

Putting Patients First

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at Hermes Pharma

Pharma is looking to the over-the-counter market as an opportunity to reduce healthcare costs and promote self-administration. By creating medicines that patients choose to take, rather than have to take, forward-thinking companies can grow their market share, despite the challenging climate

It is no secret that the pharma industry has been facing a number of challenges over the past few years. The ever-present patent cliff continues to claim millions of dollars in revenue as the patents on blockbuster drugs expire. Meanwhile, the R&D costs involved in creating new therapeutics are increasing – the number of medicines approved per billion US dollars spent on R&D has halved roughly every nine years since 1950, falling by around 80-fold in inflation-adjusted terms – and the return on R&D expenditure has dropped in the last 20 years, from an industry average of around 20% to just 10% (1,2). All in all, the success rate for discovering new medicines remains worryingly low, and progressively fewer are being successfully moved along the pipeline from development stages through to market.

Unfortunately, rather than a clear, identifiable cause, the reason underlying these hurdles is a multi-faceted one. Firstly, there are the mounting regulatory requirements placed upon approving both new

and current active pharmaceutical ingredients (APIs) for use in medicines, meaning that pharma companies have significantly more hoops to jump through and red tape to navigate. In part, this is

because regulators are increasingly cautious of approving new drugs in light of the public's demands for 'completely safe' therapeutics – a long-standing fear that has led to a reduced tolerance for the inherent risks associated with developing and taking medicines (2,3).

Furthermore, the financial burden of developing a new treatment is still an insurmountable obstacle for many smaller companies, with the cost of bringing a drug to market estimated to be anywhere from \$350 million, to as much as \$5 billion (4). This can make it financially unrealistic to try to develop a competitive new medicine, and this is already deterring R&D in some disease areas – those with an ample supply of already effective therapeutics.

Related to this is the 'low-hanging fruit' problem, with some experts believing that all of the more easily targeted molecules have already been produced within these disease areas. In certain cases, this challenge is forcing other companies into 'hard-to-treat' disease areas – resulting in an influx of competing businesses all on the hunt for that first-in-class, highly effective medicine.

Search for Innovation

Pharma is responding by tackling these difficulties from new angles and pursuing alternative solutions. Outsourcing or acquiring

small companies involved in API discovery, for example, is allowing the industry to tap into external sources of innovation, while deftly avoiding the risks of developing new active compounds from scratch. In addition, rather than working to discover and optimise completely new APIs, some companies are instead reformulating current medicines to not only improve them, but to make them more difficult to copy. At the same time, this can revitalise ageing brands and stimulate consumer interest.

Among all of these solutions, one clear trend is emerging: namely, placing patients directly at the centre of pharmaceutical business strategy and developing medicines that deliver added value to patients – not to mention healthcare providers and reimbursers. This approach could prove especially effective if the industry continues to look at the over-the-counter (OTC) market as an opportunity to promote self-administration and reduction in the need for surgery visits – thereby decreasing healthcare costs.

Under this model, consumers can have a direct influence on their medication, choosing specific brands to purchase. By creating medicines that patients will choose to take, rather than have to take, pharma companies have a chance to grow market share, even under the current challenging conditions.

Keywords

Over-the-counter market

Difficulties swallowing tablets

Solid dosage forms

User-friendly formulations

Improved compliance

OTC Opportunities

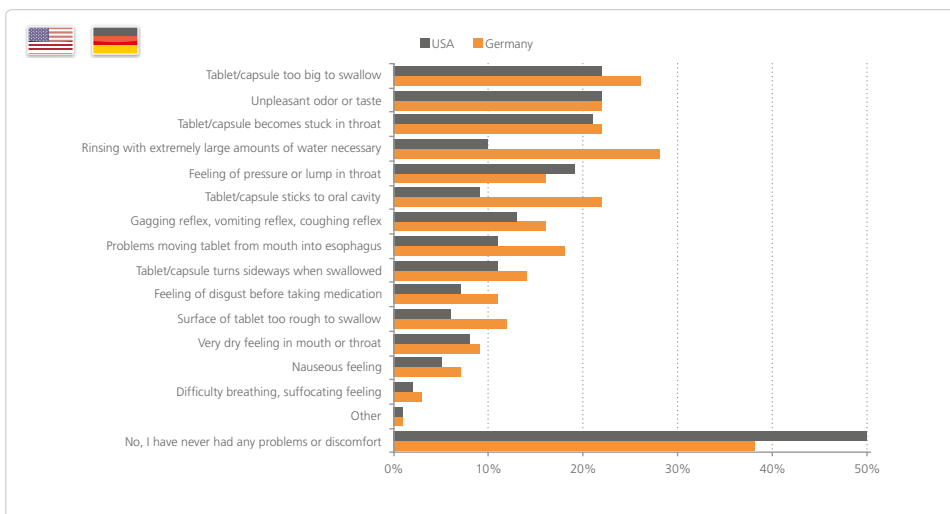
In an era of information and choice, it has become increasingly important to recognise and respond to consumer needs and preferences. Thanks to easy access to a wealth of knowledge via the internet, people are better informed – expecting choice and the opportunity to influence their own lives, especially when it comes to healthcare. Patients are conducting their own research into available medicines and making purchases from online pharmacies via computers and mobile devices. They now frequently arrive at their doctor's surgery or pharmacist with requests for specific medicines – both prescribed and OTC forms.

People will often turn to OTCs at the first sign of disease symptoms, rather than resorting to seeing a doctor and requesting a prescription (Rx) medicine. With growing knowledge of these medicines and how they work, OTCs effectively provide people with around-the-clock access to treatment. This model allows consumers to choose their medicines straight off the shelf.

The OTC market is already a substantial size: in the US, it valued \$17.4 billion in 2011, and could possibly exceed \$106 billion worldwide by 2017 (5,6). If one considers the increased costs of healthcare and the pressures on reimbursement and pricing, a shift away from Rx towards OTC medicines helps to alleviate healthcare costs by reducing visits to the doctor. In fact, OTCs are estimated to save US healthcare \$102 billion annually, relative to alternatives (7).

From the point of view of the pharma industry, a greater focus on the OTC market provides more freedom and flexibility

Question: Do you have or have you had problems or discomfort prior to or while swallowing tablets/capsules? If so, how do/did they occur? (Multiple responses were possible)



to determine sales prices (independent of the pricing policies of reimbursers). In some countries such as Germany, OTC status allows pharma companies to advertise directly to consumers – whereas this is forbidden for products with Rx status, which can only be marketed to doctors, pharmacists and other professionals. Placing more emphasis on OTCs could, therefore, offer many businesses an opportunity to grow revenues and move into new, less competitive market segments – but only if they design products that effectively capture the interest of the end consumer.

Empowering Consumers

A recent survey from Hermes Pharma and the Spiegel Institut Mannheim suggests that now is a pertinent time to be considering the requirements of modern consumers, as many people are not happy with traditional solid dosage forms such as tablets and capsules (8). The survey was conducted by polling 2,000 participants from the US and Germany, with the aim of investigating any issues around taking tablets and capsules, and how people were overcoming these challenges. It also explored

contributors' perceptions, experiences and preferences regarding various other dosage forms. The findings raised several important issues concerning the use of conventional solid dosage forms, and presented a number of new opportunities for pharma to better meet the needs of patients. These could potentially open up new revenue streams, breed brand loyalty and allow companies to capture market share in the process.

Of those surveyed, more than half reported difficulties swallowing solid tablets or capsules, primarily due to their size; the fact that they can easily become stuck in the throat; and their unpleasant taste or odour (see Figure 1).

A problem with swallowing tablets or capsules was reported across all age groups and genders – interestingly, a large number of younger people (70% of 16-34 year olds versus 44% of those aged 65 years or older) had experienced this issue. Worryingly, many participants also admitted to interfering with their medication, with a third reporting breaking tablets before swallowing; 17% crushing them up and dissolving them in water; and 8% who

Figure 1:
The reasons for difficulties swallowing tablets and capsules are manifold

stopped taking their medication entirely. A lack of compliance on this scale not only has potentially serious consequences for the quality of patients' health, but it also has a substantial financial impact – the estimated cost of non-compliance is as high as \$289 billion a year in the US alone (9).

The survey showed that people expect more from their medication than just the intended medicinal effects; they also want it to be a positive experience. Parameters such as taste and convenience were deemed highly desirable, with 64% of participants reporting that products should be easy and comfortable to swallow, and 41% saying that a pleasant taste or odour was important. In addition, 38% of those surveyed suggested that a product should be easy to integrate into their lives, with 30% wanting packaging that was easy to open (see Figure 2).

By designing or reformulating products to meet these consumer needs, it could provide a company with a significant advantage when bringing new products to market, as they would be directly catering to people's

demands. This includes both the creation of new medicines and the reformulation of existing products.

Patient Friendly

User-friendly dosage forms such as effervescent and chewable tablets, orally disintegrating granules, lozenges and instant drinks meet many of the needs cited by the consumers in the study. The most obvious benefit of these dosage forms is that, unlike tablets or capsules, they are easy and convenient to take, immediately alleviating the problem of swallowing experienced by so many people. This alone can offer a significant boost to compliance rates.

Secondly, as user-friendly dosage forms tend to spend more time in the mouth and are tasted more thoroughly, the bitter taste inherent within many APIs needs to be masked. Taste-masking requires formulation expertise, but also provides the opportunity to present medicines in a range of better-tasting flavours.

From a technical standpoint, the comparative lack of size constraints in user-friendly versus conventional dosage forms means that larger

doses or even combinations of APIs can be developed to simplify potentially complex dosing regimens, making medicines easier to take and integrate into daily routines.

Study participants that had tried user-friendly dosage forms almost always scored them higher compared to conventional tablets or capsules on a wide range of characteristics, such as ease of swallowing, sensation in the mouth, package opening and ease of intake. The results indicated a powerful overall trend in favour of the many benefits offered by user-friendly alternatives (see Figure 3).

Everybody Wins

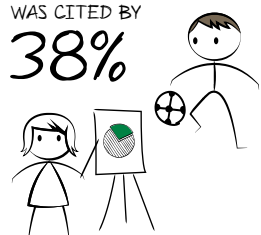
Making pharmaceuticals more user-friendly meets the needs of a large proportion of the population. More innovative dosage forms also have the potential to improve healthcare benefits through better rates of compliance. Non-compliance is a huge issue, with up to 30% of prescriptions never being filled, and up to 50% of medication failing to be taken as prescribed (6). In addition to the cost of wasted medicines, in the US, non-compliance is estimated to account for at least 10% of hospitalisations (6,10). The savings and health benefits provided by user-friendly dosage forms – through increased patient compliance – are thus critically important for stable, effective healthcare.

The introduction of user-friendly medicines allows pharma to capture valuable market share, protect intellectual property, differentiate products from the competition and promote brand loyalty. It should be noted that while reformulation into user-friendly dosage forms provides significant benefits, it does

Figure 2: Patients want their medications to provide a positive experience, beyond just offering medicinal efficacy

THE 'EASE OF INTEGRATION INTO EVERYDAY ROUTINES' WAS CITED BY

38%



1/3

OF THE PARTICIPANTS MENTIONED THAT THE PACKAGING SHOULD BE EASY TO OPEN



41%

OF PEOPLE APPRECIATE A PLEASANT FLAVOR/ODOR

64%

WANT PRODUCTS THAT ARE EASY AND COMFORTABLE TO SWALLOW



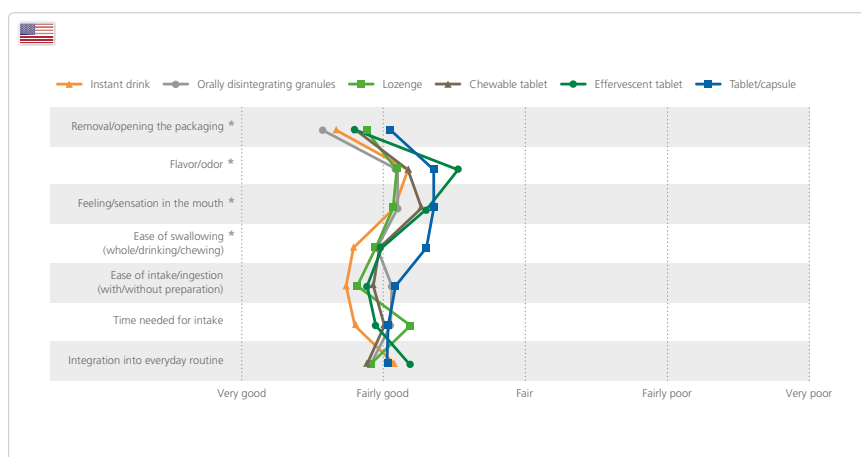
require a high degree of technical expertise to create medicines with the necessary taste, stability and dissolution characteristics. For this reason, many pharma companies are turning to experts in order to facilitate this. While such collaboration used to be rare 10-15 years ago, it is much more common now – to the benefit of all parties involved.

References

1. Scannell JW *et al*, Diagnosing the decline in pharmaceutical R&D efficiency, *Nat Rev Drug Discov* 11: pp191-200, 2012
2. Pharma business model must change radically: KPMG, *PharmaTimes*, 2014. Visit: www.pharmatimes.com/article/14-04-08/pharma_business_model_must_change_radically_kpmg.aspx
3. Weatherall M, An end to the search for new drugs? *Nature* 296: pp387-390, 1982
4. The cost of creating a new drug now \$5 billion, pushing big pharma to change, *Forbes*, 2013. Visit: www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine
5. The over-the-counter drug industry, *About Money*. Visit: <http://pharma.about.com/od/over-the-counter-medicine/a/the-over-the-counter-drug-industry.htm>
6. Visiongain, 2013. Visit: www.visiongain.com/press_release/493/the-global-over-the-counter-pharmaceuticals-market-will-reach-106-3bn-in-2017-predicts-new-visiongain-report
7. CHPA, Statistics on OTC use, 2014. Visit: www.chpa.org/marketstats.aspx
8. Hermes Pharma, Conventional tablets may no longer be the go-to-solution, 2014. Visit: www.hermes-pharma.com/about-us/news-events/detail-news/article/conventional-tablets-may-no-longer-be-the-go-to-solution-press-release.html

Figure 3: User-friendly dosage forms are almost always preferred over tablets or capsules across a number of characteristics

- A** Question: You indicated that you have taken chewable/effervescent tablets/instant drinks/lozenges/orally disintegrating granules/tablets/capsules yourself. How do you rate these in light of the following characteristics?



- B** Question: You indicated that you have taken chewable/effervescent tablets/instant drinks/lozenges/orally disintegrating granules/tablets/capsules yourself. How do you rate these in light of the following characteristics?



about-us/news-events/detail-news/article/conventional-tablets-may-no-longer-be-the-go-to-solution-press-release.html

9. Meera V *et al*, Interventions to improve adherence to self-administered medications for chronic diseases in the United States: A systematic review, *Ann Intern Med* 157: pp785-795, 2012
10. Peterson AM *et al*, Meta-analysis of trials of interventions to improve medication adherence, *Am J Health Syst Pharm* 60: pp657-665, 2003



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