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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Don't Forget About the Patient

Pharma manufacturers are not embracing patient-centric design when it comes to formulation. We need to go beyond tablets and capsules.

By Thomas Hein, Director Sales & Business Development at Hermes Pharma, Germany.

Designing products that cater to the specific needs of consumers/patients seems logical for any competitive market. In pharma, however, many companies are still not designing truly patient-centric medicines. Tablets and capsules have been the go-to dosage form for decades, but for a significant number of patients, tablets and capsules can present problems. A survey found that, of approximately 2000 people surveyed in the US and Germany, over half reported difficulties swallowing tablets and capsules, with many finding that these dosage forms were too large, became stuck in the throat, or had an unpleasant taste or odor (1). As a result, some of those questioned reported not taking their medicine in the intended way, such as by crushing conventional tablets or dissolving them in water – or not taking them at all.

These issues are particularly apparent in older patients. As explained in the February cover feature of The Medicine Maker (2), elderly patients are more susceptible to issues with swallowing. The natural aging process can cause a weakening of the muscles of the oesophagus and reduce saliva production, which makes the intuitive mechanism of swallowing much more complex. And swallowability is not the only issue to consider; a declining loss of force and dexterity can make it challenging to even open packaging. In my view, however, difficulties swallowing tablets transcend all age groups.

The idea of putting the patient at the centre of product design isn't new, and yet for many pharma companies, it is a paradigm shift from what's gone before. For example, many pain relief and cough and cold medicines available on the market today contain APIs that were developed decades ago, when usability was a minor concern for companies. Exacerbating the problem, however, is the fact that companies launching generic successors of these products often default to the same dosage forms. Many simply do not consider alternative user-friendly dosage forms that would better meet the needs of patients and consumers, and rejuvenate aging products.

Tablets and capsules are often considered the best option from a regulatory standpoint, and are also cheap and easy to formulate. There are relatively few manufacturers with the specialist expertise and technologies required to make well-designed alternative dosage forms cost-effectively. Regulatory authorities rightly require new medicines to be fully characterized and well-understood before they can be approved, but the stringent regulation has led pharma companies to adopt a cautious approach to innovation. User-friendly dosage forms, such as effervescent and chewable tablets, lozenges and orally disintegrating granules, are becoming more well known with established manufacturing methods but their use is still not the "norm". With many companies looking to bring their medicine to market as quickly as possible, tablets and capsules are often perceived as the quickest and easiest solution, despite the fact that they create challenges for

large numbers of patients and consumers.

User-friendly dosage forms present many advantages. Orally disintegrating granules (ODGs) and effervescent tablets can be combined in a single dose to overcome the issues associated with polypharmacy, for example, and coating technologies can be used to develop extended release formulations that deliver APIs over a sustained period, reducing the burden on patients who would otherwise need to take several individual doses.

Patient-centricity is particularly important for over-the-counter medicines, where patients will, undoubtedly, look for products that best match their individual needs and lifestyles. In our study, we found that around 9 in 10 people had used effervescent tablets and lozenges. In some countries, novel dosage forms are more widely accepted; in Germany, for instance, ODGs are much more widely-used than in the US and UK, while in many Scandinavian countries, the most popular dosage form for painkillers is effervescent tablets. When deciding on the best formulation route, it's very important to understand subtle market differences, but always remember that modern patients and consumers increasingly expect convenience in all areas of their life. If medicines can't be transported or fitted easily into routines then patients will look for alternatives, if available.

Of course, there are also differences when developing medicines for different age groups. Going back to elderly patients, although user-friendly alternatives may address their needs to a greater degree than traditional tablets and capsules, there can be other challenges. Orally disintegrating tablets, for example, stay in the mouth for a long duration so taste is very important, as well as mouth feel and even smell. But it takes significant expertise and experience to ensure that compatible flavoring excipients are chosen that work in harmony with the API. Appearance is also important for some alternative oral dosage forms. If you are developing an effervescent tablet that dissolves in water, for example, you must choose excipients that will dissolve fully in water leaving no residues or creating foam, and it's important to ensure the solution looks good in the glass. Developing patient-centric products that appeal to consumers isn't just essential for over-the counter medicines, it can also help patients to better comply with prescription medicine regimes by making them feel good about their medicine.