IADSA CONNECT

#03 March 2019

Where is Latin America heading?

INDONESIA EMBRACES SUPPLEMENTATION AS UNIVERSAL HEALTHCARE COSTS START TO BITE

THE SCIENCE SUPPORTING THE HEALTH BENEFITS OF EPA/DHA OMEGA-3S IS STRONGER THAN EVER

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IADSA
International Alliance of Dietary/
Food Supplement Associations

#03

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Simon Pettman,
Executive Director, IADSA

WELCOME TO IADSA CONNECT

Dear Members

We are delighted to share the latest issue of IADSA Connect.

So much good work is being carried out across the world by IADSA members who are at the sharp end of national and regional developments. We trust that this issue will help build knowledge and understanding of the opportunities and challenges, the similarities and the differences that we all face.

We know Connect is highly appreciated and we will therefore be producing three issues in 2019.

Simon Pettman
Executive Director

INDONESIA EMBRACES SUPPLEMENTATION AS UNIVERSAL HEALTHCARE COSTS START TO BITE

APSKI is the Indonesian Health Supplements Association. This association was established in 1998 in Jakarta with the purpose and objectives to promote cooperation and unity among the health supplement business in the country. Members of APSKI are companies engaged in the food supplement industry both as manufacturers, distributors or supporting manufacturers such as packaging or raw materials.

A SHAKE-UP OF INDONESIA'S HEALTHCARE SYSTEM HAS BENEFITED MILLIONS OF CITIZENS BUT RESULTED IN A SPENDING DEFICIT ITS GOVERNMENT IS KEEN TO REDUCE. CONNECT SPOKE WITH APSKI CHAIRMAN PATRICK KALONA TO FIND OUT MORE.

As Chairman of APSKI – Indonesia's food supplement association – Patrick Kalona is excited about what 2019 holds in store. It is hoped that new legislation regulating the country's supplement market will soon be passed into law, giving nutrition companies more freedom to market products with health claims. It will be the first significant evolution of Indonesia's supplement regulations in 14 years and comes against the backdrop of a complete overhaul of the Indonesian healthcare system. This began in 2014, when a national insurance scheme was introduced to deliver affordable, universal healthcare to the country's entire population of more than 260 million people, not just those with the means to pay for it privately.

Funded by individuals and – if they are in work – their employers, the program has provided access to healthcare services for approximately 190 million people a year, compared with 19 million before it was introduced. But this has come at a financial cost. "The system has run up a deficit of about US$700 million," says Patrick, "and it appears likely that this will continue to climb. This means the government is already reviewing the size of the contributions citizens and companies are asked to make, and these are likely to increase

Patrick Kalona, Chairman, APSKI

in future. In addition, it is probable that certain non-life-threatening conditions will no longer qualify for treatment under universal healthcare or will only be partially subsidised."

The Indonesian government is also looking at indirect ways to cut the cost of universal healthcare, which includes exploring the potential for preventative measures that reduce the risk of people becoming sick in the first place. It has launched public initiatives such as GERMAS, which deliver messages about healthy living, with a focus on diet and exercise. In addition, regulators have proven to be receptive to the idea that food supplements can play a role in maintaining wellbeing. This has helped to bring about the forthcoming reforms to Indonesia's existing regulations for the supplement market, which date back to 2005.

Patrick says the new legislation will give companies greater scope to communicate the health benefits of their supplements to consumers and make it easier to innovate and launch new products than it is now. "It represents a big change in mindset and it's a clear endorsement of Indonesia's supplement industry," he adds.

APSKI, whose membership comprises 62 supplement and ingredient companies, was consulted by BPOM, Indonesia's food and drug agency, when it came to draft the new regulation. Technical assistance was provided by IADSA, of which APSKI is a member organisation. "IADSA highlighted the growing body of research suggesting a link between supplementation and the potential for reducing healthcare costs," says Patrick. "They also provided numerous examples of regulatory best practice elsewhere in the world, which offers opportunities for benchmarking."

There is optimism in Indonesia's supplement sector. A modernized regulatory system is incoming, awareness of the significance of nutrition is increasing and sales of supplements are rising by about 11% annually, according to Euromonitor International. Traditional channels for supplements – local stores, supermarkets, pharmacies – remain important but government investments in telecommunication and transport infrastructures have also enabled online sales to thrive. Demand for supplements is rising strongly among the 80 million Indonesians who are aged 25 to 45 and in employment. More of them are spending their disposable income on nutrition products to maintain their wellbeing and – thanks principally to the influence of social media – their appearance.

Indonesia is the largest member of ASEAN, the pan-Asian economic and political community, and accounts for 40% of its population. Patrick is optimistic that the feelgood factor present in Indonesia's supplement sector will spread. "If regulators in Indonesia see health supplements as part of the solution to addressing growing healthcare costs, hopefully there will be positive effects across the region as a whole, ensuring a viable and sustainable flow of goods between ASEAN states," he says.

Indonesia is the world's fourth most populous nation. With such a sizeable pool of consumers, many of whom are becoming increasingly health conscious, the outlook is positive for supplement companies seeking to unlock the potential the country offers.

Juan Pablo Waimann,
Executive Director,
ALANUR

LATIN AMERICA: WHERE ARE WE HEADING TO?

The Latin American Responsible Nutrition Alliance (ALANUR) was created in 2012 as Latin America's first regional food supplement association. ALANUR's focus to ensure regulatory guidelines in the region are appropriate for supplements.

After an underwhelming economic performance in 2018, the outlook for Latin America & the Caribbean is not exactly dazzling. According to the latest estimates, the region grew at a rate of 1.2% during last year and will grow 1.7% in 2019, not reaching its full potential.

In spite of such results, the vitamins and dietary supplements sector experienced a healthy CAGR of 7.2% in 2018, up from both 2017 and 2016 and cementing a long-term trend.

Considering the current context and looking into the medium-term, what does the future of the sector in the region look like? What are the main trends to consider?

THE RISE OF THE PACIFIC

Middle-sized Pacific Alliance states – Colombia, Chile and Peru – are forecast to experience better economic performance than their larger Atlantic counterparts through 2021, making their markets more dynamic and attractive.

This is also the group of countries leading the most prominent efforts to achieve a harmonized framework for food supplements. Once accomplished, the initiative will boost their respective markets by enormously reducing production costs and matching regulatory standards; it will simplify processes and facilitate consumers' access to a greater variety of products.

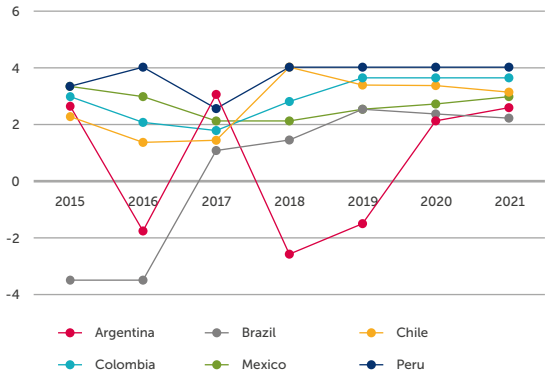
The road to harmonization is not an easy one – each negotiating country still poses regulatory challenges that call for reform.

CENTRAL AMERICA GAINS MOMENTUM

At a glance, Central America might not get a lot of attention. However, the subregion accounts for over 47 million people and has enjoyed a pace of growth that is expected to keep above the regional average for the next few years. The expansion in GDP per capita has been very high in Panama and Costa Rica and – even if slower for the rest – it is increasing the opportunities for the dietary supplements market.

On the downside, regulations in Central American countries are highly dissimilar and often in an urgent need for reform. Eliminating obstacles to trade is vital to make these markets more attractive.

GDP ANNUAL GROWTH RATE 2015-2021*f* (%)

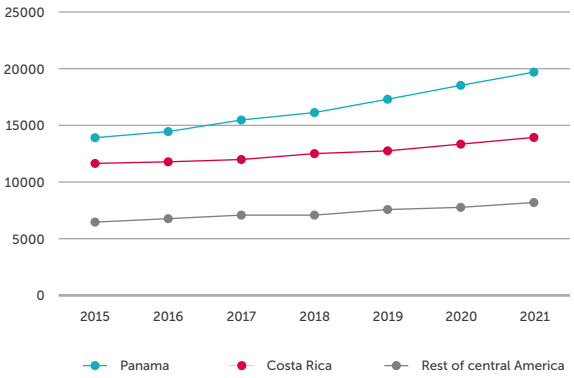


BRAZIL RETURNS TO THE SPOTLIGHT

The set of rules unveiled by ANVISA last year promises to bring renewed levels of normative certainty and higher standards to LATAM's largest food supplements market. Even if some improvements are still required – especially for probiotics and some other ingredients – this regulation is a first step in the right direction.

The launch of the update has also positively affected Brazil's MERCOSUR trading partners: Uruguay is in the process of updating its national regulations while Argentina and Paraguay are slowly beginning to reconsider their own.

GDP PER CAPITA – COSTA RICA & PANAMA
(Thoudands of US Dollars)

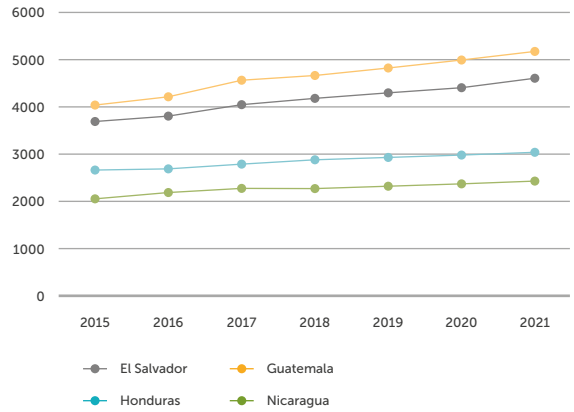


THERE IS STILL ROOM FOR IMPROVEMENT

Even if the regulatory landscape has substantially improved over the past decade, reform in most LATAM countries is still called for. Among the most pressing issues are the barriers in the use of nutritional and health claims as well as restrictions on the use of bioactive ingredients and botanicals.

The large spread of the so-called 'miracle products' possess risks for consumers and negatively affects the perception of dietary supplements, especially by health professionals and regulators. Hence, higher investment in postmarketing control should be regarded as a top priority.

GDP PER CAPITA GROWTH – SELECTED COUNTRIES
(Thousands of US Dollars)



SOME FINAL REMARKS

Even if Latin America might not be the usual first choice for business, the vigorous growth of the VDS market in the last 20 years proves that opportunities are abundant.

As the regional population gets slowly wealthier and is rapidly ageing, the interest in better nutrition and healthier lifestyles will continue to rise.

In such a context, our sector will have a key role to play in improving the lives of our region's citizens.

Michelle Stout, Chair, IADSA

PATIENCE, PERSISTENCE AND PARTNERSHIP: HOW THE IADSA APPROACH PAYS DIVIDENDS FOR MEMBERS

Michelle Stout has been IADSA Chair since in June 2018. She told Connect how building constructive, meaningful relationships with decision-makers is helping to shape better regulation for the global supplement sector.

THERE ARE MANY INDUSTRY ORGANISATIONS FOR THE NUTRITION AND HEALTH SECTOR. WHAT MAKES IADSA DIFFERENT?

Uniquely among trade associations, IADSA offers a global perspective. This benefits members, because it gives them access to news, analysis, guidance and other resources that they won't find elsewhere. But it's also appealing to regulators. We find that many of them feel isolated when it comes to making decisions on regulating supplements. Hearing about experiences and best practices in other countries via a trusted industry organisation like IADSA can be hugely helpful for them.

HEALTH HAS BECOME A MAJOR FOCUS FOR GOVERNMENTS ALL OVER THE WORLD. HOW IS IADSA WORKING TO INFLUENCE DEVELOPMENTS IN 2019 AND BEYOND?

We continue to see regulation evolving around the world, whether it's completely new as in Brazil, or modernisation as in China. It will be IADSA's ongoing priority to support national associations and ensure we get the best regulation possible – not just for our members but consumers, too. In fact, to that point, another priority is our work to help regulators and policymakers understand the value of supplementation. This represents a new direction for IADSA but it's an important one. We continue to see a lack of understanding around how supplements can enhance health and we are taking steps to educate regulators, policymakers and their scientific advisers. It isn't just about disease, although that is important. There are multiple endpoints, including growing old gracefully and improving quality of life. We're working hard to get this message out there at every opportunity and, although it's early stages, we have made some good initial steps and the information we are providing has been well received.

YOU MENTIONED THERE HOW IADSA ENGAGES WITH REGULATORS AND POLICYMAKERS. ARE YOU ON GOOD TERMS WITH THEM?

IADSA's work is built on a foundation of trust and credibility and we've made huge progress in developing meaningful relationships with decision-makers all over the world – genuine partnerships based on mutual respect. A shining example of this is our Botanicals Roundtable, which for the past five years has met before the IADSA Annual Meeting. Regulators, policymakers and scientific advisers who are engaged in botanicals sit down with industry representatives for a constructive dialogue. Bringing people together in this way is at the heart of IADSA's work.

HAS THIS APPROACH BEEN SUCCESSFUL?

Instigating a shift in regulatory mindset is a huge task but through this patient, co-operative approach we have been able to achieve that in highly significant ways. In China, for example, previously the only way to launch a health food product onto the market was via an onerous and expensive registration process that could take two to three years. Every product had to go through this, regardless of whether similar products containing the same ingredients had already been approved. There was a lot of redundant testing by the Chinese authorities and it was clear potential existed for better regulation. IADSA spent several years talking to regulators there and exposing them to the way things are done elsewhere in the world. The result was the introduction of a notification system based on a positive list, which now runs alongside the registration process. It's not perfect and the list needs to be expanded, but notification now offers a much shorter pathway to the Chinese market for supplements and ingredients companies.

WHY IS IADSA ABLE TO WORK SO EFFECTIVELY ALONGSIDE REGULATORS AND POLICYMAKERS?

Persistence is key. In 2017 we joined forces with the Confederation of Indian Industry and, with the support of regulators in India, established ReCHaN – the Resource Centre for Health Supplements and Nutraceuticals. Its role is to support efforts towards better regulation of India's supplements sector and has produced guides for businesses on subjects such as product definitions, labelling and GMP. I'm particularly proud of this achievement because of the resolve and determination it required on IADSA's part. At the outset the regulatory environment in India was uncertain for supplement companies but the government of the time wasn't interested in listening to the case for change. We refused to give up and kept the dialogue open. Eventually, the government's position shifted and it became more open to what we had to say. IADSA was instrumental in building this confidence and, when new regulations were introduced in 2018, the Food Safety Standards Authority of India adopted many of IADSA's recommendations around topics such as GMP and health claims. Work is ongoing but ReCHaN has been a huge success. It was the first example anywhere in the world of a government partnering with the supplements sector in this way and provides an excellent example of why you should never give up, even when the odds appear stacked against you.

Harry Rice,
Vice President of Regulatory and Scientific Affairs, GOED

THE SCIENCE SUPPORTING THE HEALTH BENEFITS OF EPA/DHA OMEGA-3S IS STRONGER THAN EVER

GOED represents the worldwide EPA and DHA omega-3 industry. Its mission is to increase consumption of EPA and DHA omega-3s and ensure that its members produce quality products that consumers can trust.

The omega-3 fatty acids, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), have a long history of published benefits for secondary prevention. Over the years, the secondary prevention benefits for EPA & DHA have been generalized to primary prevention based on what are thought to be similar mechanisms of action for both. However, beginning in 2010, the consensus about omega-3's cardiovascular benefits began to be questioned and last year, the 40th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) decided to discontinue, pending further scientific evidence, discussion on the proposed draft nutrient reference value non-communicable disease (NRV-NCD) for EPA+DHA.

While the Global Organization for EPA and DHA Omega-3s (GOED) supported this decision, as did the majority of other Codex Member Countries and NGOs, for GOED, it was based on a lack of consensus among delegations, not a lack of strong science. From GOED's perspective, the strength of the science has supported the adoption of a NRV-NCD for EPA+DHA since the proposal for new work was agreed to at CCNFSDU36th and approved by CAC38. In fact, the body of science has grown stronger over the years. In a GOED conference room document (CRD)[1] prior to CCNFSDU40, we summarized results from three recent large-scale clinical trials assessing the cardiovascular benefits of EPA and/or DHA supplementation, including: A Study of Cardiovascular Events in Diabetes (ASCEND), Vitamin D and Omega-3 Trial (VITAL), and Reduction of Cardiovascular Events with EPA – Intervention Trial (REDUCE-IT).

Not only do all three studies add positively to the body of scientific evidence supporting the benefits of omega-3s, but two of the three studies provide some of the first direct evidence of omega-3's benefits for primary prevention (i.e. prevention of disease before it ever occurs). While the World Health Organization (WHO) does not consider EPA and DHA to be critical nutrients for cardiovascular health[2], the Food and Agricultural Organization (FAO) did not participate in WHO's assessment and still considers previous joint recommendations[3] for EPA+DHA published by FAO/WHO on this topic to remain applicable.

Below are highlights from the three recent clinical trials. Additional details can be found in the CRD referenced above.

ASCEND

An 18% statistically significant reduction in risk of vascular death was reported in the ASCEND publication. While the coauthors concluded "no significant difference in the risk of serious vascular events between those who were assigned to receive n–3 fatty acid supplementation and those who were assigned to receive placebo," given that the primary efficacy outcome included vascular death, a statistically significant risk reduction for vascular death should be considered a clinically relevant finding. In addition, these are the first significant results to be reported for primary prevention.

VITAL

While VITAL did not achieve the trial's primary outcome of significantly reducing major cardiovascular disease (CVD) events, the following results were statistically significant, providing further evidence that omega-3s do provide primary prevention benefits:

- Total Myocardial infarction (MI): 28% risk reduction (omega-3s: 145 events vs placebo: 200 events)
- Total Coronary Heart Disease (CHD): 17% risk reduction (omega-3s: 308 events vs placebo: 370 events)

In addition, the greatest risk reductions were demonstrated in those with low dietary fish intake and in African Americans. While GOED considers this noteworthy, scrutiny of the data is required to better understand these findings.

REDUCE-IT

The following results were statistically significant when the treatment group was compared to placebo:

- primary endpoint composite of the first occurrence of major adverse cardiovascular events (MACE), including cardiovascular death, nonfatal myocardial infarction (MI), nonfatal stroke, coronary revascularization, or unstable angina requiring hospitalization: 25% risk reduction
- key secondary composite of cardiovascular (CV) death, MI, or stroke: 26% risk reduction
- CV death or nonfatal MI: 25% risk reduction
- fatal or nonfatal MI: 31% risk reduction
- CV death: 20% risk reduction
- hospitalization or unstable angina: 32% risk reduction
- fatal or nonfatal stroke: 28% risk reduction
- total mortality, nonfatal MI or nonfatal stroke: 23% risk reduction

1. http://bit.ly/2U5RvV5
2. https://www.ncbi.nlm.nih.gov/pubmed/30521670
3. https://www.who.int/nutrition/publications/nutrientrequirements/fatsandfattyacids_humannutrition/en/

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