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Executive Q&A: Thomas Hein, SVP commercial and regulatory affairs, Hermes Pharma

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In an interview with *The Pharma Letter*, Thomas Hein, senior vice president of commercial and regulatory affairs for German privately-owned company Hermes Pharma, tells us about how the company is working closely with 10 of the world's top 15 pharma companies on its user-friendly dosage forms.

Please could you give us an overview of what Hermes Pharma does?

Hermes Pharma is a division of the German pharmaceutical company Hermes Arzneimittel GmbH which was founded more than 100 years ago. We specialize in developing, formulating and manufacturing user-friendly medicines including effervescent and chewable tablets, instant drinks and orally disintegrating granules (ODGs). We have more than 40 years of experience working with Pharma, from product development and manufacturing through to regulatory support and product marketing.

In the late 1980s, Hermes Pharma was established and is now a distinct division to provide services to pharmaceutical companies and other third parties looking to tap into our dedicated formulation, development and manufacturing expertise. In 2003, we acquired an Austrian pharmaceutical company operating in a similar area – this allowed us to strengthen our position as the expert in making medicines more user-friendly, as well as to increase production capacity and flexibility.

We now routinely work with healthcare companies around the globe to help them expand their product lines, as well as grow and differentiate their brands. We offer a 'one-stop shop' providing value across the entire

pharmaceutical value chain, from initial product design and concept through to specialist project management, manufacturing expertise and assistance with regulatory submission.

What are the advantages of Hermes' products over other forms of drug delivery?

Because our products are designed with user-friendliness at their core, the most conspicuous advantage comes in the form of ease-of-use, which has the potential to boost medical effectiveness through increased user compliance. For example, solid oral dosage forms such as tablets and capsules can be difficult for many people to ingest, especially children, the elderly and those with difficulties swallowing tablets. Our user-friendly dosage forms overcome this barrier as they are designed specifically with ease-of swallowing in mind; they can either be dissolved in water before intake (e.g. effervescent tablets, instant drinks), sucked or chewed (e.g. lozenges, chewable tablets) or dissolve upon contact with saliva in the mouth (e.g. ODGs). Importantly, they are also pleasant to ingest, as our coating and flavoring technologies enable us to effectively mask the bitter taste inherent to most active pharmaceutical ingredients (APIs). In this way we can create products in a range of flavors and enable consumers to choose their favorite.

Since many user-friendly dosage forms can be taken without water they are far more convenient for busy people, who can easily take them 'on the go'. Such an approach is likely to prove particularly effective for medicines that must be taken throughout the day, such as analgesics; modern consumers now demand flexibility and convenience in most areas of their lives – medicines are unlikely to be any different.

Lastly, user-friendly dosage forms also provide an excellent opportunity to simplify complex dosing regimens. By circumventing the restrictions

imposed upon the physical size of solid tablets, it is possible to include a greater amount of API – or even multiple APIs – all within a single dose. By making everything simpler and easier, this improves the lives of both patients and care-givers.

What has been the reaction of the pharma industry to your products?

The general trend that we are seeing in the market is that pharmaceutical companies are really starting to focus on the holistic needs of patients, not just their medical requirements; when considering this and the impact of concepts like personalized medicine and patient centered healthcare, it's likely that the traditional 'one size fits all' approach may need to change to deliver on-going success in the marketplace. Our products and strategy align perfectly with the approach to put patients first, and the reaction from the industry has been overwhelmingly positive.

In our experience, more and more pharmaceutical companies are working in a collaborative fashion with specialist third parties that can add value to product development processes. This is especially true when looking to tap into sources of innovation, such as that provided by Hermes Pharma. Through a collaborative dialogue our customers utilize our services to extend the lifespan of a product, revitalize an ageing brand or expand the diversity of their product portfolios. In some cases, the expertise we provide can help to reduce our customers' formulation development from years to weeks, triggering a leap forward in product development.

Can you tell us any of the pharma companies you are currently working with?

Right now we are working closely with 10 of the top 15 pharma companies in the world, as well the top four developers of generics. On the whole we

are working with more than 90 companies – many of which are medium-size – and operating locally in many countries across both Europe and the USA. The majority of the products we develop for these companies are well-known branded products, instantly recognizable to doctors, pharmacists and consumers across the globe. We work under a model that is best suited for our customers, co-developing products in many cases, while also licensing out our own Hermes Arzneimittel products for customers to market under their own brands in others.

How have your company and its products developed over the past 40 years?

We have shifted from purely developing and marketing our own OTC products to working with numerous third parties via a number of collaborative models. Our primary service model is co-development. In this case either Hermes Pharma or the customer has an initial idea for a product, which our team then helps to realize though formulation development and subsequent upscale to manufacturing, all on behalf of the customer. The final product, manufactured by Hermes Pharma, is then launched and marketed by the customer under the company's own brand. If a client comes to us with a completed concept, we can take this through to manufacture, including support with regulatory submission, if and when required.

Our other business models mostly revolve around licensing out products we have already developed internally at Hermes Pharma. In the instances where a product is already in the late stages of development, such as during regulatory review, customers can license them to sell them under their own brand name, with our team manufacturing the product on behalf of the customer. Alternatively, we also license out products that have already been successfully released to the market and marketed under the Hermes Arzneimittel brand, enabling customers to market the same, or a very

similar, product under their own brand, for example in geographical markets where we do not sell that particular product.

Are there any challenges when creating your products?

There are two main challenges when creating user-friendly dosage forms, both of which require knowledge and experience in order to overcome them successfully: the bitter taste of most APIs, and the complex regulatory environment when working with innovative dosage forms.

The bitter taste of most APIs can be a problem, as our dosage forms spend a longer time in the mouth and are actively tasted rather than simply being swallowed, as is the case for conventional tablets and capsules. Effective taste masking without compromising on mouth feel, stability or API release profile requires the use of specific technologies and processes, such as hot melt coating (HMC) and TOPO granulation. Having optimized these processes for pharmaceutical formulation and commercial production, we have a great deal of experience providing medicines that taste pleasant, have high stability and deliver the desired onset of action.

Achieving regulatory approval for innovative user-friendly products can also be challenging. The current regulatory environment has been established principally with conventional dosage forms in mind, and the introduction of novel dosage forms can require the establishment of new guidelines and procedures. We work very closely with regulators to push forward boundaries and develop novel recommendations, helping to ensure that new user-friendly medicines meet the quality requirements necessary to ensure patient safety and deliver medicinal value.

What is the future for drug delivery?

We feel that the future is user-friendly dosage forms. People live in the 'era of choice' where the 'one size fits all' model is no longer applicable. With the advent of the internet and the wealth of medical information available at the touch of a button, people are more informed than ever, not only about the illnesses they suffer from but also the treatment options available to them. Consequently, many now visit doctors and pharmacists armed with knowledge and full of questions, requests and suggestions.

This is where we feel user-friendly dosage forms can really add benefit for patients and care-providers, as well as helping pharmaceutical manufacturers differentiate themselves in a crowded marketplace.

User-friendly dosage forms better meet patient needs and are more convenient and pleasant to take – all of which leads to enhanced patient compliance. For pharmaceutical companies, they offer the chance to reinvigorate older products, solidify brand loyalty, provide patients with choice and strengthen intellectual property. The variety of user-friendly dosage forms available also allows for a finer segmentation of the market. It enables the development of medicines that meet patient needs across different age groups taking into account factors such as geographical and cultural preferences towards flavor, packaging etc.

What does the next year hold for Hermes Pharma?

We plan to continue our research into new user-friendly dosage forms with the intention of expanding our product portfolio. Due to an on going increase in market demand, we have also recently made several important investments in new production equipment, most of which will be fully operational as we move into 2015. This will help to increase our production capabilities for specific dosage forms; for example, our new infrastructure will provide an increase in capacity for ODG production. In light of these growing market needs, we also plan to invest in additional coating

equipment to further increase capacity across the full range of our manufacturing portfolio.

What does Hermes hope to achieve in the next 5–10 years?

The true potential for user-friendly dosage forms is something we feel is yet to be fully unleashed. It is our long term goal to help increase awareness of these dosage forms and inform people about the wide range of benefits they offer, not only within pharma but also by communicating them to doctors, pharmacists and consumers.

Taking the USA as an example, there is a relatively small selection of different OTC dosage forms dominating the market and most of these are tablets and capsules packed in plastic bottles. Our analysis of the market shows that there is a growing interest in the area of user-friendly dosage forms, but this is tempered by a fear that the consumer may not readily accept a new form of medicine. It's our feeling that if we can educate the key stakeholders on the merits of these medicines, as we have done in Europe to great success, we can overcome this initial concern and bring the benefits of user-friendly dosage forms to the wider marker, both in the US and across the globe.

For us, this endeavor goes hand-in-hand with the notion of putting patients first; developing dosage forms with the needs of the end-consumer at the heart of the developmental process, rather than producing one single form that may very well result in poor compliance within a large fraction of the population.

Finally, we are committed to further strengthening our capabilities for innovation. With key decision-makers in pharma seeking widespread innovation from external suppliers, the services Hermes Pharma provides are more relevant than ever. We are showing that innovation doesn't have

to be aimed solely at discovering new APIs, but instead should encompass every aspect of product development, from concept development through to dosage form selection, flavor and packaging. For this reason, we are in a constant dialogue with our customers in order to generate an insightful readout of where the real needs, challenges and opportunities lie in the market. Such an approach continues to strengthen our position as an innovator in developing pharmaceutical products that are specifically designed to meet both the lifestyle and treatment needs of patients.