

IADSA CONNECT

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**MAXIMUM EFFORT IN
GERMANY: AK NEM
OFFERS A STEADY
HAND IN THE FACE
OF REGULATORY
CHALLENGES**



PRISA OFFERS UPDATE ON THE
COUNTRY'S SUPPLEMENT SECTOR

NEW IADSA BOARD MEMBER PROMISES
TO BRING ENERGY AND PASSION

#12

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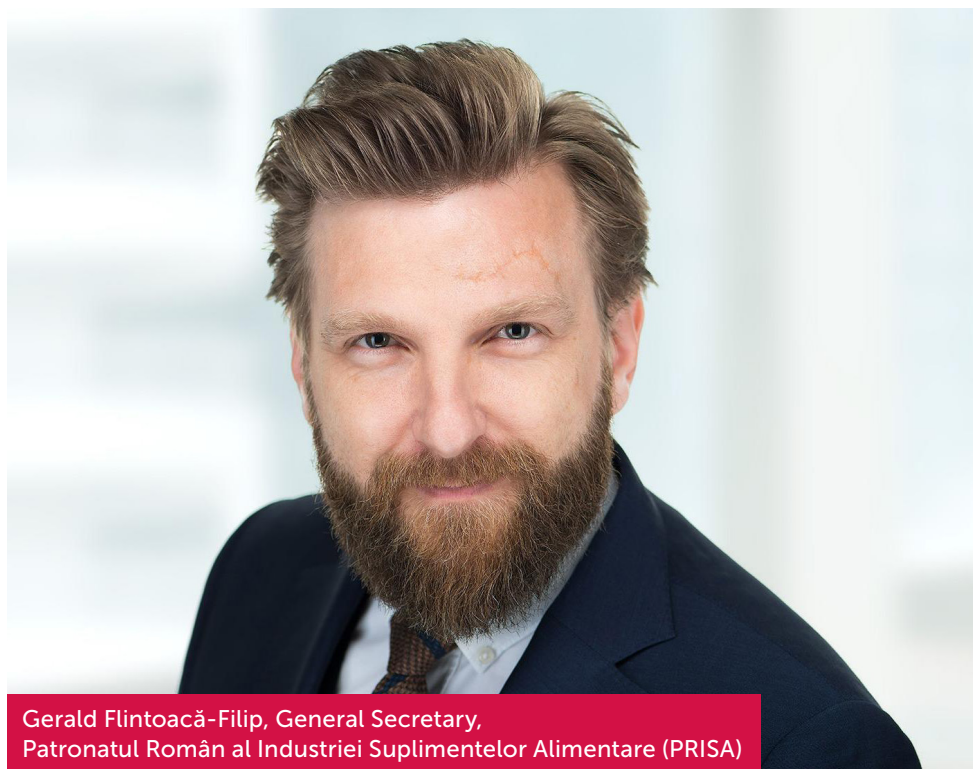
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REFLECTIONS ON ROMANIA: PRISA OFFERS UPDATE ON THE COUNTRY'S SUPPLEMENT SECTOR

PRISA Secretary General Gerald Flintoacă-Filip talks to Connect about some of the major developments in Romania's supplement sector since the country joined the EU 15 years ago.

Romania is a relatively new member of the European Union, having joined as recently as 2007. At the time, the country already had its own national food supplement regulations in place. Introduced in 2000, they were similar enough to the EU Food Supplements Directive to make the transition a smooth one.

Nevertheless, the Romanian regulatory landscape has its own unique characteristics, which sometimes present challenges to the industry. For example, regulation of the national supplement sector is divided between two government departments. The Ministry of Health is responsible for products containing vitamins and minerals, while the Ministry of Agriculture oversees botanical substances.



Gerald Flintoacă-Filip, General Secretary,
Patronatul Român al Industriei Suplimentelor Alimentare (PRISA)

"This means life can get a little complicated," says Gerald Flintoacă-Filip, General Secretary of Patronatul Român al Industriei Suplimentelor Alimentare (PRISA), which is Romania's supplement association.

"They work together but they also have their own opinions on how things should be done."

PRISA was founded in 2000, just as Romania was implementing its new legislation for the supplement sector. Flintoacă-Filip, who joined the organisation in 2011, is very active in the industry. In addition to his role at PRISA, he is a board member of Food Supplements Europe and sits on the board of the Romanian Advertising Council, which he advises on what constitutes a non-compliant health claim.

PRISA supports tough action to prevent the use of misleading health claims. It persuaded the Romanian government to introduce new legislation to ensure manufacturers are using the same health claims in their marketing and advertising as they are putting on the label of their products, in order to avoid confusing consumers.

It also drew up a code of practice for its members and subsequently convinced the Romanian Advertising Council to add it to its own code of ethics as an annex. The result of this is that all supplement companies in Romania are now covered by the PRISA code, not just companies who are members of the body.

In addition to regulatory work, PRISA undertakes a significant amount of outreach to influence opinions about supplements, including organising events "We consider it to be important for PRISA to educate consumers and medical professionals on the importance and benefits of food supplements," Flintoacă-Filip says.

Among other examples, this illustrates how, in the form of PRISA, Romania's supplement industry has an influential and pro-active organisation that energetically represents its members' interests.





Antje Preussker,
Scientific Director,
AK NEM

MAXIMUM EFFORT IN GERMANY: AK NEM OFFERS A STEADY HAND IN THE FACE OF REGULATORY CHALLENGES

AK NEM, the German supplement sector organisation, is providing members with invaluable support both nationally and at the European level. Connect spoke to Scientific Director Antje Preussker.

Germany's food supplement sector body, Arbeitskreis Nahrungsergänzungsmittel (AK NEM), was founded in 2003 – just one year after the adoption of the EU Food Supplements Directive. The timing of this was not a coincidence. Until 2002, Germany's domestic market for supplements was driven by the pharmaceutical industry. But the introduction of the EU directive changed everything, by defining supplements, decisively, as food products.

In light of this development, a group of 20 food supplement suppliers approached Lebensmittelverband Deutschland, Germany's influential food business body. They proposed to establish a dedicated working group representing their interests and subsequently formed AK NEM. Today, as it prepares to celebrate its 20th anniversary in 2023, AK NEM has 64 members – and that number is continuing to grow.

At the national level, AK NEM works in a highly challenging environment in which the German authorities and other important stakeholders, including many nutrition scientists, are openly sceptical of supplementation.

“We’re always busy addressing negativity around supplements,”

says Scientific Director Antje Preussker, with a wry smile.

“That’s our life, every day.”

Against this backdrop, meanwhile, Germany is probably the most powerful voice in the EU on matters relating to supplements, which means there is an ever-present risk of German scepticism towards the product category feeding into European decision-making. This factor further complicates AK NEM's already-difficult mission, leaving the organisation to argue for appropriate regulation and for recognition of the product benefits for the human health on both the continental and national stages.

Highlighting the scale of this challenge is the issue of maximum levels for vitamins and minerals in supplements. In March 2021, Bundesinstitut für Risikobewertung (BfR), the agency responsible for risk assessment in Germany, updated its model for setting national maximum levels for vitamins and minerals, which continues to take a very conservative approach and is, in the industry's view, unreasonably restrictive.

AK NEM argued against taking such an approach in isolation and suggested that it would be better to await harmonisation at the EU level. The European Commission, after all, had recently indicated a renewed determination to harmonise maximum levels across the single market. BfR agreed to press pause, and its model has not, as yet, been incorporated into Germany's national food supplement legislation.

On one level, this is a success. But, as ever, things are more complicated. Germany is one of the countries leading discussions in the European Union on setting EU-wide maximum levels and is promoting the BfR model as a solution. Preussker's desire is for the issue to be resolved in such a way that it benefits all parties through a Europe-wide discussion taking into account more liberal positions of other member states and stakeholders.

A few years ago, AK NEM realised that while it continued to manage perceptions of supplements in government, it also needed to engage directly and more widely with consumers and health professionals. As a result, it has invested significant resources into communications outreach to consumers to encourage the safe use of supplements and, most recently, to the nutritionists who influence the decisions that politicians make.

It's a slow burn but Preussker is confident it will make a difference over the longer term. It is her wish that within the next 20 years, supplementation will have achieved greater acceptance by the authorities in Germany. “I would like to see an end to the negative debate,” she says. “We are doing our best to resist it with positive messages. It's not easy, and change won't happen quickly, but we will keep pushing. In the meantime, AK NEM will continue to provide a steady hand for Germany's supplement sector.”





Russ Michelson,
Treasurer,
IADSA

FRESH FACE, FRESH PERSPECTIVE: NEW IADSA BOARD MEMBER PROMISES TO BRING ENERGY AND PASSION

Recently appointed to the IADSA board, Russ Michelson told Connect about his vision for the alliance and the future of the supplement sector.

It's no exaggeration to say that Russ Michelson, IADSA's newest board member and Treasurer, is passionate about supplements. Since graduating from the University of Maryland, he has built a successful career in the industry through roles at major companies including Solgar, GNC, Pfizer and, currently, Reckitt. But his dedication is not just professional; it's also a way of life.

"I take my supplements everywhere," he says. "Whenever I travel – for work or vacation – they're always in my pocket. They've been part of my DNA all my life. My dad took them when I was growing up, so they were deeply ingrained in me. When I was older, they became even more important to me when traditional medicine fell short. They're a part of who I am, and they've provided a foundation for me to become a healthy person, as well as being a huge part of my career trajectory and what I stand for."



IADSA Board: Russ with Vice Chair Carl Gibson and Chair Gerhard Gans

Michelson first became aware of IADSA 10 years ago, and soon decided he'd like to contribute to its activities in some way. "I loved the way it was carving out a world where supplements were important," he recalls. "It made me realise that I wanted to go beyond the US in my work and do more in the international space. That's why IADSA is an organisation I've long wanted to get involved in."

He acknowledges the importance of regulation to the core work of the alliance and says it's a "nice beginning point, to create business opportunities." But what excites him even more is the potential for IADSA to engage policymakers and other stakeholders on the value of supplementation to wider society, especially in the wake of Covid-19.

"The pandemic brought a global awareness of the importance of a healthy and balanced immune system," he says. "It gives us a chance to strike while the iron is hot and really make the case that supplements should be part of healthcare policies in every country. We're starting to see some national governments emphasizing the role of these products, but not enough of them."

He continues: "It's time for policymakers to look beyond the task of setting regulations, where this ingredient's allowed with this claim, at this level.

They should also be exploring how supplements could become part of what they provide to their citizens to help them stay healthy." A key part of achieving this will be education, he says, and singles out IADSA's Mind the Gap series as a good example of this in action.

Having worked for companies such as Pfizer and Reckitt, Michelson says he will bring what he describes as pharmaceutical experience but a supplement mindset" to IADSA's work. But he also pledges that, regardless of his background, he will always stand for the interests of every IADSA member.

"The strength of IADSA is in its diversity. It's a huge asset. I will bring my energy and my passion – and always with a unique perspective."



Christine Reyes, HADSAP

WORKING IN HARMONY: HADSAP OFFERS A CASE STUDY IN INDUSTRY- GOVERNMENT CO-OPERATION

With ASEAN harmonisation on the horizon, HADSAP has been able to work closely with government agencies in the Philippines, thanks to a partnership based on mutual trust. Connect speaks to Christine Reyes to find out more.

2023 looks set to be a significant year for the supplement sector in the Philippines. The country will be the venue for the next meeting of the Association of Southeast Asian Nations (ASEAN) Product Working Group on traditional medicines and health supplements, by which time it's expected that the ASEAN agreement on harmonisation of the technical requirements and guidelines for health supplements will have been signed.

By then, it will already be 19 years since ASEAN members first agreed to move forward with harmonisation (although agreement was close before the Covid-19 pandemic disrupted progress). Co-ordinating the agreement has been highly complex, and the process has demanded deep wells of patience. But the supplement sector in Southeast Asia can see the finishing line on the horizon.

In the Philippines, work towards ASEAN harmonisation has been spearheaded by the Health and Dietary Supplement Association of the Philippines (HADSAP). It was founded in 2008 2007, after it became clear that the national government needed support in terms of fulfilling its role in the harmonisation process.

The Philippines was given responsibility for developing Annex VII of the ASEAN agreement – a framework and process for substantiating the different types of health claims made in relation to health supplements. On this, it worked alongside the regional ASEAN Alliance of Health Supplement Associations (AAHSA), of which HADSAP is a member, and had access to global data provided by IADSA.

At present, supplement companies in the Philippines operate under a regulatory system which is challenging for supplement claims. Signing the ASEAN agreement will open up opportunities for claims to be used on products and in communication.

In 2021, HADSAP won the IADSA Grant, which has been allocated to fund training and coordination between industry and regulators to ensure a smooth adoption of all ten annexes in the ASEAN agreement. Christine Reyes, who is HADSAP's representative in AAHSA, with responsibility for regulation, says HADSAP has close relations with the Philippines' state agencies, including its Food & Drug Administration (FDA).

"We are the go-to organisation for the FDA," she explains. "They look to us to initiate things. For example, when GMP requirements came in a few years ago, they depended on us to run GMP training sessions." Also reflecting HADSAP's status is the fact that it was recently designated as a partner institution of the Anti-Red Tape Authority (ARTA). Reyes says:

"This recognised our efforts to make it easier to do business in the Philippines and to deliver an efficient government service."

Despite the close working relationship and regular dialogue HADSAP enjoys with government agencies, the Philippines market is nevertheless not always a straightforward place for supplement companies to do business. Besides the restrictive health claims framework, maximum levels for vitamins and minerals are also set at conservative levels, typically at approximately 1x the RDA.

As such, HADSAP's 24 members are looking forward to implementation of Annex X of the ASEAN agreement, which covers the general principles for establishing maximum levels of vitamins and minerals in health supplements. The agreement will permit levels based on safety assessment, which will enable supplement companies in the Philippines greater freedom in this area.

The Philippines will be a fitting location to celebrate the signing of the harmonisation agreement when the Product Working Group meets there in 2023. Ratification is the start of a longer-term process during which it will be necessary for ASEAN members to build effective regulatory and policy frameworks. HADSAP has shown the way in terms of how to create meaningful relations between industry and government, which is something that will be necessary to ensure ASEAN harmonisation delivers on the potential it offers. A new chapter awaits, and HADSAP will be making sure the Philippines plays a central role.



