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‘Inside Regulatory Affairs’ With Haleon’s Niels Kildemark

by David Ridley

In this installment of HBW Insight’s “Inside Regulatory Affairs” series, Haleon’s regulatory strategist Niels Kildemark welcomes the challenges that the EU Green Deal brings, but warns that meaningful consultation with all stakeholders, including industry, must be prioritized to ensure clarity of regulatory purpose and execution.

HBW Insight is shining a spotlight on the work of regulatory affairs specialists operating in and supporting the consumer health and cosmetics industries. We are profiling this important role, hearing what a typical day involves and finding out what is top of mind for these individuals today. Check out other installments in this series in HBW Insight.

The European Green Deal has brought with it a torrent of regulation, which is in turn keeping regulatory affairs professionals at European consumer healthcare companies very busy. (Also see "*Infographic: EU Sustainability Legislation All In One Place*" - HBW Insight, 19 Feb, 2024.)

For regulatory affairs specialists like *Haleon plc*’s Niels Kildemark, the challenge is a welcome one, as is the region’s increased focus on sustainability, environment, and climate.

“I support the European community’s ambition to create a circular economy and if I can make a small contribution through my work in regulatory affairs then that makes my role all the more fulfilling,” he tells HBW Insight in the latest installment of our Inside Regulatory Affairs series.

However, Kildemark – who also chairs the Association of the European Self-Care Industry’s food supplements committee, giving him unparalleled insight into the EU’s legislative process – worries that sometimes legislative proposals “become somewhat unclear or open for

interpretation" as a result of complex subject matter and diverging points of view from member states.

Meaningful consultation with all stakeholders, including industry, is the solution, Kildemark suggests.

Q What is a typical day in the life of a regulatory affairs specialist?

A In a global consumer health company like Haleon, regulatory affairs is a function with several different responsibilities. They range from compliance checks to advising on new business opportunities and on a variety of products including food supplements, cosmetics, medical devices and medicines. Regulatory affairs collaborates with several other company functions, manages external contacts to health authorities, and participates in trade association work. The sheer diversity of the tasks and responsibilities gives colleagues in regulatory affairs the opportunity to work on many different subjects and develop professionally, so it's difficult to say what a "typical day" at regulatory affairs will bring!

In my role as an EU regulatory strategist at Haleon, one of my main responsibilities is food supplements. I am involved in various European innovation projects and collaborate with colleagues in the different markets to launch these innovations. A significant part of my time is spent scanning the horizon for new regulatory developments. Together with internal experts, I assess the impact for our organization, and use the assessment to influence these developments. Once new legislation is a reality, I share it with relevant functions to ensure timely implementation.

I also have the pleasure of chairing the food supplements committee of the Association of the European Self-Care Industry. Participating in industry association activities gives an extra dimension to my work. It is a great way to get involved early in the legislative process and interact directly with European Commission officials and experts from member state regulatory authorities.

Q How has this role changed over time?

A It seems to me that the responsibilities of regulatory affairs over time have broadened from, let's call it product-specific legislation, like product composition, packaging, labeling and market access, to what I would refer to as product-associated legislation such as microplastics, extended producer responsibility or PIE (pharmaceuticals in the environment). As I see it, this is a positive outcome of the increased focus on sustainability, environment and climate. I support the European community's ambition to create a circular economy and if I can make a small contribution through my work in regulatory affairs then that makes my role all the more fulfilling.

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Q **What is currently keeping you up at night?**

A I'm very fortunate to work for a company which boasts a strong regulatory organization and for that reason I'm not troubled by current regulatory matters. I do, however, think quite a bit about new regulatory developments in Europe. Only by looking ahead you can influence future requirements, prepare the organization for what is coming, and ensure timely implementation.

In general, I consider the EU legislative process to be quite transparent, following clear and well-defined processes where there are opportunities to input and demonstrate the impact of proposed legislation. However, I believe there is a tendency for legislative proposals to become somewhat unclear or open for interpretation, which I appreciate can happen particularly if a given subject is complex and there are divergent views from member states. It is particularly in these situations I believe consultations of stakeholders active in the area intended to be regulated is something that must take place.

Q **What is your company doing to deal with these challenges?**

A When it comes to new legislation, the important thing is to keep being a constructive partner to legislators by sharing experiences, expected impact and other thoughts whenever possible. We of course participate in formal hearing processes via relevant

> industry associations - which is valuable - but sometimes the contribution drowns in the hundreds of hearing responses from other stakeholders. When possible, we share views at meetings where legislators attend.

Bio

Niels Kildemark is a Regulatory Affairs Specialist at Haleon.

He joined the organisation from Pfizer Consumer Healthcare when in August 2019 Pfizer and GSK combined their consumer healthcare businesses into a Consumer Healthcare Joint Venture, which now is Haleon. Prior to Pfizer Consumer Healthcare, Niels has work at Regulatory Affairs in various companies covering ingredients, FMCG and medical food.