Novel Swallowing Aid
School of Pharmacy

Description of invention

A soft gel unit designed to incorporate a tablet that becomes slippy on contact with saliva, making the unit very easy to swallow.

Benefits of the swallowing aid

- Easy to use: the semi-solid gel is easy to handle and is suitable for use with a range of different pill sizes.

- Easy to swallow: the gel becomes slippy once in contact with saliva which allows the pill to be swallowed without difficulty.

- Applicability across a wide range of drugs: the gel system is composed of inert constituents that do not affect tablet coatings. This means that it has broad applicability as it can be generically used to administer any oral tablet, not limited by size, shape or type of tablet.

- Generally Recognised as Safe (GRAS) ingredients: the constituent materials are already approved by the regulatory authorities.

- Taste-masking ingredients could be added to increase the appeal of the product to both older and younger patients.
A team in the School of Pharmacy at the University of East Anglia has developed this novel soft gel unit for use in human patients with dysphagia, a condition defined as difficulty with swallowing.

Dysphagia is particularly prevalent amongst the elderly population and in patients suffering from neurological diseases such as Parkinson’s disease (PD) and multiple sclerosis (MS), or recovering from stroke. Many dysphagia patients experience difficulty in swallowing conventional tablets and in where liquid formulations of some drugs are available dysphagia patients may be prescribed those liquid formulations. However, given that wide numbers of tablets prescribed in the elderly patients liquid formulations of all such drugs are not available. Where liquid formulations are available they are frequently more expensive and of a consistency that increases the likelihood of aspiration (entry into the respiratory system). Consequently, patients and carers may be forced into crushing tablets and/or opening capsules prior to administration, as well as putting them into food (e.g. yoghurt, jam or similar) to try to aid swallowing. This may lead to changes in bioavailability, due to changes in particle size and/or compromising the coating. In the case of sustained/delayed release systems, potentially disastrous rapid release of the drug due to the breakdown of the release restraint mechanism can occur. Little is known as to the effects of such methods on bioavailability and release time.

There is, to date, no standard administration aid system whereby the patients can be given a tablet, secure in the knowledge that a validated and safe method of assisting swallowing has been used.

To address this clinical need for a properly tested and validated, easy to use, method of administering tablets to dysphagic patients, pharmacists at UEA have developed this novel product, a semi-solid gel which becomes ‘slippery’ on contact with saliva or water. The gel is composed of Generally Recognised as Safe (GRAS) ingredients and does not interact with the tablet coating, ensuring that absorption is not altered. The gel could be formulated with a range of different flavours designed to be attractive to different species.

Commercial benefits
- Simple manufacturing process - and easy scale up
- Significant market opportunity

The swallowing aid targets the large and growing elderly patient population who have the need to take multiple drugs on a daily basis, as well as other groups such as children who dislike or have trouble swallowing tablets. There is an opportunity to make a unit sale of the gel system every time a tablet is administered, including for multiple administrations to the same patient, multiplying the number of uses and sales. Starting with a focus on key patient groups and drug types, and then broadening the scope across all clinically dysphagic patients, as well as those who dislike or have difficulty swallowing tablets, the potential market size for this drug delivery system is extensive.

- Variety of potential routes to market:
  - Combined with a specific drug as the dosage form
  - Standalone to be prescribed for use with a number of prescription drugs
  - Over the counter possibilities, to be sold as a patient pack for use with a number of drugs and bought by the patient
  - Limited competition, currently available swallowing aids are minimal, including:
    - A water based flavoured spray that assists in gliding tablets/capsules and can overcome the issue of undesired flavours of oral drugs
    - Flavoured viscous gels that need to be squirted over oral drugs in a spoon and administered together.

Current status
- Intellectual Property (IP): The invention has a granted patent in EU and patent applications are at advanced stages of prosecution in other international territories.
- Clinical Trials: A small scale study with healthy volunteers has shown that the gel system:
  - Can be handled and administered easily and
  - When in contact with saliva or water can be swallowed easily.
- Product development: A CRO has reviewed our manufacturing process and they have certified that:
  - The consumables for the solid gel are easily sourced and available cheaply; and
  - The manufacturing process is simple and can be produced in industrial scale.

Licensing Opportunity

The University of East Anglia is now looking for licensees to develop and bring a product to market.