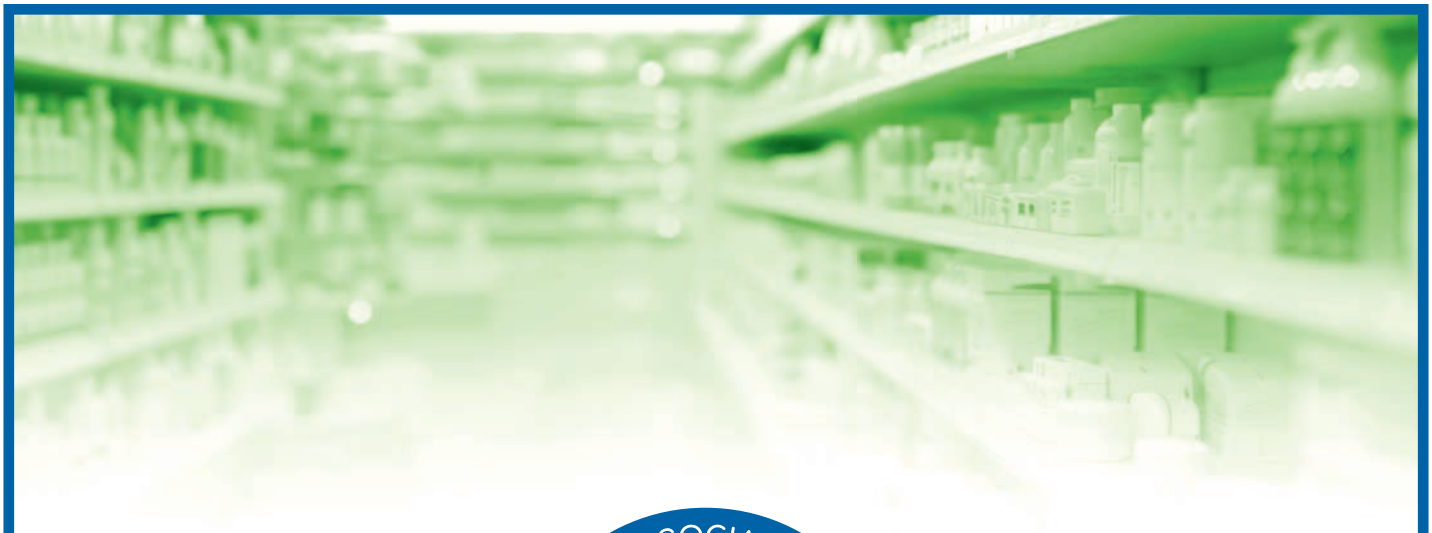
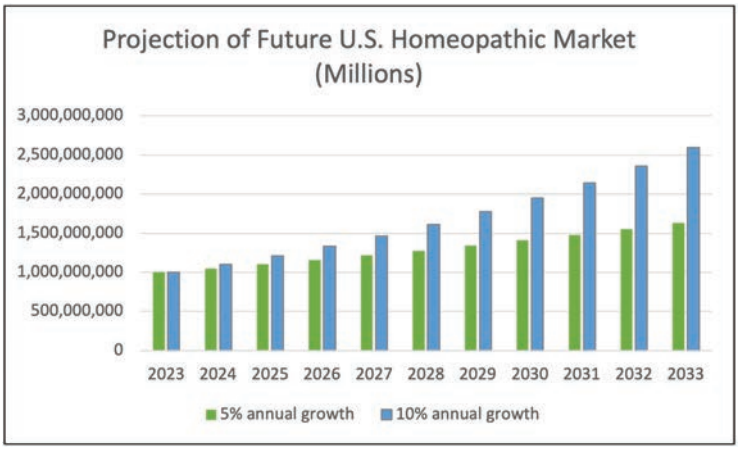


CHAPTER FOUR:

Future of Homeopathic Medicines

FUTURE OF HOMEOPATHIC MEDICINES

What will homeopathic medicines look like in the future in the United States? AAHP examines the possibilities and problems ahead with the products' dosage forms, active ingredients, packaging, and labeling.



Dosage Forms

Since the founding of homeopathy, dosage forms have been defined by their technical ease of preparation. The Homeopathic Pharmacopoeia of the United States (HPUS) asserts, "Homeopathic drugs shall be based on their simplicity."[1] Diluents for homeopathic drug products historically and most commonly have been limited to alcohol, water, glycerin, and simple sugars such as sucrose and lactose.[2] These diluents have many inherent properties that aid formulators in maintaining simplicity, such as: compatibility with homeopathic active ingredients; stability including microbiological stability; and having well-known human pharmacokinetics and metabolism.

This overall simplicity served the homeopathic industry well and favors many important facets of drug quality and performance. It kept production costs low; minimized the use of potentially bioactive compounds like preservatives; and maintained a formulation legacy with original homeopathic dosage forms.

In contrast, simplicity constrained the offering of homeopathic dosage forms mainly to tablets, pellets, and liquids by oral route and to ointments and salves by topical route of administration.[3] Nevertheless, certain drivers have prompted and will continue to prompt a wider range of homeopathic dosage forms.

One of the leading motivators of dosage form change is manufacturers' goal to present more consumer benefits such as convenience, taste, and ease of swallowing.[4,5]

Keeping pace with competition is another strong incentive. While oral dosage forms in the homeopathic category are most popular among consumers,[6] shoppers may be familiar with or prefer innovative presentations from competing allopathic OTCs. Consumers have access to more products than ever. E-commerce marketers display a range of products previously inaccessible to most consumers. This phenomenon is driving development of both innovative and "follow-on" health care products. The homeopathic category will most likely follow suit.

New science and technologies are a third inspiration for dosage form change as manufacturers explore formulations to enhance stability and improve performance of existing products.[7] Homeopathic manufacturers have access to a wide range of emergent technology, including offerings through contract manufactures and laboratories, to facilitate the development of products.

This emergence of a wider range of homeopathic dosage forms is evident in the FDA's National Drug Code (NDC) Directory. As of 2021, more than 40 dosage forms of homeopathic drug products are registered in this database.[8]

FUTURE OF HOMEOPATHIC MEDICINES

Active Ingredients

The Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2020 ("OTC Monograph Reform")[9] provides a lightweight but defined pathway for manufacturers to propose innovative formulations for existing active ingredients that may already be on the market in other countries.

OTC Monograph Reform also enables changes in dosage strength, which will incite reformulations to existing products.[10] In turn, alterations in dosage strength will cause transformations in indications, directions, and warnings. These developments in allopathic OTCs will likely be followed by homeopathic drugs.

FDA's June 27, 2022 proposed rule Nonprescription Drug Product with an Additional Condition for Nonprescription Use (ACNU) will also stimulate changes in active ingredients.[11] Rx-to-OTC switch is the transfer of proven Rx Only drugs to nonprescription, OTC status. Like OTC Monograph Reform, Rx-to-OTC switches will create and open new therapeutic categories to other products, including homeopathics.

A third incentive is new HPUS monographs which are periodically approved by HPCUS. History has shown that new monographs are generally implemented by the sponsoring manufacturer. However, ingredients with wide appeal may spark development by a broad range of other companies.

The last push for active ingredient change comes from the evolution of self-care. Consumers have demonstrated a desire for greater control over the health of themselves and their families; consumers have also shown an increased interest in proactive health care management through diet, exercise, sleep, hygiene, personal engagement in health, and medication safety.[12,13] Due to inherent safety, homeopathic medicines are often the user's first choice. For these reasons, consumer demand for more and new homeopathic drug products is likely to increase.

Packaging

Packaging has come a long way from its basic function to protect the product. Homeopathic products must keep pace with consumers' expectation for packaging, including being attractive and distinct enough to promote itself, as well as now being environmentally sustainable.[14]

Environmentally-friendly packaging is increasingly important to consumers. According to a 2020 McKinsey global survey of 10,000 people, 68 percent of U.S. consumers say they are willing to pay "a lot" or "a bit more" for sustainable packaging of foods.[15] Sustainability is already a key component of packaging changes.

The pharmaceutical industry must balance satisfying the safety demands of industry regulators with the desires of modern convenience-minded, eco-conscious consumers. This is likely more important for homeopathic manufacturers whose products have been purchased traditionally by the natural channel shopper.

Global markets for packaging materials and technology offer a variety of solutions for both the regulatory constraints and commercial demands for innovative packaging.[16] Homeopathic products are well-positioned to take advantage of new technologies given the international relationships of many U.S. marketers and manufacturers of homeopathic products.

FUTURE OF HOMEOPATHIC MEDICINES

Labeling

Manufactures also need to anticipate changes in labeling. One factor is consumer interest in more product information. Product packages have limited space to communicate important information to consumers. Over informing on the package can affect comprehension and interfere with the consumer self-selection.[17] This creates a negative customer experience. By addressing hurdles encountered during the consumer's decision-making journey, companies can increase customer satisfaction. As complexity increases and competition intensifies, optimizing the customer experience becomes even more important.[18]

To better ensure a positive consumer experience or to protect the company from poor product performance due to lack of instructional clarity, manufacturers may choose to provide supporting product information on their websites. This is especially helpful for homeopathic products that: may be unconventional in application; have extremely limited label space for information; or have packaging unable to carry an insert.

Retailers' websites, especially those for online-only retailers, are another source for labeling information. Manufacturers should establish a database of informative text and informative graphics for retailers' websites. Retailers are eager to differentiate themselves by providing consumers with more information on the health products they sell. While providing additional information at store shelves is not practical, retailers encourage it on their websites. Online retailing is also a virtual laboratory to understand the need for greater prioritization and presentation of product information.

Consumer demand — and therefore retailer demand — for more product information cannot be fulfilled on-pack. However, momentum is gathering to electronically enable access to supplemental information via technologies like QR codes leading to manufacturers' websites.[19]

Conclusion

FDA's 1999 Drug Facts Rule was designed to standardize formatting and improve consumer comprehension.[20] Currently nonprescription drug products are limited to drugs that can be labeled with sufficient information for consumers to appropriately self-select and use the drug product. This can be challenging due to labeling limitations.[21]

But the future is moving beyond the basic drug fact label requirements. Under FDA's proposed rule (Nonprescription Drug with an Additional Condition for Nonprescription Use), when labeling alone is not sufficient to ensure that the consumer can appropriately self-select, and/or use a drug product correctly in a nonprescription setting, an applicant may apply for an Additional Condition for Nonprescription Use (ACNU) that a consumer must successfully fulfill to obtain the nonprescription drug product with an ACNU. Homeopathic labelers will likely take advantage of developments in labeling of OTC drug products.

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