In My View

In this opinion section, experts from across the world share a single strongly held view or key idea.

Submissions are welcome. Articles should be short, focused, personal and passionate, and may deal with any aspect of pharmaceutical development or manufacture. They can be up to 600 words in length and written in the first person.

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Swallowability by Design

Tablets are still the most common dosage form, but today's consumers tend to have strong preferences and expect the freedom of choice. Have you considered all of your options?

By Thomas Hein, Senior Vice President Commercial and Regulatory Affairs, Hermes Pharma, Germany.

"Great news! We have our API – now, let's formulate a tablet and get to market fast."

Let's be honest; tablets remain a popular choice for manufacturers predominantly because they are easy and cost effective to manufacture, package and ship. Luckily, they also offer good physical and chemical stability, and facilitate simple, accurate dosing (even at small volumes of API). And there is a degree of flexibility: the release profile can be modified using alternative coating methods, and the shape and color of tablets can be changed for both aesthetic and practical purposes, with any unpleasant taste being masked by coating (in theory). Surely, the perfect dosage form!

Unfortunately, there is one major flaw. Few people enjoy swallowing tablets, a fact that can affect patient compliance or drive consumers to an alternative (if one exists). I think it's about time that the industry considered alternative dosage forms and took the problem of swallowability more seriously.

The problem of swallowability has been well discussed with regards to geriatric and pediatric populations, but what about everyone else? A market research institute recently conducted a survey of 2000 consumers in Germany and the US on our behalf, and the findings show that many people can have trouble swallowing tablets or capsules: 62 percent of respondents in Germany and 50 percent in the US reported difficulties in this area (1). Many respondents described negative experiences including an unpleasant odor or taste, tablets being too big to swallow, and the feeling that the tablet or capsule became stuck in the throat. All age groups surveyed were affected by swallowing difficulties, but the problem was most widely reported among people aged 16 to 34 years.

It is important that we consider the full impact of these patient experiences, including the subsequent measures that individuals adopted to take (or not take) their tablets and capsules. For example, the same survey found that 32 percent of participants reported breaking up tablets before swallowing them; 17 percent crushed them and dissolved them in water, and 9 percent chewed them. All of these actions can affect API release profile, bioavailability and medical efficacy. In addition, 8 percent of survey respondents went so far as to completely abstain from taking their medication altogether.

Our survey clearly showed that it was the younger generations who were most dissatisfied with tablets (up to 70 percent of the 16–34 year old demographic experienced difficulties), which fits with the belief that today's patients are less likely to tolerate a product that does not adequately meet their needs. Most modern patients have grown accustomed to having freedom of choice in all areas of life and enjoy the benefits of convenience. They commonly consult medical professionals where appropriate, but they will also do their own research to understand what medications and dosage forms are available, as well as what other patients recommend. Armed with this information, they are not afraid to ask their doctor to prescribe a particular product.

When survey participants (of all ages) were asked about the characteristics they considered most important in a medication or food supplement, it was clear that ease of swallowing, convenience and taste were all key. When it comes to over-the-counter medicines, there is often a range of different dosage forms so that the patient can pick what suits their lifestyle best. Unfortunately, there isn't usually the same choice when it comes to prescribed medicines since most manufacturers opt for tablets or capsules. Where are the effervescent tablets, instant drinks, chewable tablets, orally disintegrating granules, or lozenges?

Well, producing a different type of dosage form may require specialized equipment and processes, as well as expertise in adapting the API to the dosage form – all real turn offs for manufacturers. But let's not forget that developing APIs in new dosage forms can benefit pharma companies by allowing expansion of product lines. In some cases, products can be sold in a range of flavors to suit patients' preferences and to offer variety. In addition to capturing market share, this can help breed brand loyalty and better differentiate products in the marketplace. New dosage forms can also help overcome intellectual property issues by allowing companies to reformulate medicines in ways that are more difficult for competitors to copy, or by providing grounds for patent extensions.

Tablets are well established and there is a perception – especially in the industry – that patients will take them whether they want to or not. And yet researchers have identified non-adherence as a major source of waste in US healthcare, equating to about 13 percent of total healthcare spending (2, 3). So I ask again: are tablets really the best option? Other dosage forms may counter some of these compliance problems. And when companies start to develop a more customer-orientated product, there will surely be a number of financial and business benefits that follow.

References

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2. *AO Luga, MJ McGuire, "Adherence and Health Care Costs", Risk Manag Healthc Policy, 7, 35–44 (2014).*
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