at the mercy of unsafe products. To this end, the FDA has upscaled its scrutiny through enhanced screening, creating awareness, and improving enforcement of substandard goods. The FDA often uses recalls and warning letters to producers of products containing banned substances or those with unauthorized active ingredients. The NIH and the CDC have endeavored to advise the public on issues related to counterfeit supplements. They work with industry partners to

consistently label supplements and inform the public about the dangers of bottled supplements for sale on the Internet.

European Union

The European Union has imposed sound policies to safeguard and guarantee the safety of dietary supplements. Supplements legislation in the EU is informed by the scientific advice of the European Food Safety Authority (EFSA). The EFSA can also evaluate health claims from manufacturers and may ban products with wrong information, such as male enhancement products. Online sellers also have to adhere to these rules formulated by the EU in the Food Information to Consumers Regulation Passed in December 2013. Again, enforcement is a problem in some member countries. There are still national agencies in place that look for and take measures against these dangerous supplements, such as the Medicines and Healthcare Products Regulatory Agency (MHRA) from the United Kingdom. MHRA performs periodic market surveillance exercises, including analytical testing of products believed to have been degraded. Local authorities in the UK have also joined hands with overseas regulatory agencies to ban imports of fake goods.

Egypt and the Middle East

Counterfeit male enhancement supplements are highly prevalent in Egypt and other areas of the Middle East because the issues with regulation and increasing reliance on Internet-based pharmacies remain unresolved. Attempts have been made under the Ministry of Health of Egyptian authorities to improve legislation on pharmaceuticals and supplements. Egypt's EDA has recently increased its activities to counter fake drugs through increased inspections of outlets and vigorous campaigns. However, counterfeits are still prevalent in the region due to the uncontrolled internet-based pharmacy and the increasing popularity of male enhancement drugs. There is a worrying emerging trend because governments in the Middle Eastern countries are now partnering with international regulatory agencies to address these challenges. However, much needs to be done in relation to implementing the laws and regulations governing the sale of these online supplements.

10.2 International Collaborations and Regulatory Bodies World Health Organization (WHO)

The WHO is central to the global counter-struggle against counterfeit and substandard medicines and dietary supplements. WHO has used the "Fight the Fakes" persuasive campaign to raise awareness of the harms incurred by falsified products. WHO also aids members in sharing intelligence on fakes so as to track them and, therefore, recognize the channels through which they are supplied to the markets. Its activities are needed to coordinate the increasing global problem of fakes coming into the market, including male-enhancement dietary supplements.

INTERPOL

INTERPOL has always been one of the most effective forces against the global trade of fake dietary supplements. INTERPOL's coordinated action across several countries is Operation Pangea, which concentrates on the online sale of bogus medicine and supplements across the globe. The operation has resulted in the seizure of thousands of products, and arrests have been made to prevent and dismantle the supply chain of falsified male enhancement supplements from around the world. INTERPOL also cooperates in the international training law enforcement officers to enhance the capacity to combat sales of fake goods.

Global Alliance for Improved Nutrition (GAIN)

Global supplement organization GAIN has successfully targeted this problem in emerging markets for ASIA AND AFRICA. The organization believes that it can win its fight against low-quality dietary supplements by working with the private sector, governments, and consumer protection organizations to offer the public good quality products through capacity development in supporting regulation frameworks and assisting with technical needs, GAIN aids in creating better, stricter national retractive legislations to counter the fake trade. It is mostly due to the efforts put in place and the constant fight against fake and toxic male enhancement dietary supplements (ElAmrawy et al. 2016). Yet national regulators, WHO and INTERPOL, and various industries must work together to enhance enforcement, enhance consumer awareness, and eliminate the loopholes in regulations.

Table 3: Global Efforts and Collaborations to Combat Counterfeit Male Enhancement Dietary Supplements

Effort	Description	Key Players
National Efforts (USA)	FDA oversees dietary supplements; enhanced screening, recalls, and warning letters; public awareness on dangers.	FDA, NIH, CDC
National Efforts (EU)	EU policies informed by EFSA; evaluation of health claims and potential bans on misleading products; market surveillance by MHRA.	EFSA, MHRA (UK), National agencies in EU
National Efforts (Egypt & Middle East)	Increasing inspections and legislative reforms by Egyptian authorities; growing reliance on internet pharmacies; regional cooperation to combat counterfeit products.	Egyptian Ministry of Health, EDA, Local authorities, International regulatory agencies
International Efforts (WHO)	"Fight the Fakes" campaign; coordination of intelligence sharing among member countries to track and combat fake products globally.	WHO
International Efforts (INTERPOL)	Operation Pangea targets online sales of counterfeit products; global coordination, seizures, arrests, and training for law enforcement.	INTERPOL
International Efforts (GAIN)	Collaboration with private sector, governments, and consumer protection groups in Asia and Africa to enhance regulation and provide better-quality products.	GAIN, Private sector, Governments, Consumer protection organizations

CONCLUSION

Regarding male enhancement dietary supplements, the challenge of fake or substandard products infiltrating the markets of many nations is scary, bearing in mind that they pose serious health risks to consumers. Often, they contain such substances as phosphodiesterase type 5 inhibitors (PDE-5Is), which are Viagras, generic sildenafil, generic Cialis, and others, and improved blood flow; thus, regular consumption leads to cardiovascular diseases, backlash with other products, side effects, and others. Nevertheless, because the pollutants mentioned earlier are very dangerous, that is why the spreading of male enhancement supplements and the ready market on the internet for these products leads to the usage of fake and low-quality products. One severe issue with such compounds is that the manufacture and use of dietary supplements are not always sufficiently controlled worldwide. For instance, in the USA, the FDA has limited authority to regulate supplements before launching them. However, it is enforced after these products get to the consumers, and in some occasions, the products may even hurt the consumers. Most of these problems are still the same in most parts of Europe and other continents, given that legal standards and compliance measures differ and are unique. Thus, this regulatory gap creates crevices through which the fake players filter themselves and secrete low-quality products into the market through web-based pharmacies and direct-to-consumer advertising. The products are fairly available in the market, and as marketers, they have used fairly persuasive marketing strategies; hence, the products are fairly easily consumed.

Analytical procedures for identifying PDE-5 inhibitors as contaminants of counterfeit supplements are central to preventing the dangers of fake supplements. Complex chromatographic methodologies, including HPTLC, HPLC, and GC, and sophisticated mass spectrometry techniques, including LC-MS and LC-ESI-MS, are highly effective in identifying and quantifying such dangerous additives. These methods facilitate the identification of PDE-5 inhibitors even in low quantities in supplement matrices, which is a valuable defense line against counterfeit products. For example, HPTLC uses gel plates that can accommodate large samples at a relatively low cost. At the same time, LC-MS maintains an unrivaled sensitivity and specificity for describing adulterant chemicals. Nonetheless, the method of PDE-5 inhibitor detection has its limitations. The quality of counterfeits often

evolves, and trends indicate the use of different substances in counterfeits, either to produce similar effects to the genuine PDE-5Is or to avoid being detected. Due to the continually changing methodology within which illicit production is undertaken, there is a constant need for the enhancement and release of detection technology. Therefore, these enhanced techniques, including near-infrared spectroscopy (NIR), may also play a larger role in such rapid quality assessment. Still, they are less sensitive than chromatography and mass spectrometry methods.nBesides technological preconditions for counterfeit dietary supplements, a collective approach of governments, global governance, and business organizations is also necessary. New enforcement efforts and enhanced regulatory strategies require the WHO, FDA, and local bodies to enhance cooperation and address newly identified regulatory weaknesses. Both public education about the risks involved and consumer education about the risks of buying supplements from unauthorized sources are mandatory in this case. It means that despite the achievements that have been made in any case of male enhancement supplements containing contaminants, there are still activities to be done. Enhancing the legal frameworks, raising the effectiveness of detection tools, and enhancing public awareness are key aspects of the comprehensive perspective towards tackling fakes in consumer protection. However, only persistent monitoring and safety cooperation can be guaranteed for consumers, and the threat of sponsorship of foreign impurities into nearby dietary supplements can be reduced. The consumer attitude towards health care products in the future depends on one world's efforts and allows only safe products and proper control.

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