NUFFOODS Spectrum
perspectives on food technologies & business
ASIA

Inside Affronâ??s Journey to MFDS Recognition for Stress Relief

16 March 2026 | News

MarÃa MuÃ±oz, Head of Quality Assurance and Regulatory Affairs at Pharmactive Biotech

MarÃa MuÃ±oz, Head of Quality Assurance and Regulatory Affairs at Pharmactive Biotech

As consumer demand for clinically validated natural wellness solutions grows across Asia, regulatory recognition is becoming a critical differentiator for functional ingredients. Recently, Pharmactive Biotech Products achieved a significant milestone after its saffron extract, Affron saffron extract, became the first of its kind to receive an individual stress-relief claim approval under South Koreaâ??s Health Functional Food (HFF) framework from the Ministry of Food and Drug Safety (MFDS). The approval highlights the increasing importance of ingredient-specific clinical evidence, regulatory rigour, and quality consistency in the evolving functional foods market. In this interview with NUFFOODS Spectrum, MarÃa MuÃ±oz, Head of Quality Assurance and Regulatory Affairs at Pharmactive Biotech Products, discusses the scientific and regulatory journey behind the milestone, the significance of MFDS recognition, and how clinically substantiated botanical ingredients are shaping the future of stress-management solutions across South Korea and the broader Asia-Pacific region.

Affron is the first saffron extract to receive an individual stress-relief claim approval from South Koreaâ??s MFDS. Could you walk us through the scientific and regulatory journey that led to this milestone?

This milestone is the result of a structured, multi-year scientific and regulatory strategy.

From a scientific standpoint, the foundation was the generation of robust human clinical evidence with a well-characterised, standardised saffron extract. MFDS evaluates not the botanical, saffron, in abstract, but the specific ingredient as marketed, including its standardisation, manufacturing controls, and reproducibility of results.

From a regulatory perspective, the process involved a comprehensive dossier submission under the Health Functional Food (HFF) framework, followed by iterative technical review, clarification requests, and alignment with MFDS evidentiary standards. The approval reflects not only the strength of the clinical data, but also the consistency of quality specifications, traceability, and manufacturing discipline behind AffronÂ®.

The MFDS is known for its rigorous evaluation standards. What specific biomarkers, clinical endpoints, or mechanisms of action were critical in securing Health Functional Food (HFF) recognition for Affron?

MFDS places significant emphasis on clinically relevant, validated, and reproducible endpoints.

For AffronÂ®, the evaluation focused primarily on well-established psychometric tools measuring stress-related outcomes in everyday life contexts. The clinical data demonstrated statistically and clinically meaningful effects consistent with the approved functional claim: â??May help to relieve stress.â?•

In addition, supportive preclinical research helped substantiate biological plausibility. For example, a preclinical in vivo study conducted in Korea contributed to understanding potential modulation of the hypothalamicâ??pituitaryâ??adrenal (HPA) axis and other stress-related physiological pathways. While mechanistic evidence alone is not sufficient for approval, it strengthened the coherence of the totality of the evidence package.

Importantly, the approval was based on the overall weight of evidence rather than on a single biomarker or isolated result.

How does this individual license differentiate Affron from other saffron-based or botanical stress-relief ingredients currently available in the APAC market?

The key differentiator is that this is an individual ingredient recognition, not a general botanical reference. The MFDS approval applies specifically to AffronÂ® as a standardised extract with defined specifications and a dedicated scientific dossier. It is not a generic â??saffronâ?• authorisation.

The approval marks a significant step forward, delivering regulatory clarity and reinforcing the ingredient-specific scientific substantiation behind AffronÂ®. It guarantees quality consistency aligned with the approved dossier and secures a clear and compliant pathway for claims within Korea, strengthening our global regulatory footprint.

In highly regulated markets, this distinction is significant. It reduces interpretative risk and offers partners a validated regulatory framework rather than reliance on traditional botanical positioning.

Stress is a growing concern among Korean consumers. How do you see demand evolving in South Korea and the broader Asia-Pacific region for clinically validated, natural stress-management solutions?

Stress management is increasingly recognised as a daily wellness priority rather than an episodic concern. In South Korea in particular, consumers are highly informed and responsive to regulatory validation. The HFF framework carries credibility, and ingredients with individual recognition benefit from increased trust.

Across the broader APAC region, we observe a shift toward evidence-backed natural solutions. While interest in botanicals remains strong, there is a growing expectation for clinical substantiation and regulatory transparency. Ingredients that combine traditional origin with modern scientific validation are particularly well-positioned.

Your collaboration with Hyundai Bioland Co., Ltd. was key to this process. How important are local partnerships when entering highly regulated functional food markets like Korea?

Entering a market such as Korea requires not only scientific robustness but also a precise understanding of regulatory expectations, documentation standards, and procedural nuances. A partner such as Hyundai Bioland provides essential expertise in local regulatory interaction, dossier alignment, and market execution.

This collaboration model ensures regulatory compliance is maintained without compromising scientific integrity or commercial agility.

With this approval secured, what are Pharmactiveâ??s next strategic priorities: geographic expansion, new health claims, or further clinical research for Affron?

Following this approval, our priorities are clearly defined. We are focused on consolidating AffronÂ®â??s position within the Korean market under the HFF framework, while carefully evaluating expansion opportunities across selected APAC territories based on regulatory feasibility and scientific alignment. At the same time, we will continue investing in clinical research and quality development to further strengthen the ingredientâ??s evidence base and ensure long-term regulatory resilience.

Our approach remains disciplined: scientific validation first, regulatory alignment second, and sustainable commercial growth as a result of both.

Shraddha Warde

shraddha.warde@mmactiv.com