IADSA CONNECT

#01 MAY 2018

New Day for Health Supplements in India

ONE STEP FORWARD, TWO STEPS BACK
New Zealand governments natural health products regulations

THE ONLINE WELLNESS LIBRARY (OWL):
An American approach to transparency and accountability

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IADSA
International Alliance of Dietary/
Food Supplement Associations

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WELCOME TO THIS FIRST ISSUE OF IADSA CONNECT

Our ability to help build an appropriate policy and regulatory environment lies in our ability to share information, experience and best practice across our Alliance and with decision-makers in government. With the help of our members, we have therefore launched this publication that will be issued twice a year to help explore in more detail the major developments in the world.

With best wishes

Ric Hobby
IADSA Chair

NEW ZEALAND GOVERNMENTS TAKE ONE STEP FORWARD, TWO STEPS BACK ON NATURAL HEALTH PRODUCTS REGULATIONS

Natural Health Products New Zealand is a national industry organisation representing this country's natural products, functional foods, complementary medicines, cosmeceuticals and nutraceuticals industries within New Zealand and internationally.

New Zealand's natural health products sector is enjoying strong ongoing growth but could be doing even better if the country's regulations were modernised.

New legislation, the Natural Health Products Bill, was put forward years ago but stalled following concerted political campaigning by a small group of very determined, well-funded detractors. The latest development saw New Zealand's new Labour-NZ First coalition government quietly remove the Bill from the Parliamentary order paper late last year.

It has been a case of 'one step forward, two steps back' for updating New Zealand's natural health product regulations. Concerted efforts are now underway to reinstate the Bill and move it into law.

The Bill had proposed to more strongly regulate natural health products sold and marketed directly to consumers. This would have provided New Zealand's domestic and export markets with a higher level of assurance that products are safe, approved, effective and contain what is stated on the label.

It would also have enabled natural health products companies to provide New Zealand consumers with more information about what their products can and will do for them.

For example, the current law prevents natural health product companies from making therapeutic claims about either traditional evidence or successfully clinically trialed products unless the product is licensed under the more expensive pharmaceutical medicine category. This is because New Zealand's outdated regulations do not define 'natural health product'.

Alison Quesnel, Corporate Affairs Director, Natural Health Products NZ

While the Natural Health Products Bill was designed to provide greater consumer confidence, it also recognised the integral role health care professionals play in this industry. As such it did not apply to products that are prescribed or directly made available through trained health practitioners or traditional medicine practitioners.

Many of the Bill's detractors had been against it because they had been misled into believing that its regulations would prevent traditional and trained health practitioners from prescribing or making certain natural health products available, something that contributed to the Bill's demise.

Despite the regulatory challenges, New Zealand law requires products to be true-to-label and New Zealand has a deservedly good international reputation as a source of high quality products. However, aligning our regulations to be more like those of our major overseas markets will make it easier to sell New Zealand-made products there and could potentially even provide automatic barrier-free access into some countries.

NATURAL HEALTH PRODUCTS NZ™

IADSA PROJECT GRANT: ROADMAP FOR THE IMPLEMENTATION OF THE ASEAN AGREEMENT

By Thach Do

The Vietnam Association of Functional Foods (VAFF) is the association of businesses, institutions, entrepreneurs and consumers involved in the areas of production, trading, marketing, scientific research, application, and transfer of technology for health supplements.

Vietnam Association of Functional Food ("VAFF") was the first winner of the inaugural IADSA Grant in 2017.

The project objective is to reduce technical barriers to trade for the Health Supplement Industry via full and uniform implementation of the ASEAN harmonized technical standards for Health Supplements in Vietnam. This should help ensure that the Vietnamese consumer has fast and sustainable access to innovative, high quality and safe Health Supplement products.

Vietnam Official Delegation participating in the 30th ASEAN PWG TMHS in Siem Reap, Cambodia 16 – 20 April 2018, including Thach Do on the right

To achieve this, some critical steps have been essential:

- Ensuring a common understanding of all elements of the ASEAN agreement in Vietnamese (original text is in English only).

- Developing a legal analysis and detailed roadmap of current local legislation that would need to be amended/ added to transpose the commitments made in the ASEAN Agreement on Health Supplements. These documents are for consideration by the relevant Vietnamese government departments.

At the recent 30th ASEAN Product Working Group on Traditional Medicines and Health Supplements (PWG TMHS) which was held in Siem Reap, Cambodia in April, Dr. Le Van Giang, Deputy Director General of the Vietnam Food Administration (Ministry of Health) recognized the initiative as a timely and pro-active collaboration between the industry and regulators with the expectation that the ASEAN Agreement on Health Supplements will be finalized in October 2018. Importantly, the Vietnam Food Administration will co-host a workshop with VAFF in June – July 2018 to further present the findings of this Analysis as well as further increase the awareness of stakeholders on opportunities and challenges that this important regional trade integration initiative will bring.

What has been learnt through the project so far is that positive results can be achieved for all parties where all are committed to work closely from the very beginning with a common and collaborative approach.

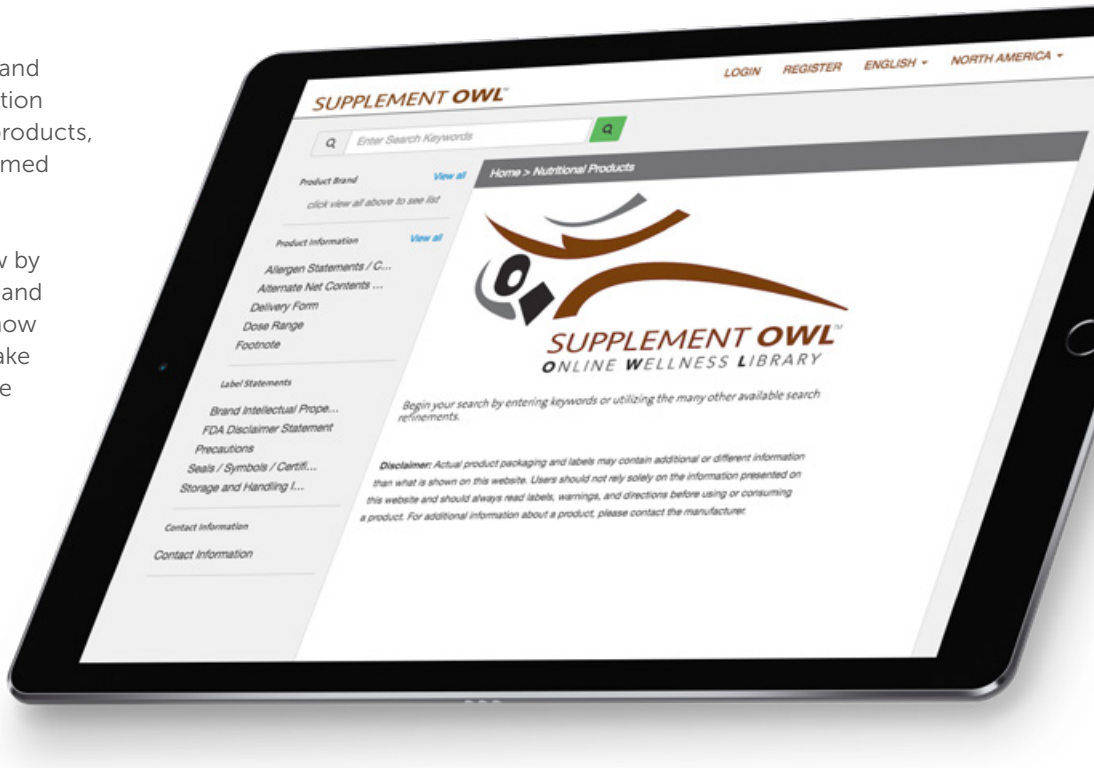
The Project is not yet finalized, but the signs so far are that Vietnam will be well prepared for the implementation process of this important regional legislative framework. VAFF will be sharing the learnings from this with the other associations in the ASEAN region.

Steve Mister,
President & CEO, CRN

THE ONLINE WELLNESS LIBRARY (OWL): AN AMERICAN APPROACH TO TRANSPARENCY AND ACCOUNTABILITY

The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., represents more than 150 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics.

The use of vitamins, minerals, herbs and botanicals, amino-acids, sports nutrition supplements, weight management products, and specialty products—together termed "dietary supplements" has increased substantially in the U.S. over the past decade. Data show the industry grew by 77 percent between 2005 and 2015, and results of a 2017 consumer survey show that 76 percent of American adults take dietary supplements each year. These numbers illustrate the success of modern science and innovation, our understanding of achieving optimal nutrition, and the emergence and popularity of a holistic approach to health and wellness.



Despite FDA's clear, prominent role in establishing and enforcing dietary supplement regulation, many misconceptions still exist about the industry, its integrity, and its safety: and the voices of critics perpetuate the fallacy that supplements are unregulated.

Dietary supplements are regulated in the United States—from GMPs for the facilities and labeling requirements to restrictions on claims and mandatory post-market surveillance. But even as responsible supplement manufacturers adhere to the laws established, an industry-wide desire exists to do more than just follow the rules. Consumer safety is the industry's number one priority, and industry recognizes it must self-impose additional requirements, guidelines, and expectations upon itself to enhance regulation already in place. This objective to self-regulate demonstrates to lawmakers that the industry is not afraid to take a critical look at itself and fill in regulatory gaps where needed.

Currently, a U.S. supplement industry-led, self-regulatory initiative has been created, developed and implemented to change the way regulatory audiences, retailers, and even the general public examines and evaluates products currently on the market. FDA has expressed concern that, for an agency trying to effectively regulate the industry, it was unaware of exactly how many products were on the market, their ingredients, which companies market which products, and/or even a company quality contact to answer specific questions. Industry hypothesized that it would be helpful if there was a single repository where FDA and other audiences would find the answers. Thus, the Supplement OWL (effectively serving as the dietary supplement product registry) was hatched.

Anyone with an internet connection can access the Supplement OWL (Online Wellness Library). The registry (www.SupplementOWL.org) is the result of trade associations and their member companies investing significant effort to create a tool to help increase transparency and accountability. The Council for Responsible Nutrition (CRN) has taken the lead developing the Supplement OWL, and Underwriters Laboratory (UL), a global independent safety science company, is providing additional funding in the OWL's development, administration, and technology.

Emphasizing industry's willingness to be transparent, the OWL provides an image of the product and a complete product label, along with separate searchable fields of information on ingredients, dosage forms, serving sizes, categories of use, product claims, contacts, and other information. As there is no fee to participate in either submitting information or using the registry: companies of all sizes and budgets are able to participate and demonstrate their accountability and transparency to OWL users.

The Supplement OWL is just one of the many ways the supplement industry in the US proactively elects to work with regulators, honoring the laws in place while imposing additional standards upon itself in order to protect consumers. As the Supplement OWL grows, it will continue to shine a light on the integrity and responsibility of manufacturers, fostering increased trust among lawmakers. By assisting our stakeholders in better understanding the breadth and depth of the supplement market, this registry will raise the bar and ensure consumers have access to safe, consistent, and beneficial products.

Carl Gibson, CEO, Complementary Medicines Australia

AUSTRALIAN REGULATORY REFORMS

Complementary Medicines Australia (CMA) is the peak industry body for the complementary medicines industry, representing stakeholders across the value chain, including manufacturers, raw material suppliers, distributors, consultants, retailers, allied health professionals and educators. CMA promotes appropriate industry regulation and advancement to ensure consumers have access to complementary medicines of the highest quality.

REVIEW OF MEDICINES REGULATION

In Australia, the regulation of complementary medicines falls within the remit of the Therapeutic Goods Administration (TGA), which has the responsibility of regulation of all therapeutic goods including complementary, OTC and prescription medicines and medical devices. In 2014, the Review of Medical and Medical Devices Regulation (MMDR) was established by then Prime Minister, Tony Abbott, to identify:

- areas of unnecessary, duplicative, or ineffective regulation that could be removed or streamlined without undermining the safety or quality of therapeutic goods available in Australia; and
- opportunities to enhance the regulatory framework so that Australia continues to be well positioned to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods.

The MMDR Review Panel provided a report about the regulation of complementary medicines (and the advertising of therapeutic goods) to the Health Minister on 31 July 2015, and the Government accepted the majority of the recommendations.

THERAPEUTIC GOODS AMENDMENT BILL 2017

Passed into law in March, the Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017, has amended the Therapeutic Goods Act 1989 to support the continued implementation of the Government's response to the MMDR. These amendments include:

Permitted Indications: The government accepted the recommendation for the introduction of a list of 'Permitted Indications' for low-risk Listed complementary medicines. This creates a definitive list of indications from which sponsors must exclusively draw and will help reduce inadvertent non-compliance. The industry has been working with the TGA to ensure that the list is as comprehensive as possible.

New Assessment Pathway for Complementary Medicine: The Bill establishes an intermediate pathway for complementary medicines sitting between Aust L listed products and Aust R registered products. This Assessed pathway will offer the ability to make intermediate claims beyond the list of permitted indications up to health benefits for serious diseases. When implemented, this will represent a unique opportunity for complementary medicine products to gain recognition for undergoing rigorous scientific assessment, and will include the benefits of a Positive Claimer that the product has been assessed by the TGA for efficacy. It will also include a much needed and long overdue protection for propriety research and clinical trials. The final details are still under development.

Advertising & Complaints System: The current advertising pre-approval system will be phased out over a two year period. The regulatory changes also include the abolition of the Complaints Resolution Panel (CRP) and the establishment of a streamlined complaints system within the TGA. The decision to provide, through the regulator, a single body to manage all complaints is expected to address many of the criticisms made about the current arrangements and help to deliver consistency in decision-making, compliance and appropriate enforcement.

Regulation under the TGA sets a very high standard that can support a strong and innovative industry; however, coming under the auspices of the medicines regulator always brings the possibility of a regulatory framework that is not aligned with the real-world low risk of complementary medicines.

cma Complementary Medicines Australia

Dr. Tatiana Pires,
President of Abiad, Brazilian Association of Special Products

NEW FOOD SUPPLEMENTS REGULATION COMING SOON IN BRAZIL

After years of discussion, the food supplements industry in Brazil can finally see potential changes for regulations in the market: in January 2018 ANVISA, the Brazilian FDA-like agency, published six Public Consultations that aim to create and review the current regulation for food supplements.

The new category will combine six current regulatory categories of food products:

1. vitamins and minerals supplements,
2. bioactive and probiotics substances,
3. novel foods,
4. functional foods,
5. supplements for athletes and
6. supplements for pregnant and breastfeeding

Plus one category of drug (specific medicine with no prescription).

With the exception of enzymes and probiotics, food supplements will not be registered anymore (only notified).

The new regulation also purposes the adoption of:

a. a positive list of ingredients, additives and processing aids, so all content should be based on the lists,
b. maximum and minimum limits for nutrients (not based in 100% IDR anymore) and
c. positive list of claims (that were not allowed previously).

Important to emphasize that before the public consultation, ANVISA have had several open discussions with the industry sector from June to September 2017, in a quite transparent process. Abiad had the opportunity to work closely with ANVISA, being recognized as an association leader of the segment and principal interlocutor at ANVISA.

But actually this is a long term discussion that started around 2009-2010 in which IADSA supported Abiad in creating a discussion based on the safety and benefits of food supplements. IADSA had a key role supporting Abiad in organizing three technical and scientific workshops (2010, 2011 and 2014). The main discussion points were always based on:

1. the need for a category/specific definition for food supplements,
2. possibility of having combinations of ingredients (not vitamins and minerals only),
3. food supplements as a food category (not to treat or cure, as a drug),
4. maximum levels of vitamins and minerals based on safety (not 100% IDR) and notification stead of registration.

In 2015 Abiad conducted a National Survey about food supplement consumption and the protocol was developed together with ANVISA. The findings were key to support ANVISA in moving forward the review of the regulation: in more than 50% of the houses in Brazil we have at least one person consuming food supplements.

In summary, most of the topics discussed over the years related to the included safety and benefits. The challenges of the industry are related to those ingredients or additives not included in the positive list, such as natural sources of vitamins and some plant extracts and also the timing proposed by ANVISA to implement the new regulation (two years), considered a short period for the industry as a whole.

According to ANVISA, the new regulation is expected to be published by July 2018. The Abiad companies and the whole industry sector is continuing to follow this discussion, expecting to support the market for food supplements in Brazil, the biggest player in Latin America.

Signing the agreement to establish ReCaHN: Meetu Kapur (Executive Director, FACE CII) and Simon Pettman (Executive Director, IADSA)

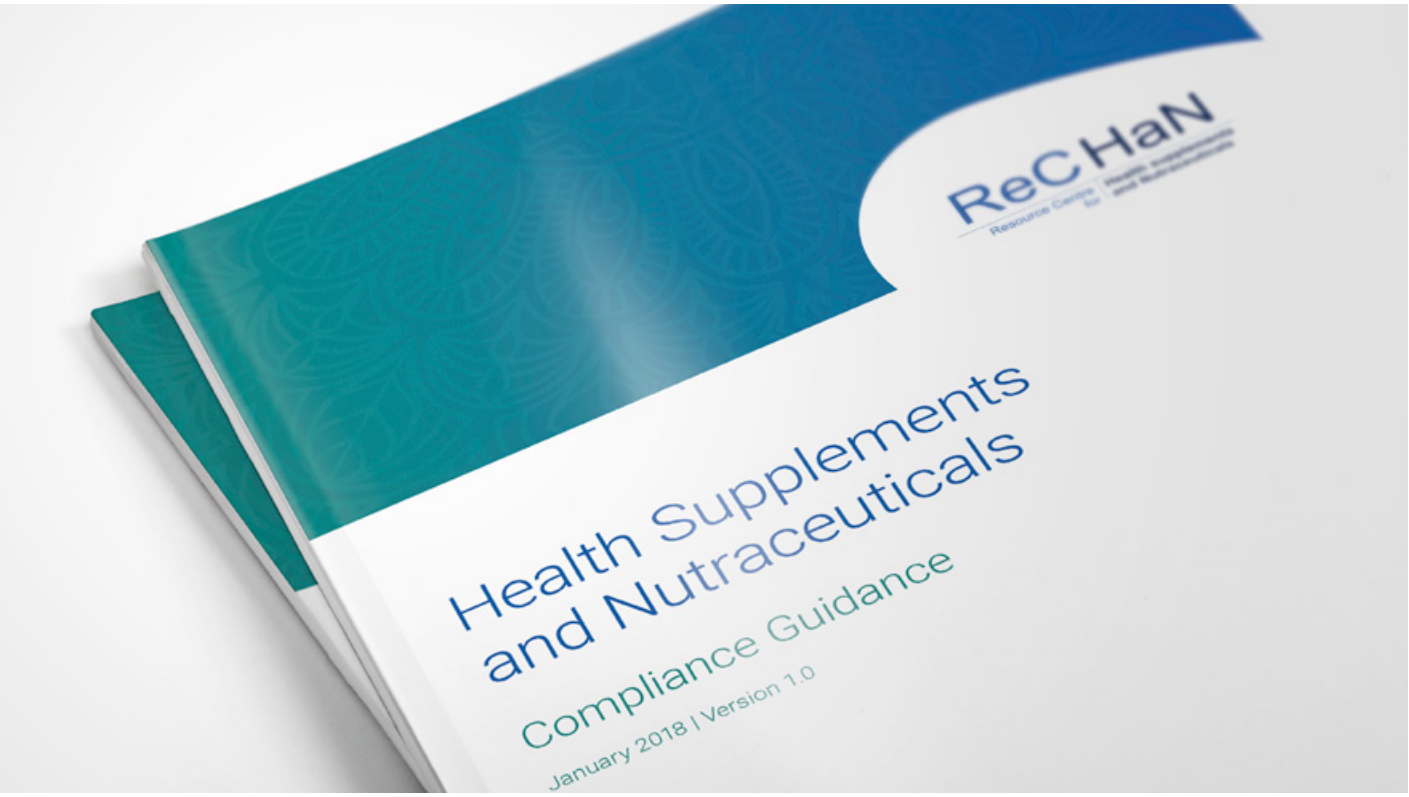
NEW DAY FOR HEALTH SUPPLEMENTS IN INDIA

In December 2016, the Health Supplement and Nutraceuticals Regulations were published in India and become effective this year. The need for these had been established in the original Food Safety Act of 2006, but it was to take 10 years for these to become a reality.

They establish some very important detailed requirements about the composition, claims, and labelling.

While these rules are still not perfect and will continue to need further revision over the coming months, they are a huge step forward for a country with a population in excess of one billion. However, making these regulations work in practice in such a vast and diverse country is far from easy. It is to help in this that the Resource Centre for Health Supplements and Nutraceuticals (ReCHaN) was formed.

Indian food regulation is developed centrally by the Food Safety Standards Authority of India (FSSAI) and there are FSSAI offices in every state that play a critical role in enforcement. In addition, there are literally thousands of companies who are either in the health supplement market or nationally who may only be selling their products at state level. Ensuring a common basis for manufacturing and alignment on regulatory interpretation is therefore of great importance.



To achieve this goal, the CEO of the FSSAI in New Delhi, Mr Parvan Agarwal, recognised the need to bring essential expertise together and in early 2017 he asked Meetu Kapur of the Confederation of Indian Industry and IADSA to partner in the creation of ReCHaN and help India achieve these objectives.

After nine months of operation ReCHaN has achieved its target of developing a Compliance Guide for the implementation of the regulation, taking into account international experience and best practice. It has also developed the first phase of Good Manufacturing Requirements for companies operating in this market. It has also facilitated discussion between international scientific experts and the Indian scientific bodies that make recommendations to FSSAI in this area.

FSSAI was very clear with both CII and IADSA that it was up to the two organisations to demonstrate the benefit and then FSSAI would consider engaging formally in the exercise. This has now been completed and a Memorandum of Understanding between FSSAI and ReCHaN has been signed that helps facilitate much closer cooperation on all elements of the workplan.

Where is ReCHaN headed next during 2018? At our 1st Stakeholders Forum on 1 May in Delhi, there was significant discussion between Indian and international scientific experts on approaches to claims substantiation. Creating an approach to claims substantiation that can capture both innovation and tradition is a key priority for everyone involved in the sector and IADSA will be working closely on this over the coming months.

In addition, it is very important that we complete the work we have started on the two Guidance documents on regulatory compliance and GMP. Training materials have been created for use across India and the role of the Indian health supplement association, HADSA, will be important for achieving the targets that have been set by the government.

The ReCHaN concept started off being experimental but the substantial work over the past months has demonstrated the value that it can bring.

ReCHaN
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