AMERICAN ASSOCIATION FOR HOMEOPATHIC PRODUCTS

AAHP

— EST. 1923 —

CELEBRATING

100 Years

Promoting Integrity, Quality, and Trust in Homeopathic Medicines

TABLE OF CONTENTS

Table of Contents

Acknowledgements

AAHP extends its gratitude to the Consumer Healthcare Products Association (CHPA) for its support in the graphic design of our 100th anniversary logo.

Thanks to the following companies and individuals for providing historic memorabilia, photographs, and images:

- Jay Borneman
- The Craig Family of Standard Homeopathic Company
- Eric L. Foxman, Pharm. (Ret.)
- Pat Hubbell of Brooklyn Pharmacy
- Mark Phillips, Pharm.D.
- Washington Homeopathic Products

100

Years of Promoting

Integrity • Quality • Trust

AMERICAN ASSOCIATION FOR HOMEOPATHIC PRODUCTS

AAHP

EST. 1923

AMERICAN ASSOCIATION FOR HOMEOPATHIC PRODUCTS

AAHP

— EST. 1923 —

CHAPTER ONE:

Mission of AAHP

MISSION OF AAHP

Mission of AAHP

Founded in 1923 under the name American Association of Homeopathic Pharmacists, AAHP is the leading trade association for the manufacturers, distributors, and marketers of homeopathic drugs. Representing more than half of the industry, we promote excellence by supporting requirements, criteria, and published guidelines in the HPUS, relevant federal statutes, as well as other industry regulations and compendia — all to help members provide safe, effective homeopathic medicines to consumers, retailers, and health care practitioners across the United States. Together we elevate the homeopathic industry and provide our members with the resources and knowledge to successfully operate in the marketplace.

Our Mission

- Promote excellence in the practice of homeopathic pharmacy, manufacturing, distribution, and marketing.
- Enable effective legislation and growing the prestige of the industry through positive and productive dialog with lawmakers and regulators.
- Enhance the reputation of homeopathic medicine.
- Support retailer acceptance and consumer demand for homeopathic medicines.
- Facilitate mutually beneficial relationships with leaders and experts in the homeopathic and self-care communities.

Our Promise

All persons engaged in the development, research, manufacture, distribution, marketing, and sales of homeopathic drug products owe a special duty to the public seeking alleviation of suffering, restoration of health, and protection against disease. Physicians, pharmacists, patients, and consumers depend upon our integrity to provide them with safe, reliable, and efficacious products; correct and honest information; and dedicated, sincere, and professional service. All AAHP members commit to upholding the following.

Code of Ethics

- Members support the Principle of Similars, the primary foundation of homeopathy.
- Members support the manufacture, distribution, marketing, and sales according to all applicable regulations and guidelines, including but not limited to the HPUS, CFR/CPGs, FDA's GMPs and labeling requirements, worker safety, and environmental requirements.
- Members agree to maintain a level of professional competence by promoting training and education to stay current with regulations and industry requirements.
- Members agree to respect the values of competitors, recognizing differences of viewpoint or philosophy, when consistent under regulations.
- Members act with honesty, integrity, and sincerity in all professional relationships.
- Members agree to manufacture, distribute, market, and sell only those homeopathic drug products that uphold the reputation, integrity, and growth of homeopathy in the United States.
- Members agree to conduct marketing activities using accurate information and fair balance.

MISSION OF AAHP

Membership Benefits

- Critical alerts from FDA and FTC, and implications facing manufacturers and marketers of homeopathic drug products.
- Breaking news emails to keep members current on developing issues impacting the industry.
- Professional development and educational events at reduced rates or complimentary to members. Session topics include regulation updates, compliance how-tos, and much more.
- In-depth member-exclusive newsletter articles (e.g., analysis on products and services for technical manufacturing; nuances of accurately completing federal regulatory documents; valuable checklists; forms and templates for use within member companies; GMP topics; global perspectives). Access to some newsletter articles is limited to members-only, for example, "New FDA Documents on Cough/Cold Products and Annual Reporting" and "FDA Report on the State of Pharmaceutical Quality."
- Practical solutions through "Ask AAHP" — a support group with real-world experience that can provide technical advice and suggestions from board members and other industry experts.
- Connections to vetted vendors as guest speakers.
- A seat at the table to learn from thought-leaders and a voice on policies being shaped.
- Advocacy alliances in Washington D.C. with a dedicated working committee, including a seasoned lobbyist that regularly educates lawmakers on Capitol Hill about our industry and our unique needs.

Together, We Are the Voice of the Homeopathic Industry

* AAHP member companies during the association's 100th anniversary in 2023.

AMERICAN ASSOCIATION FOR HOMEOPATHIC PRODUCTS

AAHP

— EST. 1923 —

CHAPTER TWO:

History of AAHP

HISTORY OF AAHP

Introduction

AAHP was founded in 1923 and its early members included Boericke & Tafel, Ehrhart & Karl, Humphrey's Pharmacal, John A. Borneman and Sons, Luyties Pharmacal, and Otis Clapp & Sons.

From the early part of the century until the 1970s, the trajectory of the U.S. homeopathic market was in decline. (Read more in "Homeopathy in the United States and Milestones.") This caused both a decline in homeopathic manufacturers and a shift away from homeopathic products being primary offerings at the remaining manufacturers.

For instance, Standard Homeopathic Company (now Hyland's Consumer Health) focused on Hyland's Pink Aspirin for Children; Borneman and Sons and others were drug wholesalers; and Luyties Pharmacal formed a company called Inland Alkaloids that concentrated on various alkaloids and chemical constituents. The homeopathic industry was shifting from "mom and pop pharmacies" to small manufacturers beginning to operate on larger scales. Due to these divergences, the association functioned more as a friendly social forum for competitors than an association working on behalf of a disparate membership.

The resurgence and consistent growth of the U.S. homeopathic market in the late 1970s through today parallels AAHP's extraordinary growth and its activities, which is the focus of this article.

1970s

Several factors converged in the late 1960s/early 1970s that made the environment ripe for both homeopathy and AAHP to grow in the U.S. At this point in time, 50 years of experience with allopathic "miracle drugs" had been amassed along with increased awareness of these products' side effects. "Health food stores" became common in the United States. A new generation of health care providers sought to learn from the last practicing generation of homeopaths then in their 60s.

Eric Foxman, current and longtime AAHP Secretary, remembers, "I went to my first meeting in 1978 — the year I graduated pharmacy school. The grandfather of Jay Borneman (current and longtime Chair of AAHP's Legal and Regulatory Committee) gave a talk about harvesting plants wherever he could find them. I was in my 20s and this was a group of older guys who knew one another very well; their wives even knew one another well." The small AAHP business meetings would often take place in someone's hotel room — mostly Willard "Bud" Eldredge of Humphrey's Pharmacal. The meeting was followed by an evening dinner for social interaction.

A year later in 1979, the Homeopathic Pharmacopoeia Convention of the United States (HPCUS) was launched at a pivotal meeting of the American Institute of Homeopathy (AIH) in San Francisco. "AAHP leaders Bud Eldredge, Glenn Hill of Luyties Pharmacal, Jack and Jay Borneman of Borneman and Sons, Tariq Kurashi of Standard Homeopathic Company, Bob Pinco, Esq., and Ralph Packman attended along with physicians, including Allen Neiswander, Henry Williams, and Wyrth Post Baker," recalls Jay Borneman. Concurrently, AAHP briefly joined with AIH, the National Center for Homeopathy (NCH), and the American Board of Homeotherapeutics under the umbrella of American Foundation for Homeopathy.

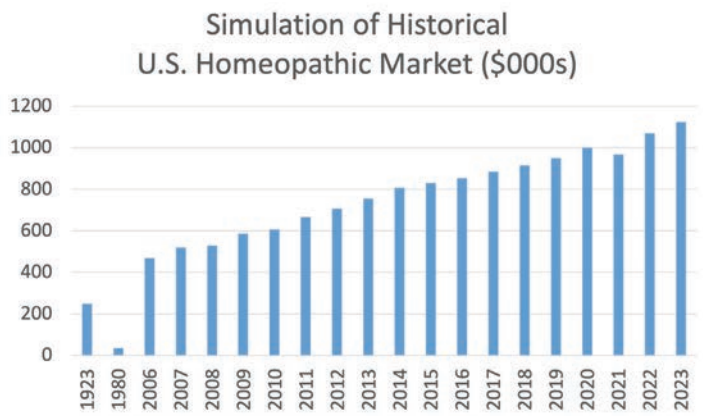
National distribution by homeopathic companies became common; this melted away previous geographic frictions that had existed between manufacturers, and which had limited AAHP activities in its first decades.

As it had been for more than a century, the definition of a homeopathic product continued to be the focus of passionate discussions among manufacturers and the homeopathic community. Traditionalists valued the known while progressives sought to further advance the market. As new members applied for AAHP membership, discussions arose on acceptable methods and dosage forms. Eventually the responsibility to define this class of drug fell to HPCUS. Similar discussions persist today as the industry changes and advances, which illustrates the challenge and success of AAHP in unifying a wide range of manufacturers throughout the years.

The industry truly began to galvanize when faced with common issues, especially negotiating with government agencies and bureaus on matters affecting business in the 1980s such as reimbursement of alcohol drawback tax. AAHP advocated to retain the status that products above 4X were subject to tax reimbursement called "drawback." This status was put at jeopardy following an early 1970s shuffle in government agency duties. AAHP formed a special committee to write and file a petition addressing the points of non-potability and the inconsistencies of the Bureau of Alcohol, Tobacco, and Firearms applying its own standards.

1980s

As consumer demand increased, more manufacturers entered the homeopathic market, including European homeopathic companies. Among the longest lasting is the French homeopathic manufacturer and AAHP member Boiron, which opened its U.S. headquarters in 1983 by purchasing John A. Borneman and Sons outside of Philadelphia.



1923 and 1980 in 2023 dollars; adjusted to current population

More active manufacturers resulted in more association activities that continue to this day. Three educational seminars were organized that decade. In 1981, AAHP proposed to FDA criteria to categorize individual homeopathic products into either prescription drugs or over-the-counter drugs. This occurred against a backdrop of FDA's episodic attention to the 1951 Durham Humphrey Amendment that considered all homeopathic products as prescription only. However, the agency's attention was unevenly applied in relation to imported homeopathic products verses domestically produced homeopathic products. This intermittent attention created problems for FDA, U.S. Customs, and manufacturers — a situation which together cried out for a fair and even-handed resolution.

For five years, AAHP members worked together to address FDA's concerns, which led to an appropriate compliance policy. Al Lorman was brought on as AAHP's Legal Counsel to represent the industry during negotiations with FDA. This resulted in the regulatory framework that governed the marketing of homeopathic products for nearly 30 years: the 1988 Compliance Policy Guide 400.400, Conditions Under Which Homeopathic Drugs May be Marketed.[1] This was a major victory for AAHP and significantly advanced the U.S. homeopathic market.

1990s

The CPG 400.400 brought stability; manufacturers and retailers now felt safe investing in homeopathic products on a wider scale. This resulted in products jumping from health food stores with the then-niche natural shopper to the Food/Drug/Mass retail channel with a wider general audience of shoppers.

With set government rules in place, retail barriers broken down, and demand for products building, the question became, "was the industry equipped to deliver?" AAHP turned its attention to educating manufacturers on quality issues to ensure public safety. At the same time, AAHP wrote and sponsored a Continuing Education Course for pharmacists.

In 1995, AAHP hosted a compliance roundtable for industry with FDA's Edward Miracco, who was assigned by the agency to field questions about CPG 400.400. AAHP's educational programs, now branded as "Compliance Through Education," offered an efficient way for FDA to reach many manufacturers at once.

This industry-wide consensus provided by AAHP is a requirement when dealing with most government entities. Mark Land, current AAHP President and Boiron USA Vice President of Government and Regulatory Affairs, recalls his French-based employer experienced issues importing homeopathic products into the United States. The company filed a petition with the U.S. Customs Service (now the U.S. Customs and Border Protection) in the late 1990s. The petition argued that, although the starting material of a homeopathic product may be too dilute to test at that time, the sugar spheres used as the inactive substrate in homeopathic OTCs were different than sugar used as a sweetener. The Customs Service — much like BATF in the 1980s — asked for industry agreement on the point and AAHP assisted in verifying and speaking on behalf of the industry with an outcome that was favorable to all.

AAHP took full advantage of this decade-long pipeline into FDA created by Miracco, working on the following issues:

- Drug listing complexity/potential solution for homeopathic drug products.
- English names only requirement on homeopathic drug product labels.
- Exemption from the Imprinting of Solid Oral Dosage Form Drug Products for Human Use.
- Exemption from Alcohol Content Limits.
- Solution to BATF drawback issues.

As an approachable liaison to the industry, Miracco formed an invaluable and successful relationship between FDA and the industry through AAHP. Equally significant, AAHP provided FDA with the industry-wide representation it required; the agency did not want to hear viewpoints of single companies. Miracco had a particularly strong relationship with HPCUS President Jack Borneman; they spoke regularly. It is unfortunate that when Miracco retired in 2006, his replacements at the agency were not interested in homeopathic products; this connection between FDA and AAHP was lost to the detriment of both.

2000s

Interest in natural products continued to grow into the new century. Increasing consumer demand enticed "Big Pharma" companies to purchase homeopathic product lines and smaller niche manufacturers. Land notes, "This created new challenges and new opportunities for AAHP." The association entered an era of diversified members: small and large, as well as companies solely dedicated to homeopathy and others with varying product lines.

A new era in adverse event reporting also began in 2006. The reporting requirements applied to homeopathic products as well. From that point on, AAHP emphasized information to its membership on the importance of ensuring public safety through quality controls in production.

Throughout the 2000s the association focused on:

- Presenting 13 educational events for the industry.
- Supporting AIH's rededication of the Samuel Hahnemann Memorial.
- Conducting a market survey on size, sales, and product line distribution.
- Requesting an exemption for a stay of revocation of final product testing.
- Successfully reversing U.S. Customs Service's classification of homeopathic drug products as "foods."
- Contracting a survey of American Association of Poison Control Centers (AAPCC) on the safety of homeopathic drug products.

2010s

AAHP's educational events jumped to the next level; 17 in-person and virtual programs were organized during this decade whereas just one annual seminar was held in the past. During one three-year period, AAHP educated more than 500 people, engaging more and more members of the industry.

AAHP worked with FDA to address challenges with the electronic drug listing that were unique to homeopathic products. For example, multiple attenuations/dosage forms of homeopathic drug products would not require individual submissions and unique identifiers for homeopathic starting materials were created for use by all interested manufacturers.

Behind the scenes, AAHP was also active in maintaining a favorable regulatory environment. It worked with the Consumer Healthcare Products Association, a reciprocal member and ally, to ensure homeopathic prescription drugs were exempt from new requirements on supply chain tracking imposed by the newly passed Drug Quality and Security Act. AAHP also successfully defended the industry against unintended consequences of OTC monograph reform by monitoring and advising lawmakers on provisions of the legislation that would have subjected homeopathic manufacturers to user fees.

Government Relations

The efforts mentioned above were the result of a federal relations program that AAHP launched in 2011. For more than a dozen years, AAHP has worked to educate Congressional members and their staffers on homeopathic drug products and appropriate regulations. AAHP members continue to receive regular and breaking news reports of legislative and regulatory activities that may affect the future of their business.

This program has included:

- A Congressional luncheon briefing at the U.S. Capitol Visitor Center for dozens of Capitol Hill staff.
- Honoring Senator Tom Harkin (D-Iowa) with AAHP's Legislative Excellence Award in appreciation for introducing and supporting legislation that safeguards Americans' right to choose complementary health care.
- Honoring Senator Barbara Ann Mikulski (D-Maryland) with AAHP's Legislative Excellence Award for her support of policies that safeguard homeopathic manufacturers and medicines.
- Organizing an intimate luncheon with Senator Bob Casey (D-Pennsylvania) with prominent members of the homeopathic community in Pennsylvania, including local NCH and AIH representatives and homeopathic manufacturers with employees in the state.

Each year AAHP works to ensure a favorable regulatory climate for homeopathic products while maintaining public safety. Congressional staff are continually educated through meetings. AAHP members also attend fundraisers and local events through organizations such as a Chamber of Commerce to raise awareness of homeopathy directly to Members of Congress.

FDA Hearing and Guidance (2015–2022)

In 2015, FDA held a public hearing on the regulatory framework of homeopathy due to its concerns about unexpected market growth and corresponding safety statistics. Within three weeks, AAHP identified a wide variety of experts, obtained speaker time slots, and hired a firm specializing in FDA communications to review presentations and prepare the speakers. AAHP financially supported these efforts as well as hiring a prominent toxicologist to analyze data maintained by the American Association of Poison Control Centers (AAPCC). Some of the funding for this intensive analysis was contributed by the Consumer Healthcare Products Association, an AAHP member to whom AAHP expresses much gratitude for this support. The analysis revealed the number of exposures to homeopathic medicines in any given year was less than 1 percent of all pharmaceutical reports to AAPCC, which is proportionally below their market share. Furthermore, 99 percent of all exposures were managed outside of a health care facility.

Two years later, FDA published a guidance document[2] on homeopathic product enforcement, which underwent subsequent revisions. (Read more in "Regulatory Framework for Homeopathic Medicines.")

FTC Workshop and Disclaimer (2015–2017)

AAHP rallied again for the Federal Trade Commission (FTC) "Workshop on Homeopathic Medicine & Advertising," also held in 2015. The workshop focused on clinical trials of homeopathic products or a disclaimer statement on labeling and advertising.

The association identified, nominated, and prepped half of the 20 panelists/subject experts in industry growth, scientific support for advertising claims, and legal/regulatory issues, including class action lawsuits. The workshop resulted in FTC publishing an enforcement policy a year later,[3] which included a very negative and lengthy recommended disclaimer. AAHP met with FTC, developed a research protocol leading to the

creation of and consumer-testing of disclaimer language. This was presented to FTC and achieves both of its goals: to inform consumers about the nature of the evidence supporting homeopathic product claims; and to protect the seller from claims of misrepresenting the product. AAHP underwrote the costs of this effort in the amount of $100,000 — a sum that would have been difficult, if not impossible, for most companies on their own. (Read more in "Regulatory Framework for Homeopathic Medicines.")

2020s: Recent Activities

For activities related to the FDA Guidance and the FTC enforcement policy, AAHP members raised around $450,000. "That was heroic by our standards at the time," recalls Land. "It is a strong measurement of how much coalescence could happen within the membership. And it led the entire industry and homeopathic community."

With more members and more budget, the association's focus has shifted to building compliance and a relationship with FDA by working on regulatory and technical ambiguities in cGMP observance. AAHP has hosted a series of industry-wide "summits," the first of which drew more than 100 in-person attendees from the U.S. and five other countries. FDA's Director of Office of Manufacturing Quality served as the keynote speaker; this led to engagement with FDA's Office of Compendial Affairs to identify and solve technical gaps.

The second summit continued to build relations with FDA by together exploring compliance solutions related to the agency's enforcement priorities. This summit included a frank dialogue with the presenter from FDA who also provided breaking insights into FDA's concerns with potential contaminants impacting inactive ingredients commonly used in homeopathic products. These insights helped the industry avoid problems by knowing of their possibilities ahead of time. FDA presentations at AAHP Summits continue an ongoing collaborative educational effort with FDA personnel that began a number of years earlier with their presentations at in-person and virtual seminars.

AAHP responded to FDA's enforcement action against homeopathic injectable products by engaging in meaningful discussions with FDA's Office of Compliance. These meetings revealed the agency's concern about safety. AAHP then filed an amicus curia in support of the safety of homeopathic medicines in general.

On behalf of membership and the industry in general, AAHP filed comments and alerted industry on FDA's draft guidance on annual reporting of quantities of drugs manufactured or compounded. AAHP's comments focused on the large variety of homeopathic drug products and the small quantities produced in comparison with the goals of collecting the information. AAHP requested revision of the guidance to only require submission of relevant and meaningful information.

Last, in recent years, AAHP launched an annual Industry Reception. This forum is designed to connect and support retailers who champion the industry's products with manufacturers' sales executives. At the receptions, the AAHP Integrative Medicine Retailer Award has been presented to Wegmans, Rite Aid, Meijer, H-E-B, and Walgreens. Concurrently, the association launched a successful Annual Executive Briefing for C-level leaders within member companies.

Second Century

As the organization's second century begins, the shifting constellation of members and changing association focus has made the original name misleading to many. As noted above, the "industry" has evolved from individual pharmacies to manufacturing and marketing companies. Thus, beginning in 2024, a new name has been adopted: **American Association for Homeopathic Products.**

AAHP Legacy

The legacy of AAHP is in substantially shepherding the development of the regulatory framework over the last decades. The resulting stable environment attracted investment and business flourished.

The stability in the marketplace increased broader retail access to and visibility of the products. In turn, a broader audience continues to discover and benefit from homeopathic products. Despite a current less-than-friendly regulatory environment, much is built upon AAHP's regulatory expertise and decades of work with FDA and FTC as described throughout this article.

The development of these positive marketing conditions would not have been possible without the support of AAHP member companies, and the collegial relationship fostered through working together.

Many factors have dramatically required AAHP to evolve, yet the core goal remains the same: educating manufacturers to offer high-quality products and communicate clearly with consumers.

References

1. 53 Fed. Reg. 221728 (June 9, 1988).
2. United States Food and Drug Administration, Homeopathic Drug Products Guidance for FDA Staff and Industry. (December 7, 2022).
3. United States Federal Trade Commission, Enforcement Policy Statement on Marketing Claims for OTC Homeopathic Drugs. Federal Register. Vol. 81, No. 239. (December 13, 2016).

AMERICAN ASSOCIATION FOR HOMEOPATHIC PRODUCTS

AAHP

— EST. 1923 —

CHAPTER THREE:

Regulatory Framework for Homeopathic Medicines

REGULATORY FRAMEWORK

Introduction

The principal federal regulators of the manufacture, sale, and marketing of homeopathic drug products are the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC). Both agencies recognize the drug status of homeopathic products and believe that the regulatory requirements for drugs in general apply to homeopathic drug products. However, owing to the uniqueness of homeopathic drug products, both FDA and FTC have chosen to use guidance and enforcement policy statements to state their view of how the law applies to homeopathic drugs.

United States Food and Drug Administration

STATUTORY RECOGNITION OF HOMEOPATHIC DRUGS

Since the passage of the 1938 Federal Food, Drug, and Cosmetic Act (FDCA), homeopathic drugs are the only form of alternative or complementary medicine which is explicitly recognized by FDCA. Section 201(g)(1) of the Act, 21 USC. 321(g)(1), defines a drug as, *inter alia*, an article "recognized in the official United States Pharmacopeia [or] official Homœopathic Pharmacopœia of the United States (HPUS)." Section 501(b) of FDCA, 21 USCA 351(b), provides that a drug shall be deemed to be adulterated, "if it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium." Similarly, Section 502(e)(3), 21 USCA 352(e)(3), provides that a drug labeled as homeopathic is misbranded unless it bears the "established name" of that drug in the HPUS.[1]

Given its prominence in both law and regulation, the HPUS is an invaluable reference for both FDA and industry. The HPUS is the legally recognized source of identification and quality standards for the 1,300 homeopathic active ingredients which are the subject of HPUS monographs. In addition to containing specific monographs, the HPUS also contains manufacturing protocols and other information applicable to homeopathic drugs generally.

HOMEOPATHIC DRUGS CLASSIFIED AS PRESCRIPTION

The 1951 Durham-Humphrey Amendment[2] to the FDCA created a statutory distinction between over-the-counter (OTC or nonprescription) and prescription (Rx Only) drugs. FDA had previously enforced this distinction by a regulation which relied upon its view that the statutorily required "adequate directions for use" could not be written for certain drugs because of their toxicity or the need for physician supervision. Although the amendment did "not appear to directly encompass homeopathic preparations as prescription drugs," FDA was persuaded by the American Institute of Homeopathy to categorize virtually all homeopathic drugs as prescription due to the individualized nature of treatment. This view was tempered, however, in that the agency noted it would not act against homeopathic products "without the prescription legend which are offered to the laity or minor ailments."[3]

REGULATORY FRAMEWORK

HOMEOPATHIC DRUGS EXCLUDED FROM OTC DRUG REVIEW

The 1938 FDCA required only that "new drugs" be examined by FDA for safety. In the Drug Amendments of 1962 (aka Kefauver-Harris Amendment), Congress added a statutory requirement that "new drugs" must also be shown to be effective.[4] That law also required FDA to re-review all previously approved "new drugs" for effectiveness. The agency created two separate structures for this review of existing drugs: the 1967 Drug Efficacy Study Implementation (DESI) system, under contract to the National Academy of Sciences/National Search Council for prescription drugs, and the 1972 OTC Drug Review for OTC drugs.

Neither the 1962 Drug Amendments nor the two FDA-created review processes included homeopathic drugs. In a consumer paper published by FDA 26 years later, the agency implied the reason for this exemption was similar to the exclusion from the FDCA safety review: [homeopathy] "was of little concern at the dilution being used".[5] The exemption might also have been due to the therapy's dwindling popularity at the time, as another 1988 FDA consumer publication implied action might not have been taken until "a growing problem."[6]

Due to low safety risks, no homeopathic drugs had undergone the "new drug" approval process prior to 1962, so they were not included in the prescription-only DESI Review.

When it created the 1972 OTC Drug Review, FDA decided it would be more efficient to review OTC drugs by active ingredient category rather than review drugs individually, as it had in the as-yet unfinished DESI Review. In announcing the procedures for that review, FDA stated: "Because of the uniqueness of homeopathic medicine, the Commissioner has decided to exclude homeopathic drugs from this OTC drug review and to review them as a separate category at a later time after the present OTC drug review is complete."[7]

More than a half century later, FDA had not completed the review of allopathic OTC drugs nor indicated any interest in starting the promised homeopathic OTC review.

CPG 400.400

As previously stated, while implementing the Durham-Humphrey Amendment, FDA categorized homeopathic products as prescription drugs, but the agency seldom enforced this against homeopathic OTCs and almost never against domestic manufacturers. FDA did, however, episodically and inconsistently enforce the Rx Only requirement against imported homeopathic drugs, including seizures of imported homeopathic drugs not labeled as Rx Only.

In the mid-1980s, AAHP took the lead in working with FDA to solve this inequitable situation. The result was the 1988 issuance of Compliance Policy Guide (CPG 400.400) "Conditions Under Which Homeopathic Drugs May be Marketed."[8] This CPG allowed homeopathic products to be marketed as OTC drugs for mild and self-limiting conditions as well as prescription drugs that must be dispensed under the care of a licensed practitioner for the treatment of serious disease conditions.

CPG 400.400 restated the existing statutory or regulatory requirements for marketing homeopathic drug products. It also provided educational information on homeopathic products for FDA personnel and key definitions, including:

- A definition of "homeopathic";
- Reference resources for traditional uses of homeopathic drugs;
- How to handle instances in which the active ingredient was not in the HPUS;

- Recognition of the different way in which the strength of homeopathic active ingredients is declared (e.g., 10X, 20X, 10C); and
- A recitation of statutory and regulatory labeling requirements.

CPG 400.400 led to major changes in the homeopathic industry and the marketing of homeopathic drugs. Prior to the CPG, the only indication on the label of most homeopathic drugs was, "Use according to standard homeopathic indications." While that fit well with the symptom-based approach central to the practice of homeopathy, FDA insisted in the CPG that the statute required a specific indication. The addition of familiar indications to homeopathic labels aided many consumers as they sought alternatives to other available medicines.

GUIDANCE CHANGE FROM COMPLIANCE TO RISK-BASED ENFORCEMENT

In 2015, 27 years after publishing CPG 400.400, FDA conducted a public hearing to evaluate its enforcement policies for drug products labeled as homeopathic from scientific, risk, and process perspectives.

The result of the hearing and subsequent multiple engagements between FDA and multiple stakeholders was the revocation of the compliance-based guidance in 2017 and the finalization of a risk-based enforcement priority guidance on Dec. 7, 2022.[9] Homeopathic Drug Products Guidance for FDA Staff and Industry contains many important policy considerations, including several recommended by AAHP. It also reiterates FDA's position that homeopathic drugs are unapproved new drugs and lists the agency's six categories of enforcement priorities. In the guidance's introduction, FDA states, "The agency anticipates that many homeopathic drug products will fall outside the categories of drug products that FDA intends to prioritize for enforcement and regulatory action."

FDA's view is any drug that does not have an approved New Drug Application, or which is not subject to an OTC monograph, is an "unapproved new drug." Despite its language, the new guidance does not change the legal status of homeopathic drugs. AAHP's position is that FDA's failure to fully implement the Drug Amendments of 1962 does not make homeopathic drugs illegal; FDA's inaction does not determine the legal status of these products.

Given the inherent safety of this class of drugs and remarkably low enforcement history against the category, AAHP believes that regulation via guidance is an effective way for FDA to protect the public health while preserving the agency's resources. The newly-stated risk-based approach is, in fact, simply a recognition of how FDA regulated homeopathic drugs under CPG 400.400.[10] However, guidance needs to be clear and complete enough to provide adequate direction to both industry and agency staff.

Recognizing FDA's reliance on risk-based enforcement, AAHP and the homeopathic community's future focus should be on addressing the issues outlined below.

FUTURE

Guidance documents are subject to interpretation by various FDA staff conducting facility inspections and as well as thousands of industry staff trying to comply with the guidance every day. An incomplete guidance compounds this problem and facilitates uneven enforcement. Unpredictable enforcement is resource intensive and distracts both FDA and industry from more important priorities. The current guidance and regulation fail FDA and industry alike. AAHP proposes the homeopathic community focus on advancing the following areas to ensure the reputation of homeopathic products.

Quality Gaps in Regulatory Guidance: While homeopathic products are part of the pharmaceutical industry in the United States, there are significant differences between homeopathic and allopathic drug products

that require specific attention. Most of the differences relate to the nature of homeopathic active ingredients, which are often below the limit of detection of most modern analytical instrumentation in the final drug product. This reality impacts many facets of manufacturing and quality control of these products. Despite analytical challenges associated with homeopathic active ingredients, AAHP believes that every attempt should be made by industry and FDA to effectively establish the identity and quality of homeopathic drug products.

Specific guidance related to the unique characteristics of homeopathic drug products is necessary for both industry and FDA to meet expectations and ensure public safety Specifically:

- Starting materials: Clear guidance for the identification, inspection, and receipt of homeopathic starting materials from many varied sources.
- Dilution validation: Practical methodology to apply validation principles to the homeopathic dilution manufacturing process.
- Discrete dosage forms: Testing objectives related to content uniformity of discrete dosage forms.
- Finished products: Sound strategies for quality testing of final homeopathic products across the range of dosage forms.

Recognition of Safety Evaluation: A key consumer benefit of homeopathic products is the remarkable safety record of this class of drugs. The safety of homeopathic products is primarily due to the products being labeled for self-limiting conditions (with limited duration of use) and the extremely low level of active ingredients in the products. With adequate safety limit testing, diluted starting materials attenuate any potential toxicity of the active homeopathic ingredient.

Most jurisdictions and regulatory authorities around the world have adopted this foundational attribute of homeopathic products. The European Union (EU) has adopted a methodology for establishing the first safe dilution for homeopathic starting materials.[11] HPCUS also calculates the lowest permissible (or first safe) attenuation.

These methodologies are powerful tools to establish safe dilution levels for all age groups, which should be recognized by U.S. regulators when evaluating the safety of homeopathic medicines. FDA's acknowledgement of these methods would be an effective way to protect the public and further preserve the agency's resources.

Recognition of Medical Literature to Substantiate Efficacy: The clinical use of homeopathic drugs by generations of physicians and consumers has been carefully recorded within homeopathic medical literature. This collection of data documents the symptoms associated with a given homeopathic active pharmaceutical ingredient (symptom picture) and corresponding clinical application. The rich literature base provides the justification for doctors to determine treatments for patients and supports claims made on product labels.

The literature serves as the basis for approval of homeopathic drugs in most jurisdictions around the world. Acceptable references of traditional homeopathic use were included in previous guidance in the U.S. but not the current guidance. Establishing reference to homeopathic literature would not only recognize the homeopathic clinical tradition, but also establish metes and bounds for claims on product labels.

REGULATORY FRAMEWORK

United States Federal Trade Commission

Section 5 of the Federal Trade Commission Act of 1914 prohibits "unfair or deceptive acts or practices in or affecting commerce," and Section 12 prohibits the dissemination of false advertisements for foods, drugs, devices, services, or cosmetics.[12] Section 15 of the FTC Act defines "false advertisement" as "advertising that is misleading in a material respect".[13]

FTC's authority extends to claims made for health care products, including homeopathic drugs. Given the overlapping authority for health care products, FDA and FTC adopted a Memorandum of Understanding in 1971 that allocates primary jurisdiction for advertising to FTC and primary jurisdiction for labels and labeling to FDA.

Due to increasing consumer interest in homeopathic products, FTC conducted a workshop in 2015 to investigate the policies and practices of the industries and its own enforcement policies related to substantiation of claims made in advertising of homeopathic drugs. At that time, FTC staff asserted in comments to FDA that there was a "potential" conflict between the requirements of CPG 400.400 and the FTC Act's advertising substantiation requirement: "the requirement that labeling for homeopathic drugs display an indication for use, even when the product has not been demonstrated to be efficacious for that indication, creates a potential conflict with the FTC's requirement that health claims be substantiated by competent and reliable scientific evidence."[14]

In 2016, FTC published its Enforcement Policy Statement on Marketing Claims for OTC Homeopathic Drugs that stated: "The FTC Act does not exempt homeopathic products from the general requirement that objective product claims be truthful and substantiated."

"However," the Commission added, " FTC has long recognized that marketing claims may include additional explanatory information in order to prevent the claims from being misleading. Accordingly, the promotion of an OTC homeopathic product for an indication that is not substantiated by competent and reliable scientific evidence may not be deceptive if that promotion effectively communicates to consumers that: (1) There is no scientific evidence that the product works and (2) the product's claims are based only on theories of homeopathy from the 1700s that are not accepted by most modern medical experts."[15]

While AAHP disagrees with the factually incorrect language of FTC's proposed disclaimer, the association generally believes that FTC struck a good balance by encouraging explanatory information on product labels to minimize risk of consumer confusion. AAHP hired an acknowledged university expert in consumer perception to conduct extensive research to develop a disclosure statement that met FTC's communications objectives. Based on that research, AAHP recommends that product labels and advertising for homeopathic drugs not supported by clinical research prominently bear the following disclosure: "Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated."

FTC's Health Products Compliance Guidance, published in 2022, reinforced the Commission's position that health claims should be supported with adequate, competent, and reliable scientific evidence. Homeopathic products are specifically named among categories of health products covered by the guidance. This reiterates, but doesn't replace, FTC's expectation stated in its 2016 Enforcement Policy Statement.[16]

AAHP believes that products bearing health claims supported by the homeopathic literature for reasonable self-limiting conditions and prominently bearing the disclaimer developed by the association are non-deceptive and well labeled.

REGULATORY FRAMEWORK

AAHP calls on the research community to continue the work of advancing the knowledge of the mechanism of action of the category of products related to their clinical application to the satisfaction of the consumers and regulatory authorities alike.

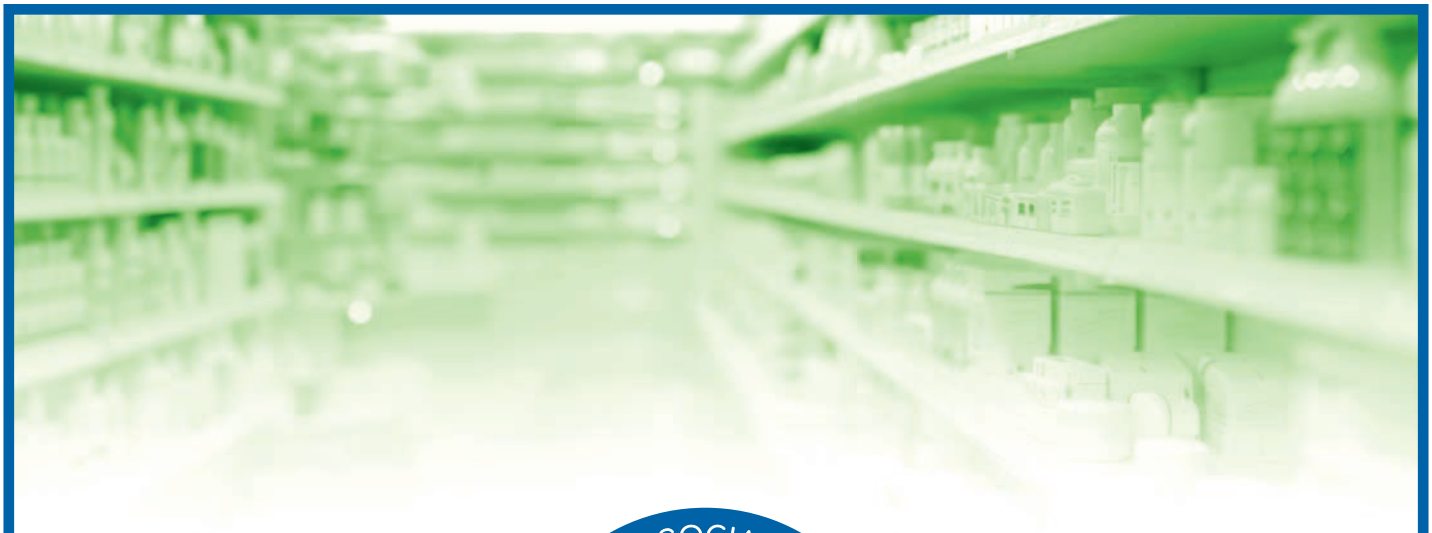
To that end, the association has sponsored more than one public virtual presentation by the Homeopathic Research Institute (HRI) regarding the current research situation and the need for duplication of research to meet accepted standards expected by the greater research community. AAHP also encourages both industry and the homeopathic research community to conduct trials on actual product formulations to support label claims based on historical homeopathic literature.

Conclusions

There is a well-established framework of guidelines, regulations, and quality standards for homeopathic drugs. There are still some gaps in cGMP requirements and possibilities for varying interpretations of the guidance documents; thus while the situation is relatively stable, AAHP and the homeopathic community can help fine tune the regulatory environment to minimize misunderstandings and inconsistent compliance activity. Compliance is enforced by FDA through routine pharmaceutical manufacturing site inspections and surveillance of product labels marketed to consumers. This process safeguards public safety while ensuring consumer access to this drug class, which is known for its safety and medical-economic value.

References

1. Pub. L. 75–717, 52 Stat. 1040 (1938).
2. Pub. L. 82–215, 65 Stat. 648 (1951).
3. Administration Information Letter No. 269, 500.13 Homeopathic drugs are classified as prescription drugs under the Durham-Humphrey Amendment (July 3, 1953) cited in S.W. Junod, "An Alternative Perspective: Homeopathic Drugs, Royal Copeland, and Federal Drug Regulation," 55 Food Drug Cosm. L.J. 1, 161–183 (2000).
4. Pub. L. 87–781, 76 Stat. 780 (1962).
5. Press Office, & Gregg, W., FDA Talk Paper T88-68, (September 15, 1988), pp. 1–3. Silver Spring, MD; United States Food and Drug Administration.
6. "Updates: FDA Sets Homeopathic Drug Guidelines," FDA Consumer, (December 1988–January 1989), p. 5. Silver Spring, MD; United States Food and Drug Administration.
7. 37 Fed. Reg. 9466 (May 11, 1972).
8. 53 Fed. Reg. 221728 (June 9, 1988).
9. United States Food and Drug Administration, Homeopathic Drug Products Guidance for FDA Staff and Industry. (December 7, 2022).
10. United States Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Report on the State of Pharmaceutical Quality: Fiscal Year 2021. (August 2022) p. 5. Accessed at: http://www.fda.gov/media/161172/download.
11. Heads of Medicines Agencies, Homeopathic Medicinal Products Working Group. Introduction of the List of First Safe Dilutions. (Adopted May 2010). Accessed at: https://www.hma.eu/about-hma/working-groups/homeopathic-medicinal-products-working-group.html.
12. 15 U.S.C. §§ 45, 52.
13. 15 U.S.C. § 55(a)(1).
14. "Comments of the Staff of the Federal Trade Commission." Submitted to the Food and Drug Administration, Department of Health and Human Services in Response to a Request for Comments Related to Its Public Hearing on Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century. 80 Fed. Reg. 16327 (March 27, 2015). Submitted on August 21, 2015. Matter Number: P114505 Docket 80 Fed. Reg. 16327 (March 27, 2015). Accessed at: https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-food-drug-administration-regarding-current-use-human-drug-biological-products/150821fdahomeopathic.pdf.
15. United States Federal Trade Commission, Enforcement Policy Statement on Marketing Claims for OTC Homeopathic Drugs. Federal Register. Vol. 81, No. 239. (December 13, 2016).
16. United States Federal Trade Commission, Health Products Compliance Guidance. (December 20, 2022). Accessed at: https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

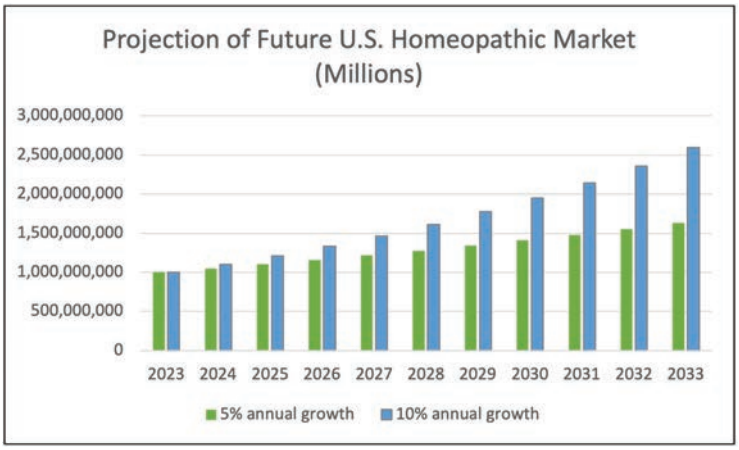


CHAPTER FOUR:

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.

References

1. Guidelines for Manufacturing Homeopathic Medicines §40.1 Dosage Forms. Homeopathic Pharmacopoeia of the United States. Homeopathic Pharmacopoeia Convention of the United States. 2023. www.hpus.com (accessible by subscription).
2. Guidelines for Manufacture of Homeopathic Medicines §2 Diluents and Vehicles. Homeopathic Pharmacopoeia of the United States. Homeopathic Pharmacopoeia Convention of the United States. 2023. www.hpus.com (accessible by subscription).
3. United States Food and Drug Administration, National Drug Code Directory 2021. Accessed at: https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm.
4. McNally, G., "OTC Dosage Form Innovation in OTC Pharmaceuticals." *Pharmaceutical Technology*, (April 2020), pp. S4–9. Accessed at: https://www.researchgate.net/publication/340565860_Oral_Dosage_Form_Innovation_in_OTC_Pharmaceuticals.
5. Hein, T., "Market Survey — Dosage Forms: It's Time to Listen to Consumers. Drug Development & Delivery." (September 2015), pp. 22–29. Accessed at: https://drug-dev.com/market-survey-dosage-forms-its-time-to-listen-to-consumers.
6. United States Food and Drug Administration. National Drug Code Directory 2021. Accessed at: https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm.
7. Laffleur, F., Keckesis, V., "Advances in Drug Delivery Systems: Work in Progress Still Needed?" *International Journal of Pharmaceutics.* X. 100050, (December 2, 2020), pp. 1–15. Published online June 12, 2020. Doi: 10.1016/ j.ijpx.2020.100050.
8. United States Food and Drug Administration. National Drug Code Directory 2021. Accessed at: https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm.
9. Coronavirus Aid, Relief, and Economic Security Act (CARES Act). (March 27, 2020). Public Law No. 116–136, 134 Stat. 281, 457.
10. United States Food and Drug Administration, OTC Drug Review Process | OTC Drug Monographs. Accessed at: https://www.fda.gov/drugs/otc-drug-review-process-otc-drug-monographs.
11. United States Food and Drug Administration, Overview of FDA's Proposed Rule: Nonprescription Drug Product with an Additional Condition for Nonprescription Use. (February 1, 2023). Accessed at: https://www.fda.gov/drugs/news-events-human-drugs/overview-fdas-proposed-rule-nonprescription-drug-product-additional-condition-nonprescription-use.
12. Albuck, M., & Gillis, L., "The Evolution of Self-Care." (June 2021), pp. 1–12. Chicago, IL: Information Resources, Inc. (IRI). Accessed at: https://www.iriworldwide.com/IRI/media/Library/IRI-Evolution-of-Self-Care-POV.pdf.
13. Reagan-Udall Foundation for the FDA, "Snapshot 2022: A Changing Environment for FDA-Regulated Consumer Products; Symposium Summary." (April 28, 2022), pp. 1–18. Washington, DC. Accessed at: https://reaganudall.org/sites/default/files/2022-12/112122_Snapshot%202022_FINAL.pdf.
14. GlobalData Plc., "Pharmaceutical Packaging Market Size, Share, Trends and Analysis by Region, Material, Product , Drug Type and Segment Forecast to 2026." (March 10, 2023), pp. 1–235. London, UK. Accessed at: https://www.globaldata.com/store/report/pharmaceutical-packaging-market-analysis.
15. Eriksson, D., Granskog, A., & Feber, D., "Sustainability in Packaging: Inside the Minds of Global Consumers." (December 16, 2020). New York, NY.: McKinsey & Company. Accessed at: https://www.mckinsey.com/industries/paper-forest-products-and-packaging/our-insights/sustainability-in-packaging-inside-the-minds-of-global-consumers.
16. Quelch, R., "Sustainable Pharma Packaging: Breaking Down the Barriers to Adoption. European Pharmaceutical Review." (October 5, 2022). Accessed at: https://www.europeanpharmaceuticalreview.com/article/174874/sustainable-pharma-packaging-breaking-down-the-barriers-to-adoption.
17. United States Food and Drug Administration, The Nonprescription Drug Facts Label in a Changing Consumer Marketplace 2021. (June 9, 2021). Accessed at: https://www.fda.gov/drugs/news-events-human-drugs/nonprescription-drug-facts-label-changing-consumer-marketplace-2021-06092021-06092021.
18. Ascher, J., Höglund, D., Mlika, A., & Vancauwenberghe, M., "From Product to Customer Experience: The New Way to Launch in Pharma." (August 15, 2018). Washington, DC: McKinsey & Company. Accessed at: https://www.mckinsey.com/industries/life-sciences/our-insights/from-product-to-customer-experience-the-new-way-to-launch-in-pharma.
19. United States Food and Drug Administration, The Nonprescription Drug Facts Label in a Changing Consumer Marketplace 2021. (June 9, 2021). Accessed at: https://www.fda.gov/drugs/news-events-human-drugs/nonprescription-drug-facts-label-changing-consumer-marketplace-2021-06092021-06092021.
20. United States Food and Drug Administration, Drug Facts Rule (64 FR 13286). (March 17, 1999). Codified at 21 CFR §201.66.
21. United States Food and Drug Administration, FDA Announces Proposed Rule: Nonprescription Drug Product with an Additional Condition for Nonprescription Use. (June 28, 2022). Accessed at: https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/fda-announces-proposed-rule-nonprescription-drug-product-additional-condition-nonprescription-use.

CHAPTER FIVE:

Future of AAHP

FUTURE OF AAHP

Increase and Diversify Membership

With the growing consumer interest in homeopathic drug products, more manufacturers enter the homeopathic industry each year. AAHP welcomes all industry members committed to delivering compliantly marketed and quality manufactured homeopathic products to American consumers. AAHP is working diligently to expand membership to as many of our industry colleagues as possible. The AAHP Board of Directors has set a goal of doubling our membership within the next five years with the aim of increasing the diversity of membership.

For 100 years, AAHP has represented the manufacturers of homeopathy. Over time, AAHP's scope grew into representing distributors, labelers, and marketers. Along the way, membership welcomed foreign-based manufacturers conducting business in the United States as well as companies providing relevant products and services to homeopathic manufacturers and marketers.

As explored in "History of AAHP," one of the association legacies has been bringing together a wide variety of industry members. This goal was difficult in the early years of the association due to regional and structural differences. The challenges have changed and will continue to change as manufacturers and marketers remain vastly diverse. Yet our commonalities and needs grow stronger with each passing year.

Thus, AAHP will strive to adequately and equitably represent a future membership whose business objectives become increasingly divergent. This is reflective of an increasingly heterogeneous homeopathic community with a common goal of providing high-quality compliant homeopathic drug products.

Expand Programs to More Stakeholders

AAHP's history and strength lie in communications and education with manufactures and regulators. In the last decade, the association has expanded its programs to include lobbying on Capitol Hill, an annual retailer award, and social media platforms followed by manufacturers, consumers, and health care practitioners. AAHP will expand and strengthen communications among all key stakeholders to further improve the reputation of homeopathic medicines:

- Manufacturers: Education
- Regulators: Surveillance, Advocacy, and Representation
- Legislators: Capitol Hill Advocacy and Education
- Retailers: Education and Recognition
- Consumers and Health Care Practitioners: Outreach and Education

While emphasis continues on existing programs and services, the association plans to increase communications with retailers, consumers, and health care practitioners utilizing social media. While social media now makes it much easier to spread a consolidated message, it can also easily amplify disparaging and false information. AAHP endeavors to amplify unified arguments and statements to a much broader audience, in the retail environment, the larger pharmaceutical environment, and the dietary supplement environment. AAHP has launched programs to connect with and stabilize the retail environment.

FUTURE OF AAHP

Meet Future Challenges to Develop the Market

Although AAHP's mission to create a fertile climate for the business of homeopathic medicines to thrive has remained steadfast throughout the years, emerging challenges dictate the necessity of new perspectives. AAHP's work in the immediate future will focus on:

- Stabilizing the regulatory framework for homeopathic drug products.
- Building the reputation of homeopathic products among key stakeholders.
- Supporting the work of the Homoeopathic Pharmacopoeia Convention of the United States.
- Encouraging best practices in manufacturing and quality of homeopathic drug products through education.

As the market continues to grow, AAHP will continue to work for solutions to tomorrow's issues, including:

- Hurdles and consequences of national distribution.
- Breaking through to mainstream shoppers and developing practices that a unified association membership can do to accomplish this goal.
- Educating manufacturers and marketers who are unfamiliar with required compliance measures.
- Developing stable sources for starting materials.
- Defending the reputation of the industry and combatting disinformation facilitated by social media that, among other effects, destabilize the retail environment.

AAHP is proud to have served the homeopathic community for its first 100 years and looks forward to advancing homeopathy for the next 100 years!

AAHP member companies represent about 80% of the homeopathic products in the U.S. market.*

** Products of AAHP member companies during the association's 100th anniversary in 2023.*

CHAPTER SIX:

Research: Past, Present, and Future Support

RESEARCH: PAST, PRESENT, AND FUTURE SUPPORT

The Beginning of Homeopathic Research: Provings

The first recognized clinical trial is attributed to James Lind in 1747.[1] Reflecting the thinking of the age, the first homeopathic pathogenetic trial, or "proving," was published by Samuel Hahnemann in 1796.[2] Using the empirical model, Hahnemann began studying the effects of active homeopathic ingredients by experimenting on himself and others at the founding of homeopathy in the late 18th century. He and his successors at the time were innovators. They were the first scientists to widely embrace experimental blinding, placebo controls, and even testing of medicines before their clinical use — which are all critical aspects of modern randomized controlled trials (RCTs). Few today realize provings were based upon such rigorous scientific practice.[3]

These trials historically used for homeopathy are called "provings," from the German word "prüfung" meaning "test" or "examine."[4] This drug discovery tool is one of the most compelling aspects of homeopathic medicine. Substances are administered to healthy human volunteers ("provers") in concentrations aimed at provoking a symptom picture while minimizing the risk of acute toxicity from the study material. Symptoms experienced by volunteers are rigorously recorded and collated. Analysis of the symptoms aims to reveal the constellation of symptoms associated with a given homeopathic active ingredient. The "symptom picture" is used to indicate possible therapeutic uses for the substances. To a homeopath, if a substance causes a particular symptom, individuals experiencing that symptom would be treated with a diluted solution made from that substance.

After Hahnemann's first ground-breaking proving in 1790 established the uses of Cinchona, he faced the daunting task of conducting as many provings as possible. By 1805, Hahnemann published 27 provings in his *Fragmenta* and 65 provings in his *Materia Medica Pura* (1811–1831).[5] Today's digital *Materia Medicas,* with hundreds of records of substances and the symptoms they produce, are an abundant resource to help practitioners choose appropriate medicines for their patients.

In the modern era, homeopathic pathogenic trials or provings continue to be conducted. Methods have been updated based on contemporary benchmarks and are standardized by principal investigators in concert with organizations including the Homeopathic Pharmacopoeia Convention of the United States (HPCUS), European Committee for Homeopathy (ECH), and LMHI (translated as the International League of Homeopathic Physicians). Blinding and placebo controls are required to control for observer bias. Clinicians must be trained so that they observe and record in a precise method consistent with established protocols. Trial participants (provers) need to understand how to report symptoms to establish precision in cause and effect of symptoms. For the final analysis of the data, an experienced homeopathic prescriber is essential. Problems for prescribers are caused by speculation about causes is recorded rather than a precise observation of what occurred. This mistake invalidates an otherwise good proving.[6]

Despite past and current efforts, there is a gap between demonstrated experiences reported by patients and practitioners for this 200-year-old therapy and what can be proven scientifically to 21st century reviewers. Three types of research are needed to support homeopathy: fundamental (or basic), applied, and clinical. This article explores today's leading-edge research techniques paving the way for future discoveries, and benefits to consumers, practitioners, and manufacturers.

Current Fundamental (or Basic) Research

Fundamental (or basic) research in general explores a law of nature. Specifically for homeopathy, fundamental research is necessary to fully understand the potential mechanism(s) of action. To develop meaningful hypotheses, research teams worldwide review 1) the effect of potentization, 2) the physicochemical properties of homeopathic medicines, and 3) and demonstrate the biological action of homeopathic solutions.

RESEARCH: PAST, PRESENT, AND FUTURE SUPPORT

Historically, fundamental research for homeopathy has been challenging. Now, however, there is a range of experimental models being applied to homeopathic attenuations to demonstrate their biological action.

Additionally, a systematic review of physicochemical study methodologies and outcomes has given direction to the broader basic research agenda to the homeopathic research community.[7] This systematic analysis of the existing research database was conducted by the Homeopathic Research Institute, a London-based non-profit dedicated to promoting high-quality research in homeopathy at an international level. It establishes a methodological approach that can be applied to both basic and clinical research. The goal of the three-part study was to update and expand the current state of knowledge of physicochemical properties of homeopathic preparations.[8]

Although the physicochemical research is in early stages, the homeopathic industry and practitioners should start to consider implications of theories under examination and results from completed preclinical studies. Pharmacologically, any specific treatment effects associated with theorized mechanisms of action such as "quantum coherence domain" hypothesis, the "dynamic water cluster" hypothesis, and the "weak quantum" theory must be assessed experimentally.

In vitro and other preclinical work has yielded important results. Experimental models have demonstrated with specificity objective measurable outcomes in simple biological systems.[9] Learnings from preclinical research must now be applied to complex organisms and humans.

A well-reasoned and demonstrated mechanism of action will also provide a response to the narrative of critics of homeopathy.

Applied Research

While basic research focuses on curiosity and the pursuit of knowledge for its own sake, applied research takes a different approach by examining how real-world phenomena or outcomes can be altered. At its core, applied research is oriented towards identifying practical solutions to specific problems. Its primary objective is not just to add to the existing knowledge base but to leverage that knowledge to develop solutions, innovations, or interventions that can be directly applied in the real world.[10]

For homeopathy, applied research includes in vitro studies; bioassays; agriculture studies; and population effects. Leading researchers in this area include Stephan Baumgartner at the University of Bern, Switzerland; Leoni Bonamin at the University of Paulista, Brazil; and P. Christian Endler at the Interuniversity College for Health and Development, Austria.

Current Clinical Research

Clinical research demonstrates 1) the efficacy of homeopathic medicines, 2) the relevance of the homeopathic approach in real-life situations, and 3) the safety and tolerability of homeopathic medicines.

One challenge in clinical research for homeopathy is maintaining the individualized approach to treatment while enhancing possibilities in trial replication. Researchers in Israel used the Symptom Cluster Approach to facilitate subject identification and medication assigned in individualized homeopathic treatment. This study approach addresses some of the criticisms of homeopathic research methodology and promises to improve study outcomes.[11]

RESEARCH: PAST, PRESENT, AND FUTURE SUPPORT

Another model that presents opportunities in homeopathic clinical research is "Real-World Data" and "Real-World Evidence." For example, an analysis of a large health care database has yielded interesting insights into the use[12] and outcomes of homeopathic medicines at large scale.[13]

Currently there are more than 7,000 published research studies on homeopathy listed in PubMed's database. Clinical research is increasing in quality and better informs patients, prescribers, and decision-makers about homeopathy.[14]

The Homeopathy Research Institute states there is high-quality evidence showing homeopathy works. In a December 2023 press conference, HRI showed there are currently 255 randomized controlled trials (148 of which are double-blind clinical trials) that show homeopathy is more effective than a placebo for 136 clinical conditions.

In that press conference, HRI showed clinical research outcomes in homeopathy are similar to those for conventional medication. For homeopathy, 43 percent of double-blind randomized control trials are positive. In comparison, systematic reviews of conventional medication show 45 percent of double-blind randomized controlled trials are positive.

For manufacturers, clinical research of individualized homeopathic prescriptions is a rich database of information that can be used as a foundational point for formulation of new products for commercial application. Manufacturers may consider results from published research as a basis of developing new product formulas.

Supporting Vital Work of the Research Community

Vital to the growth of the homeopathic market in the U.S. is the development of efficacy review standards appropriate to homeopathy. Industry must unite and support the scientific community to develop review standards that are practical for manufacturers and applicable to homeopathic drug products. The alternative is that regulators will continue to misapply the standards developed to regulate allopathic drugs to homeopathic products.

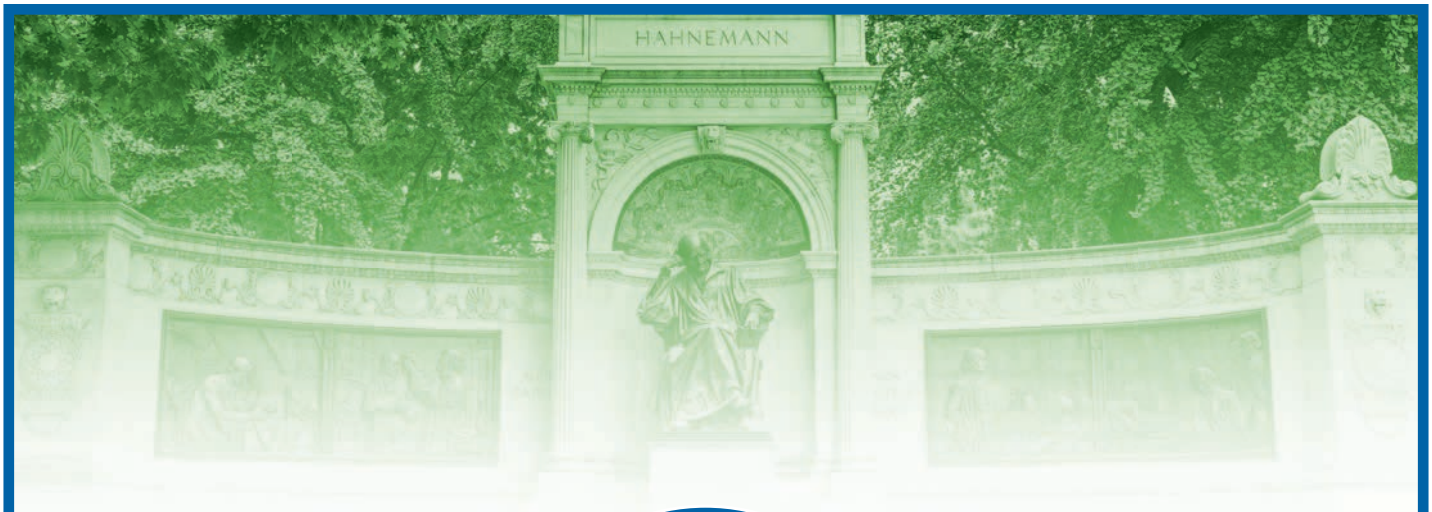
HRI HOMEOPATHY RESEARCH INSTITUTE

While homeopathic practitioners and manufacturers accept the underlying paradigm of homeopathy, homeopathy today exists in a world which values a different approach to medical evidence. Producing that evidence is time-consuming, very difficult, and expensive. Since most homeopathic companies have limited resources, AAHP urges manufacturers and labelers to amplify their research budget by contributing to the vital work being done by homeopathic research institutions and foundations on their behalf.

RESEARCH: PAST, PRESENT, AND FUTURE SUPPORT

References

1. *Perspect Clin Res.* January–March 2010. 1(1): pp 6–10.
2. *J R Soc Med.* December 2026. 99(12): pp 607–610.
3. "Industry Leader Spotlight: Todd A. Hoover, MD, DHt," American Association of Homeopathic Pharmacists. (October 17, 2023.). Accessed at: https://TheAAHP.org/newsletter/industry-leaderspotlight-todd-a-hoover-md-dht.
4. Sheffield, F., MHlthScEd, MAAPH, Tutorial 6 – Provings. Homeopathy Plus! Accessed at: https://homeopathyplus.com/tutorial-6-provings.
5. Peter Morrell, BSc, PGCE, MPhil, "Hahnemann's First Provings." Homéopathe International. (June 2006) Accessed at: http://www.homeoint.org/morrell/articles/firstprovings.htm.
6. "Industry Leader Spotlight: Todd A. Hoover, MD, DHt," American Association of Homeopathic Pharmacist. (October 17, 2023). Accessed at: https://TheAAHP.org/newsletter/industry-leader-spotlight-todd-a-hoover-md-dht.
7. Tournier, A., Klein, S., Würtenberger, S., Wolf, U., & Baumgartner, S. (2019). Physicochemical Investigations of Homeopathic Preparations: A Systematic Review and Bibliometric Analysis — Part 2. Journal of Alternative and Complementary Medicine, 25(9), pp. 890–901. Accessed at: https://www.liebertpub.com/doi/10.1089/acm.2019.00647.
8. Klein, S., Würtenberger, S., Wolf, U., Baumgartner, S., & Tournier, A. (2018). Physicochemical Investigations of Homeopathic Preparations: A Systematic Review and Bibliometric Analysis — Part 1. Journal of Alternative and Complimentary Medicine, 24(5), pp. 409–421. Accessed at: https://www.liebertpub.com/doi/pdf/10.1089/acm.2017.0249.
9. Homeopathic Research Institute 5th International Homeopathy Research Conference. London. (June 15–18, 2023). https://www.hri-research.org/2023/03/full-london-conference-programme-announced.
10. Atlas.ti. Accessed February 9, 2024 at: https://atlasti.com/research-hub/basic-vs-applied-research#:~:text=While%20basic%20research%20 focuses%20on,practical%20solutions%20to%20 specific%20problems.
11. Yakir M, Klein-Laansma CT, Kreitler S, Brzezinski A, Oberbaum M, Vithoulkas G, Bentwich Z (2019). A placebo-controlled double-blind randomized trial with individualized homeopathic treatment using a symptom cluster approach in women with premenstrual syndrome. Homeopathy; 108(4): pp. 256–269.
12. Isabelle Chanel, "Survey of Research on Homeopathy." American Association of Homeopathic Pharmacists. (March 14, 2023.). Accessed at: https://theaahp.org/articles/survey-of-research-on-homeopathy.
13. Medioni, J., Scimeca, D., Lopez Marquez, Y., Leray, E., Dalichampt, M., Hoertel, N., Bennani, M., Trempat, P., Boujedaini, N. Benefits of Homeopathic Complementary Treatment in Patients with Breast Cancer: A Retrospective Cohort Study Based on the French Nationwide Healthcare Database. *Clinical Breast Cancer* (January 2023). 23(1), pp. 60–70.) Accessed at: https://www.clinical-breast-cancer.com/article/ S1526-8209(22)00224-5/fulltext. DOI: https:// doi.org/10.1016/j.clbc.2022.10.001.
14. Homeopathic Research Institute. Clinical Trials Overview. Accessed at: https://www.hri-research.org/resources/essentialevidence/clinicaltrials-overview.



AMERICAN ASSOCIATION FOR HOMEOPATHIC PRODUCTS

AAHP

— EST. 1923 —

CHAPTER SEVEN:

Homeopathy in the United States and Milestones

HOMEOPATHY IN THE UNITED STATES AND MILESTONES

Immigrants, primarily German, brought homeopathy to North America. Early practitioners established the first U.S. teaching academy in Pennsylvania, followed shortly thereafter by one in New York, then Massachusetts. The first pharmacy selling homeopathic medicines opened in 1835 in New York City (and was bought by Boericke in 1862). Otis Clapp & Sons opened in Boston five years later. The growth of homeopathy led physicians to found the American Institute of Homeopathy in 1844. Within a decade, Humphrey's Homeopathic Company opened in New York and Luyties Homeopathic Pharmacy Company in St. Louis.

The latter part of the 19th century was a high point for American homeopathy with Boericke & Tafel opening pharmacies in multiple cities, and many other pharmacies stocking homeopathic products. The first edition of the Homeopathic Pharmacopoeia of the United States was published in 1897, creating standards to identify starting ingredients and to manufacture homeopathic products.

Soon after, George Hyland opened a pharmacy in Los Angeles; this merged with others to become Standard Homeopathic Co. Then Borneman Laboratories opened outside of Philadelphia. In this period, there were 22 homeopathic medical schools; Boston University, Stanford University, and New York Medical College also had courses on homeopathy. Homeopathic care was provided through 100 hospitals and there were an estimated 1,000 pharmacies offering homeopathic medicines, including Ehrhart & Karl; Dr. Frost's; Wise's K.C. Homeopathic Pharmacy; Woodard, Clark & Co; and Halsey Bros. Looking back, one sees homeopathy's remarkable successes, including being one of the most widely used modalities of treatment during the American Civil War and its significant contributions to saving lives during the Spanish flu pandemic of 1918 and 1919.

Yet by the 1920s homeopathic schools were closing, partly due to a growing requirement for upgraded laboratory facilities in medical schools. Many homeopathic schools had neither interest nor resources to undertake such investments. Simultaneously, most schools were forced to change their curriculum to focus on biochemistry and pathology; neither are important in the homeopathic medical modality with its focus on the individual, and the one-on-one relationship between homeopath and patient. Also during the 1920s, other drug companies developed allopathic "miracle drugs" that were easy to prescribe to a wide range of patients.[1] Homeopathy did not encompass the right characteristics to adopt those "modern" medical methods of the era. Moreover, the homeopathic profession's numbers dwindled through retirement and attrition.

It is not surprising that a core group of homeopathic pharmacists and manufacturers would come together in the early 1920s to discuss the changing market conditions and take what steps they could for the preservation of homeopathy in the face of a shrinking practitioner pool. Each had their own path to follow in the coming years; yet in 1923, several influential homeopathic companies with their dedicated pharmacists banded together in a loose grouping to support one another. Thus was born the American Association of Homeopathic Pharmacists, which would come to promote quality and consistency in the preparation and manufacture of homeopathic medicines. Early member companies included Boericke & Tafel; Ehrhart & Karl; Humphrey's Pharmacal; John A. Borneman and Sons; Luyties Pharmacal; and Otis Clapp & Sons. The following year, a similar process happened within the practitioner community with the formation of the American Foundation for Homeopathy (AFH).

The newly formed AAHP could not reverse the tides of change impacting the entire homeopathic community. Yet, the collegiality and communication within the association, despite the members' natural competition in a slowly shrinking market, made it possible for the industry to survive the next 50 years while being well positioned for the amazing changes that would follow. After 50 years of experience with the allopathic miracle drugs along with increased awareness of side effects and long-term problems, the 1970s brought a revived interest by U.S. consumers in homeopathic products. This change led to the development of a third leg of support: the founding of the National Center for Homeopathy, which advanced the legacy of AFH and helped to foster the growing consumer interest for homeopathy into the 21st century.

Today this growth continues, fueled by consumer demand for natural products. This has resulted in a sustained growth in sales of homeopathic products that has risen faster than the U.S. economy and has outpaced the overall growth rate for conventional OTC products. For a century, AAHP has remained a stalwart promoter of excellence in the manufacture of homeopathic medicines.

References

1. https://www.wholehealthnow.com/homeopathy_info/history.html

Milestones for Homeopathy in the United States and Significant AAHP Activities

1796	Hahnemann experiments with quinine and articulates "Law of Similars."
1825	Hans Birch Gram introduces homeopathy in the United States.
1835	First homeopathic school in United States opens.
1835	William Radde begins selling homeopathic remedies in New York City. Boericke purchases the business in 1862.
1840	Otis Clapp & Sons opens in Boston.
1844	Physicians establish the American Institute of Homeopathy.
1853	Humphrey's Homeopathic Medicine Company opens in New York City. Later changes name to Humphrey's Pharmacal.
1853	Luyties Homeopathic Pharmacy Company opens in St. Louis. Later changes name to Luyties Pharmacal.
1860	Nelsons Homeopathic Pharmacy opens in London. U.S. subsidiary opens in 1996.
1869	Boericke & Tafel opens in Philadelphia; now a part of Schwabe N.A. Inc.
1884	Boericke & Tafel opens pharmacy in Washington, D.C. In 1927 it becomes Washington Homeopathic Pharmacy; now Washington Homeopathic Products in WV.
1897	American Institute of Homeopathy publishes the first edition of the Homeopathic Pharmacopoeia of the United States.
1903	George Hyland opens pharmacy in Los Angeles. It merges with others into Standard Homeopathic Co.; now called Hyland's Consumer Health.
1906	U.S. Federal Pure Food and Drug Act holds drugs to USP and NF standards of strength, quality, and purity.
1907	Borneman Laboratories opens outside Philadelphia; Later changes name to John A. Borneman and Sons, and sold to Boiron in 1983.
1910	Flexnor Report publication leads to defunding and closure of many medical schools, including (within a decade) the homeopathic medical schools.
1912	Misters Ehrhart and Karl open their eponymous pharmacy in Chicago.
1915–1935	Use of homeopathy declines as homeopathic practitioners age, training opportunities dwindle, and use of chemical drug products is promoted.
1920	Last purely homeopathic medical school closes.
1920–1940	Sales through homeopathic pharmacy and the number of these pharmacies serving doctors and consumers directly slowly declines.

HOMEOPATHY IN THE UNITED STATES AND MILESTONES

1921	Weleda opens in Switzerland; opens a New York City pharmacy in 1931.
1923	AAHP founded; early members include Boericke & Tafel, Ehrhart & Karl, Humphrey's Pharmacal, John A. Borneman and Sons, Luyties Pharmacal, and Otis Clapp & Sons.
1932	Boiron opens in Paris as a pharmacy and moves to Lyon in 1974; its U.S. subsidiary opens in 1983.
1938	U.S. Federal Food, Drug, and Cosmetic Act requires drugs to be safe, and bear adequate direction for use; the Act recognizes HPUS equally with USP and NF.
1951	Durham-Humphrey Amendment resolves distinction between OTC drugs and those requiring a prescription before being dispensed.
1962	Kefauver-Harris Amendments address safety and effectiveness; establishes GMPs; creates conditions in which all homeopathic drug products are considered Rx Only.
1965–1975	Back-to-Nature movement begins and grows. Interest renews in alternative methods of healing.
1965–1985	Homeopathic pharmaceutical companies experience first wave of growth and focus on sales through retail stores.
1972	FDA introduces OTC Drug Review for allopathic drugs; it states the agency will address homeopathic drug products at a later date.
1975–1980	AAHP members renew interest in working together in response to evolving regulatory circumstances and to further develop positive market conditions.
1980	Homeopathic Pharmacopoeia Convention of the United States is incorporated.
1980	U.S. market attracts overseas companies that establish U.S. subsidiaries and affiliates, which further accelerates market growth.
1980s	The 1951 Rx only conditions for homeopathic drugs is unevenly enforced by FDA against imports, causing problems with U.S. Customs and manufacturers.
1981	AAHP meets with FDA with proposal on criteria for Rx homeopathic drug products.
1983–1988	AAHP members work together to further the dialog with FDA and address the agency's concerns, which leads to the development of Compliance Policy Guide 400.400.
1988	FDA publishes Compliance Policy Guide 400.400 Conditions Under Which Homeopathic Products May Be Sold.
1980s	AAHP launches Compliance Through Education events for industry members.
1990	AAHP meets with FDA regarding solution to complexity of drug listing requirements.
1991	AAHP successfully petitions FDA to rescind requirement for English-only names on product labels.
1994	AAHP successfully petitions FDA for exemption from Imprinting of Solid Oral Dosage Form Drug Products for Human Use rule.

HOMEOPATHY IN THE UNITED STATES AND MILESTONES

1994	AAHP successfully petitions FDA for exemption from alcohol content limits.
1995	Homeopathic pharmaceutical companies experience second wave of growth, expanding in numbers and size. Sales focus expands from retail stores to reaching new consumers.
1999	AAHP writes and sponsors continuing education course for pharmacists.
2000	AAHP supports American Institute of Homeopathy's rededication of the Samuel Hahnemann Memorial.
2000	"Big Pharma" companies slowly turn their attention to consumers' interest in alternative products and begin to buy product lines and companies.
2002	AAHP conducts market survey on size, sales, and product line distribution.
2005	AAHP successfully reverses U.S. Customs Service classification of homeopathic drug products as "food."
2007	AAHP contracts for first of two analyses of data on homeopathic drug product safety from the American Association of Poison Control Centers.
2011	AAHP launches a federal relations program to educate congressional members on homeopathic drugs and appropriate regulations.
2011	AAHP hosts a luncheon briefing at the U.S. Capitol Visitor Center for Capitol Hill staff.
2011–2012	AAHP works with FDA to simplify Electronic Drug Registration and Listing for multiple attenuations of homeopathic drug products.
2013	AAHP honors Senator Tom Harkin with an award in appreciation for his support of health care choices.
2015	Renewed FDA attention on homeopathic products due to unexpected growth of consumer usage leads to two-day hearing in which AAHP takes leading role.
2015	AAHP contracts second analysis of data on safety from the American Association of Poison Control Centers to address FDA's interpretation of the data. AAHP thanks Consumer Healthcare Products Association for project support.
2015	In response to FDA hearing, AAHP submits 98-page document proposing reasonable requirements for industry while addressing FDA's concern to protect public health.
2015	FTC holds workshop to address clinical trial of homeopathic drug products or a disclaimer statement on labeling and advertising; AAHP takes lead, coordinating support and presentations.
2016	AAHP honors Senator Barbara Ann Mikulski for her support of policies that safeguard homeopathic manufacturers and medicines.
2016	AAHP develops, consumer tests, and adopts disclaimer wording to address FTC's concerns.
2016	AAHP meets with former Senator Harkin to discuss long-term legislative strategies.

HOMEOPATHY IN THE UNITED STATES AND MILESTONES

2016	AAHP hosts a luncheon between Senator Bob Casey and the homeopathic community.
2017	AAHP successfully defended the industry against unintended consequences of OTC monograph reform by monitoring and advising lawmakers on provisions of the legislation that would have subjected homeopathic manufacturers to user fees.
2017	FDA withdraws 1988 Compliance Policy Guide and publishes draft Drug Products Labeled as Homeopathic Enforcement Guidance.
2018	After more than 40 legislative visits, AAHP successfully works with Senators and Representatives to send letters to FDA regarding consequences of CPG withdrawal.
2018	AAHP submits comments to Enforcement Guidance with suggested changes.
2019	AAHP meets with FDA to voice industry concerns regarding Enforcement Guidance.
2019–2021	AAHP hosts a series of "Summits" to create basis for the industry and FDA to move forward. The events address technical gaps in cGMPs and other topics to provide additional education opportunities for compliance.
2019	AAHP launches industry reception and Integrative Medicine Retailer Award.
2020	AAHP supports members in litigation with FDA by filing amicus briefs.
2021	AAHP educates industry members on new reporting requirements from CARES Act.
2022	FDA finalizes revised draft guidance, incorporating some of AAHP's suggestions such as FDA's definition of homeopathic drug products includes only those monographed in HPUS.
2023	AAHP celebrates 100 years of service and dedication to integrity, quality, and trust. Presents history and achievements to multiple audiences both within and outside the homeopathic community.
2024	AAHP begins its second century with a new name to better reflect its contemporary membership and focus: American Association for Homeopathic Products.

CHAPTER EIGHT:

Select World History and Impact of Homeopathy

SELECT WORLD HISTORY AND IMPACT OF HOMEOPATHY

Homeopathy has a long history complete with twists, turns, and divergent paths around the globe. This therapeutic method was born out of the dissatisfaction of its founder, German physician Samuel Hahnemann (1755–1843), with the harsh medical procedures of his time which relied heavily upon toxic chemicals, bloodletting, and purging. Hahnemann was so disillusioned that he stopped practicing medicine and began translating medical texts.

While translating a treatise, Hahnemann became interested in a description of South America's cinchona tree bark. However, the author's explanation for the basis of the bark's usefulness in treating malaria made little sense to Hahnemann, as other substances had the same characteristics but were not useful for malaria.

When Hahnemann ingested some of the bark, he discovered it caused symptoms similar to malaria. Thus began his research with various substances and their effects. In compiling his findings, he was struck that the symptoms these substances caused in healthy persons were similar to those cured by those same substances in ill persons. Hahnemann expressed this principle as *Similia similibus curentur*, the Latin phrase meaning "let likes be cured by likes." Due to this primary principle, he referred to his healing method as "homeopathy," which joined the two Greek words *homoios* (or similar) and *pathos* (or suffering).

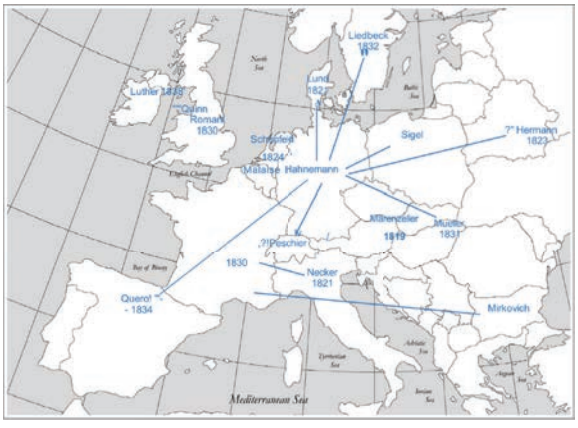
Inspired by Hahnemann's theory, others began to learn his therapeutic method and added to the body of knowledge on homeopathic therapeutic substances. While there was active antagonism from many established doctors, others were more open-minded and traveled from afar to embrace this new medical modality. These practitioners returned to their homelands, bringing with them this new practice, and thus introducing homeopathy across continental Europe and then via various paths around the world.

There are interesting and engaging stories of homeopathy's growth in other countries.[1] With far too many to be told within this article, the following is a cursory look at the expansion waves of the therapy. Popular first in Germany, homeopathy expanded through Europe due to widespread support, often in rural areas where it enabled lay persons to treat themselves.

Western Europe

The expansion of homeopathy radiated from Germany to Austria, Switzerland, and the Netherlands — all with similar languages — from the 1820s to 1830s. Each of these countries has a long and rich tradition of homeopathy use, leading to a surprisingly deep acceptance of this medicine. Today in all four countries, at least 60 percent of patients are interested in homeopathic therapies. A majority of German pharmacies stock homeopathic products, and many drug wholesalers can provide thousands of homeopathic products on a same-day or next-day basis to retail pharmacies. One of the oldest Swiss medical associations, founded in 1856, is homeopathic,[2] and a Dutch homeopathic drug company founded in 1913 is still one of the Netherland's domestic manufacturers.[3]

Snapshot (Partial) of Homeopathy's Spread Through Europe



Based on map in *Aux Origines de l'Homéopathie* by D. Raichvarg, A. Giordan, and C Mure. Paperback, Paris (1998).

SELECT WORLD HISTORY AND IMPACT OF HOMEOPATHY

Homeopathy arrived in Italy with the military physicians of the invading Austrian Army in the 1820s and throughout the years was used to treat Italian presidents and a number of popes.[4,5]

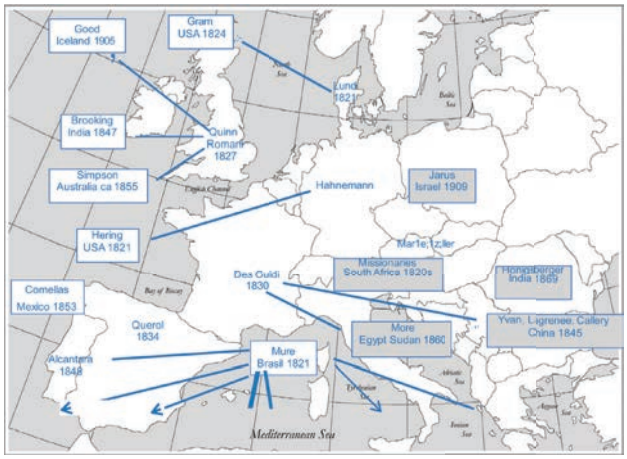
Italian physicians were the teachers of many who introduced homeopathy to France, Brazil, Spain, and Great Britain. France, Belgium, and Spain were also early fertile grounds. A homeopathic pharmacy opened in 1833 in Paris and, by the end of the 19th century, the relatively small nation of Belgium had 50 homeopathic pharmacies.[6,7] Spain's first pharmacy also opened in 1833. By the middle of the 19th century, enthusiastic Spanish homeopaths had followed merchants to Latin America, starting yet another expansion wave. After a forced decline through the Spanish Civil War and WWII, a resurgence of interest occurred in the 1970s; in an ironic twist, Spanish homeopaths turned to Latin America's teachers for courses and trainings.[8]

In Britain, the first homeopathic pharmacy opened in 1839. Today homeopathic products are easily available through most chemist and pharmacy stores, as well as through an extensive network of natural product stores.[9, 10] Homeopathy was introduced directly to the British royal family; every monarch since Queen Victoria (reign 1837–1901) has been a patient. Homeopathy's expansion can be traced through the reach of the British Empire, such as the medicines appearing in Australia in 1840. An Australian homeopathic pharmacy has been operating continuously since opening in 1860 — for 164 years!

Scandinavia and Eastern Europe

Use of homeopathy in Scandinavia began in Sweden (1826). Over the next decades, it spread to Norway and into the area of Finland bordering Sweden, though it would be another century before homeopathy spread throughout the rest of Finland. Around the same time, homeopathy arrived in Iceland from the U.K. Throughout Scandinavia, coordinated practitioner and consumer influence repeatedly overturned government restrictions. Access to the medicines varies in these countries. In Sweden, homeopathic drug products are legal but must be obtained from natural product stores.[11] Norway has a limited selection, including some from the U.S. The Finnish registration process makes availability difficult and expensive. Iceland's physical isolation creates difficulties in obtaining a wide variety of products, leading homeopaths there to develop a number of unique locally sourced medicines.[12,13]

Snapshot (Partial) of Homeopathy's Spread Beyond Europe



Based on map in *Aux Origines de l'Homéopathie* by D. Raichvarg, A. Giordan, and C Mure. Paperback, Paris (1998).

In Russia, two homeopathic pharmacies opened by the middle of the 19th century and the therapeutic substances had enduring support from the imperial family. Homeopathy survived the Soviet period despite the lack of official acceptance; this may be due to people trusting homeopathy simply because it was not a part of the governmental offerings. By the 1990s, approximately 15,000 doctors (out of a total of 1 million) used homeopathic medicines throughout the countries of the former Soviet Union.[14]

The language and cultural mores in Latvia share a commonality with Germany, which permitted homeopathy to prosper early on. There, a homeopathic pharmacy from 1833 is still in operation, and for decades supplied

the three Baltic republics and Belorussia with homeopathic medicines. Lithuania's first homeopathic pharmacy opened in 1864; 35 years later at least six pharmacies were operating around the turn of the century. Today Lithuania's national museum of medicine and pharmacy has a homeopathic laboratory supporting scientific and research work for the benefit of doctors and pharmacists and it is home to a library of homeopathic literature.[15]

Homeopathy's presence in the former Soviet socialist republics varied from long yet scant involvement (Poland 1829) to very active practice (Bulgaria 1850s). In some countries like Hungary, books and pamphlets were published for the general public that led to widespread use, particularly in rural areas not served by medical doctors. In other countries like Slovenia,[16] the use of homeopathy was augmented by clergy members who were a primary source of information and prescribing. Hungary was at the forefront of establishing homeopathic hospitals, with the first of a dozen opening in 1833.[17,18] Yet, all of the former Soviet socialist republics went through a common contraction: homeopathy became illegal because "there was no scientific explanation making it compatible with materialism." Suppression varied. Some countries seemingly turned a blind eye (Romania[19]). In other countries, suppression was forceful and effective (Czechoslovakia). After the breakup of the Soviet Union, homeopathy burst forth as if making up for lost time. Much of this was due to training programs and support primarily from the U.K. (e.g., in Bulgaria) and Germany (e.g., in Romania). This led to a rapid increase over four decades in the number of practitioners: Romania has more than 700 homeopaths and Ukraine has more than 5,000. Homeopathy is now taught in some university settings (e.g., Moldavia).

The availability of the medicines varies widely.[20] In Serbia, accessibility is unreliable due to scant importation. The unmet demand creates a need for a local source. In contrast, Ukraine has a wide range of homeopathic products available from more than 30 companies. Of these suppliers, seven are domestic and account for approximately 15 percent of homeopathic turnover; of the total, 60 percent are liquids and tablets with the remaining in 10 other dosage forms.[21,22] In Croatia, homeopathic labels are required to state "no curative effects have been proved"[23] — a disclaimer statement that may sound familiar to American consumers.

Asia

It is the "Indian subcontinent," however, where the British Empire's introduction of homeopathy had the greatest impact, spreading this medicine through the area now comprising India, Pakistan, and Bangladesh by the mid-19th century. Homeopathy is India's third most popular method of medical treatment after allopathy and Ayurveda. Along with a quarter million practitioners, there are approximately 7,000 government supported dispensaries, 250 homeopathic hospitals, and 200,000 pharmacies that stock homeopathic drug products. In Pakistan, there are more than 70,000 registered homeopaths, government hospitals employ homeopaths, and hundreds of free government dispensaries dot the provinces. All this helps rank homeopathy as the second most widely used medical modality in Pakistan and creates a strong homeopathic pharmaceutical industry that includes a number of domestic manufacturing companies. Likewise in Bangladesh, 30–40 percent of the population use homeopathic medicines.[24,25]

Indians in the British Army were responsible for introducing homeopathy to Malaysia (1940) as other Indians had already done in Nepal (1922). The Nepalese government currently provides free or inexpensive homeopathic treatment and services in Pashupati Homeopathic Hospital near Kathmandu where 65,000 patients were treated in one recent year. Across the country there is a growing number of new pharmacy shops that stock homeopathic drug products.[26] Malaysia has a modern, well-equipped homeopathic clinic and is a very active training center for Southeast Asia. With more than 1,000 practitioners, Malaysia's Homeopathic Doctors Without Barriers has provided humanitarian services for almost 45 years to more than 100,000 people in Sri Lanka, Thailand,

Afghanistan, Pakistan, Indonesia, and Malaysia.[27]

Support from India's homeopathic community extends elsewhere. Indian scholarships for homeopathic training are available to students from Sri Lanka; these are greatly needed as the number of Sri Lankan clinics has recently risen from four to seven with a 100 percent increase in patients seeking homeopathic treatment. India, along with other countries, provides training in Singapore, where the government recognizes homeopathy as an alternative medical practice[28] and for doctors from Kazakhstan, where homeopathy's acceptance has been unexpectedly quick. A homeopathic medical center was fully operational within a decade of its recent introduction there.

Western Hemisphere

Another expansion wave of homeopathy hit the shores of Latin and South America principally, but not exclusively, via immigration of Spanish doctors. In Argentina (1817) epidemics were often successfully treated homeopathically, leading to popular support of the medicines throughout the 19th century.[29] Columbia (ca. 1825–1830), Venezuela (1850), and Costa Rica (1890) were also influenced by the Spanish. Colombia's religious orders, especially Dominicans, played an outsized role in the use and teaching of homeopathy, leading to its growth there with five homeopathic pharmacies by the end of the 19th century. Today the country has roughly 40 homeopathic pharmacies.[30] France left its Latin American homeopathic mark in Cuba (1826)[31] and Brazil (1840).[32,33]

Other Latin and South American countries embraced homeopathy in the second half of the 20th century (Chile, 1950s), with increased official acceptance (e.g., Costa Rica, 1986; Ecuador, 1998; Columbia, 2007). The Brazilian Board of Pharmacy recognized homeopathy as a pharmaceutical specialty in 1992, offering regularly scheduled seminars for homeopathic pharmacists. Brazil's 2,000 physicians using homeopathic drug products make the market fertile for manufacturers and marketers.[34] Argentina's strong tradition of use resulted in multiple suppliers of homeopathic drug products. About 51 percent of Costa Ricans use homeopathy as their first-choice medicine, with these products available both in specialized homeopathic pharmacies and regular pharmacies.[35] Likewise, Chile has specialty pharmacies and the large chains sell some products, especially for common ailments like flu.

Homeopathy arrived in the southern and northern neighbors of the United States via very different paths. Cuban practitioners introduced homeopathy into Mexico (1850s), with the first homeopathic pharmacy opening in 1870. Now, homeopathic OTC drugs are present in many dedicated homeopathic drugstores and medical practices, as well as large numbers of pharmacies and drugstores throughout the country.[36,37] In Canada, recent emigres from northern Europe and especially from India created a strong demand and market for domestic manufacturers and importers.[38] In both countries, the leading homeopathic manufacturing companies have formed national trade associations similar to AAHP: ANIFHOM in Mexico and CHPA/APHC in Canada.

Middle East and Africa

In the Middle East, the United Arab Emirates recently celebrated 20 years of homeopathy being legally regulated in the health care system and with a clear process of product registration. The basic health insurance plan covers homeopathic medicines and use is growing quickly, with many medical centers incorporating it in their facilities. All this may be the influence of a large Indian expat community in the country.[39,40] Homeopathy is also legally recognized in Iran as an alternative method of therapy. In contrast, it is not recognized in Egypt where only 30 homeopaths (of approximately 200 who are trained) practice under difficult conditions.

A very different picture exists in Israel where homeopathy has no formal recognition as an accepted therapy, yet it has been integrated into various allopathic clinics and at least three hospitals have on-staff homeopaths within "multi-therapy" clinics. The largest Israeli health care provider has six alternative clinics, in which classical homeopathy is one of the available therapies. The medicines are readily available over the counter everywhere with several large pharmaceutical companies importing and distributing homeopathic drug products; competition is strong in this rapidly growing market.[41]

In Africa, there are small enclaves of support for homeopathy in both Nigeria and Tunisia. The former has a college of homeopathic medicine.[42] In the latter, almost every pharmacy in major cities stock 20 to 30 significant polychrest medicines.[43] The continent's major center of homeopathic activity is in the country of South Africa, where the aforementioned initial expansion wave that flowed with the Germanic language reached its most distant land (1820). Homeopathy grew slowly and steadily in a few areas of the country beginning in 1850 and then saw explosive growth after WWII with the opening of many homeopathic pharmacies. Today, homeopathic products are available from both domestic companies and importers, and reasonable criteria for registration of proprietary complementary medicine products have been established based on recommendations of the World Health Organization.[44,45]

Conclusion

We may be familiar with the historical story of homeopathy in the United States, though the rise and abundance of pharmacies is often overlooked. At the same time, it is enlightening to see the incredible breadth and depth of homeopathy's growth across six continents. And it is both heartening and promising to learn of the many ways homeopathy has been actively used to benefit so many people in so many places.

As a part of AAHP's 100th anniversary celebration, the association's newsletter published a series of 12 monthly articles providing far more detail of homeopathy's amazing historical and contemporary successes in more than 30 countries. To receive the free newsletter, sign up at the bottom of the AAHP's homepage (www.TheAAHP.com). To find already published articles, use the website search function to look for "Snapshots from There and Then."

References

1. https://www.lmhi.org/Home/NvpAndCountries
2. https://www.wholehealthnow.com/homeopathy_pro/switzerland.html
3. https://www.wholehealthnow.com/homeopathy_pro/netherlands.html
4. https://hpathy.com/homeopathy-papers/history-in-italy
5. http://www.omeoto.it/en/istituto/ist_history.html
6. https://www.wholehealthnow.com/homeopathy_pro/france.html
7. https://www.wholehealthnow.com/homeopathy_pro/belgium.html
8. https://www.wholehealthnow.com/homeopathy_pro/spain.html
9. http://www.homeoint.org/morrell/articles/ pm_brita.htm
10. Email correspondence, Steve Mann, Director of External Regulatory Affairs & QPPV, Nelson Bach, (United Kingdom).
11. https://d-nb.info/990663078/34
12. https://d-nb.info/990663078/34
13. https://www.biovea.com
14. https://www.wholehealthnow.com/homeopathy_pro/homeopathy_russia.html
15. https://pihma-fpre.org/wp-content/uploads/ 2015/07/History-of-Homeopathy-in-Latvia.pdf
16. https://homeopathyeurope.org/regulatory-status/slovenia
17. https://www.wholehealthnow.com/homeopathy_pro/hungary.html
18. https://d-nb.info/990663078/34
19. https://www.wholehealthnow.com/homeopathy_pro/romania.html
20. https://www.homeobook.com/scope-legal-status-of-homeopathy-in-european-countries
21. https://www.homeopat.org.ua/en/history-of-homeopathy-in-Ukraine-before
22. https://www.thepharmajournal.com/archives/ 2018/vol7issue4/PartM/7-4-52-734.pdf
23. https://www.wholehealthnow.com/homeopathy_pro/croatia.html
24. Reports at World Integrative Medicine Forum Regulations of Homeopathic Medicinal Products: Advancing Global Collaborations, Goa, India, pp. 23–25, (January 2019).
25. https://www.wholehealthnow.com/homeopathy_pro/pakistan.html
26. https://hpathy.com/homeopathy-papers/development-of-homeopathy-in-nepal
27. https://www.wholehealthnow.com/homeopathy_pro/malaysia.html
28. https://www.wholehealthnow.com/homeopathy_pro/singapore.html
29. https://hpathy.com/homeopathy-papers/history-of-homeopathy-in-argentina
30. https://hpathy.com/homeopathy-papers/homoeopathy-in-colombia-south-america
31. https://hpathy.com/homeopathy-papers/brief-history-homeopathy-cuba
32. https://hpathy.com/homeopathy-papers/new-era-homeopathy-brazil
33. https://www.homeopathy360.com/2019/12/06/ history-of-homoeopathy-in-world
34. https://www.homeopathy360.com/2019/12/06/ history-of-homoeopathy-in-world
35. https://homeopathic.com/homeopathy-in-costa-rica
36. Email correspondence, Eduardo Acosta Rodreiguez, Chief Executive Officer, Nartex Laboratorios Homeopaticos, (Torreón, Mexico).
37. https://www.wholehealthnow.com/homeopathy_pro/mexico.html
38. Telephone conversation, David Skinner, Canadian Homeopathic Pharmaceutical Association, (Ottawa, Onterio), December 12, 2022.
39. https://gulfnews.com/uae/homeopaths-celebrate-20-years-of-practice-in-uae-with-international-conference-1.92157713
40. https://www.wholehealthnow.com/homeopathy_pro/homeopathy_1900_1924.html
41. https://www.wholehealthnow.com/homeopathy_pro/israel.html
42. https://www.wholehealthnow.com/homeopathy_pro/nigeria.html
43. https://www.wholehealthnow.com/homeopathy_pro/homeopathy_1975_1999.html
44. https://hpathy.com/homeopathy-papers/homoeopathy-south-africa/
45. History of Homeopathy in South Africa, PowerPoint presentation given at LMHI Conference, Cape Town, 2018, provided by Peter Kreft, CoMED Health (Pty) Ltd.