contains the medicine in the firm's 'Parvulet' composition under a film that is peeled off before use. Water is added to the spoon and it swells to form a flavoured 'pudding' that is ready for use.

Egalet has already started testing the Parvulet technology for the delivery of medicines for children in collaboration with Novartis' generics subsidiary, Sandoz.

Curiously, the over-the-counter (OTC) medicines sector has plenty of examples of innovative delivery and packaging systems that are well-received by the public, but there is resistance when this approach is applied to prescription medicines.

"In OTC you see innovative stuff for children on the shelf, and people will clearly pay for it, but as soon as it is on prescription, for some reason they won't," explained Tuleu. "We are still stuck with more traditional technologies when it comes to prescription medicines."

Outside Europe there are other factors to consider, which have implications for pharmaceutical manufacturers. Medicines destined for the developing world also need to be easily stored and transported and while child-friendly formulations have traditionally been syrups, these are bulky and can require refrigeration.

For this reason, the World Health Organisation suggested in 2008 that drugs for distribution in the developing world should be flexible, solid oral dosage forms, although there are clear benefits for a similar approach in more developed markets as well.

One focus at the moment is on tablets that can be divided up into more manageable sizes, or minitablets that are easier for children to take. Novartis has adopted this idea in the development of a new antimalarial product that delivers minitablets in a stickpack, which can be emptied into the mouth and swallowed with water, for example.

Meanwhile, other projects are looking at orodispersible tablets that dissolve in the mouth, multi-particulate systems within capsules, which allow doses to be divided more easily, and even fast-dissolving films that could have active ingredients printed on them, using technology similar to inkjet.

Cost issues

"There is work going on in these areas, but this is somewhat limited by the fact that many of these technologies are patented, raising the cost issue once again, while the doses that can be delivered in this way are relatively low," noted Tuleu.

Of course this route of administration also brings taste considerations to the fore, which has been a key hurdle even for conventional liquid formulations used in children. This is an enormously challenging area at the moment, according to Tuleu, but there have been interesting advances in the area of taste assessment, such as the use of 'electronic tongues', that could facilitate formulation development in the future.

For example, the ultimate outcome would be for electronic tongues to be used early on in the drug development process to allow taste to be a factor in the selection of drug candidates alongside safety and activity considerations.

These *in vitro* systems are still in the early stages, mainly because of problems associated with validating the technologies, but there is a lot of effort going into this area from both industry and academic groups.

"In the coming years we can expect to see innovative formulations for children reaching the market, but at the moment we're still at the R&D stage," concluded Tuleu.

The Author

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Editor's note:

In the March 2012 Innovation article, '*Mucosal drug delivery: beyond buccal*', there was an error in the table. Buccastem (prochlorperazine) was wrongly attributed to Reckitt Benckiser (RB), instead of Alliance Pharmaceuticals Ltd. Alliance acquired Buccastem from RB in 2009.

'If I could change one thing...'

I would challenge pharma to move beyond reiterating product benefits to customers. Ideally customers, (particularly payers), want to see a 'Value Assurance Package' which is a step beyond the traditional value proposition.

This is because buying decisions can be summarised in 5 stages: need recognition; information search; evaluation of alternatives; purchase and post purchase evaluation. Traditionally, value proposition development and articulation focuses on the first four elements of the pharma buying process, where the 'purchase' decision can be summarised as either a formulary decision or the actual generation of a prescription. The fifth stage is the post-purchase evaluation of the customer. Commonly customers experience concerns after making a purchase decision; they may feel that an alternative would have been preferable or potential benefits promised have not been realised in practice. In such circumstances a prescribing customer will not repurchase immediately, but is likely to switch brands next time. The implications for payers can be more significant. At best questioning the true value of a particular intervention or at worst the integrity/trust of the organisation delivering the value proposition.

Value assurance requires careful planning that integrates product value with a blend of pre and post support services and a high-quality implementation plan with pre-determined compliance measures. Only when all these components are integrated, health outcomes can be realised for patients.

To ensure joint accountability, the value assurance package should be created by pharma, payers and clinicians. How can this be achieved?

- Mapping the "value points" of your key customers in accordance to the patient pathway
- Understand how the value points can be linked with incentives in the healthcare system
- Challenge marketing spend and question if you're allocating the right investment on customer insight generation
- Identification of additional support or value added services that are needed by customers
- Develop integrated customer-marketing plans. Often payer, prescriber and patient plans are not integrated. In fact overlaps between customers will need to have separate communications plan to ensure value assurance
- Organisational capability: the value assurance package will be realised if you have the right internal capabilities to work with customers coupled with an optimal level of staff autonomy and authority.

Achieving excellence in value assurance, will ensure value is realised for all concerned.

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