
DIRECT-TO-PATIENT: HOW BIG AN OPPORTUNITY FOR EXPRESS CARRIERS?

In order to cut time and costs from hard pressed healthcare budgets, one of the latest models being evaluated is the potential for Direct-to-Patient (DtP) shipments. For the sector this would mean a greater number of smaller shipments and packages, many requiring sensors to measure environmental conditions, which would by-pass distribution facilities and medical centres en route to the home of the patient.

This paper looks at the opportunities which this distribution channel might provide for express parcels companies.

REASONS BEHIND THE INITIATIVE

The e-commerce revolution and its impact on the retailing sector has not been lost on the healthcare sector. Companies such as Amazon have shown that delivery can be fast and reliable, providing consumers with a range of convenient delivery services. E-commerce has cut out many traditional 'bricks and mortar' distribution channels, replacing them with more efficient distribution networks. At the same time, but largely separately, the 'on-demand' industry has burgeoned providing consumers with immediate delivery, mainly of takeaway meals.

Healthcare organizations and pharmaceutical companies are looking at the benefits which these models could provide, obviously balanced against the specific regulatory and product requirements of the industry.

There are several key reasons why DtP is being scrutinized.

- Growing medication needs of the population
- 'Bed blocking' due to inadequate home-care
- Overstretched hospital facilities
- Shortage of doctors
- Pharmacies unable to store 'delicate therapeutic product'

Firstly, there is the increasing medication needs of the population. According to a health survey in the UK¹, 43% of men and 50% of women said that they had taken at least one prescribed medicine in the previous week and 22% of men and 24% of women had taken at least three. This proportion increases with age, with more than half of participants aged 65-74, and more than 70% of those aged 75 and over, having taken at least three prescribed medicines, according to the survey.

In the United States, people aged 50-64 consumed on average 27.6 prescriptions per person in 2017, more than double the number of prescriptions for adults 26-49.²

The increasing age profile of the demographic will mean that drug consumption will increase especially as the most widely prescribed medications are more likely to be for conditions which worsen with age: cholesterol-lowering statins, high blood pressure drugs and prescription-only painkillers.

The ageing population also means that there are increased mobility issues. The elderly find it more difficult to access healthcare facilities, either GP surgeries, pharmacies or out-patient clinics at hospitals. In addition, many elderly patients can not be discharged from hospital if they have no way of accessing

¹ The Health Survey for England 2013, results analysed at <https://www.nhs.uk/news/medication/almost-half-of-all-adults-take-prescription-drugs/>

² <https://www.mckesson.com/blog/retail-pharmacy-trends-to-watch/>

medication at home. This leads to so-called bed-blocking, providing additional pressures on healthcare facilities.

More generally, treating patients in their own home is an important aspect of the benefits of this new model, not only freeing up some in-patient beds, but by reducing the numbers of patients coming to Accident and Emergency (A&E) or out-patient clinics. The latter can be achieved by shifting out-patient procedures to home in conjunction with nursing services. This can also help address the pressures on doctors which in many parts of the world are in short supply. This is examined in further detail below.

Growing need for 'cool chain'

Another challenge faced by the healthcare sector is the growth in what is called 'delicate' or 'fragile' therapeutic products,³ especially biopharmaceuticals which require temperature-controlled conditions in movement and storage. Around half of newly approved medicines are of this type.⁴

These types of drugs should not be shaken and usually stored between 2-8 degrees Celsius (frozen medications at -15 degrees or colder). There has been progress in making these drugs more stable at room temperature. Some can be held for up to 3 days, a change from the norm of 1 hour only a few years ago.

Pharmaceutical cold chain logistics is a \$12.6bn global market, according to the annual Biopharma Cold Chain Sourcebook by Pharmaceutical Commerce⁵. The study shows the sector is growing at 8-9% per year and will reach a market value of \$16.7bn by 2020.

The shift towards biologics and other speciality pharmaceuticals that require refrigeration is driving growth, the study says, adding that the proliferation of insulin and vaccines in Asia and developing markets is also generating higher demand.

In more developed markets, the rise of personalised medicine for the treatment of cancer patients is having an impact. According to Grand View Research, the North America dominant sector will grow at 11.8% per year through to 2022, when it will reach a market size of \$2.45 trillion⁶. This has major implications for healthcare companies and logistics – it is critical to ensure the right drug reaches the right patient on time and at the right temperature.

Manufacturers of these products have responsibility for the conditions in which they are stored and shipped up until the point they are delivered to the distributor, pharmacy, hospital or other clinic. After that point they can only influence these conditions indirectly by advising on the environment in which they should be handled. The responsibility passes to downstream supply chain partners which by their

³ Therapeutic purpose has been defined as:

- Preventing, diagnosing, monitoring, alleviating, treating, curing, or
- compensating for, a disease, ailment, defect, or injury; or
- Influencing, inhibiting, or modifying a physiological process; or
- Testing the susceptibility of persons to a disease or ailment; or
- Influencing, controlling, or preventing conception; or
- Testing for pregnancy; or
- Investigating, replacing, or modifying parts of the human anatomy.

Source: <http://www.medsafe.govt.nz/regulatory/Guideline/G RTPNZ/overview-of-therapeutic-product-regulation.pdf>

⁴ <https://eipg.eu/wp-content/uploads/2013/07/seminar-armin-presentation-eipg-madrid.pdf>

⁵ <http://pharmaceuticalcommerce.com/sourcebook/>

⁶ <https://www.grandviewresearch.com/press-release/global-personalized-medicine-market>

very nature are far more fragmented, with many less suited to the more onerous burden of the logistics requirements.

Least of all suited to this role are local pharmacies. Whilst traditionally they have been able to store many types of stable drugs, it is more of a challenge to provide appropriate refrigerated facilities to hold biopharmaceuticals. This will become an increasing problem with the growth of popularity of these medications, especially given the pressure on space in what, after all, are usually retail, high street premises. Also, there are increased risks involved in ensuring the integrity of biopharma product. In many parts of the world consistent electricity supply cannot be guaranteed. Even short power outages would result in temperature levels in refrigerators rising, resulting in unusable drugs which will need to be discarded. Records logging the temperature in the fridge need to be kept, adding to administration costs.

Traditional retail has addressed the problem of retail space in two ways. Firstly, ensuring that products are delivered just-in-time, rather than stored in a backroom (many fashion retailers keep no stock on site which is not on display). Secondly, the e-commerce model has by-passed the retailer completely, more effectively keeping inventory levels low through centralization at national or regional distribution centres. It is this model which the DtP model seeks to emulate.

ONLINE PHARMACIES WORLDWIDE

- UK

In the UK, Pharmacy2U has been established for many years as the first centralised pharmacy in the market. The company claims that it can deliver high volume prescription orders direct to patients 'at a lower cost than the traditional high street model.'

The company, which has been in existence since 1999 and asserts 99.98% order accuracy, claims that its model is in line with the UK's NHS goals of providing more choice to patients, cutting costs and alleviating pressure of pharmacies. A new facility allows it to dispatch 1 million prescriptions a month.

However, this is just a tiny proportion of the overall market. According to the UK newspaper, The Independent, '...the NHS in England dishes out one billion prescriptions a year to half of the population, 2.7 million items every single day.'⁷ Most medications are dispatched using Royal Mail's 48 hour service.

In the UK, the Co-operative Group has acquired a start-up, Dimec which also allows patients to order repeat prescriptions online, possibly combined with a click-and-collect service and e-consultations for new prescriptions.

- US

In the US, almost inevitably, Amazon has entered the market. In June 2018, Amazon and online pharmacist, PillPack, entered into a definitive merger agreement, in a deal worth reportedly \$1 billion. PillPack delivers medications in pre-sorted dose packaging, coordinates refills and renewals. PillPack holds pharmacy licenses in all 50 states in the US and has built a proprietary set of software systems and tools called PharmacyOS. It is believed that other retailers with drugs operations, Walmart, CVS, Rite Aid and Walgreens Boots Alliance were also bidding for the company showing just how important this sector is at the moment. The company uses UPS or FedEx to ship its orders, offering overnight deliveries if

⁷ <https://www.independent.co.uk/voices/comment/with-one-billion-prescriptions-written-every-year-it-s-time-to-wean-ourselves-off-the-drugs-10254599.html>

urgent. If the medication requires refrigeration, the company uses temperature-safe packaging and expedited shipping.

- Emerging markets

Emerging markets are also following suit. US health company, CVS, has invested in Brazilian pharmacy Onofre to develop its digital services. The large geography of Brazil means that an online model has significant opportunity which will be supported in this case by 49 bricks-and-mortar facilities as the distribution platform. It combines an 'on-demand' element, allowing for the delivery of prescriptions in Sao Paulo within 90 minutes⁸.

In India, the online pharmacy business is, according to reports, worth \$400m and doubling in size each year. The government is undergoing a consultative exercise to regulate the sector as traditional pharmacies oppose the new business model, worried about the discount policies.

HEMOCARE MEDICINES SERVICES

The DtP model for prescription drugs is relatively simple (which is its strength) and with major opportunities for parcels companies. However, there is another segment of the market which involves higher value services, that of 'homecare' services. The model, which is becoming increasingly popular with healthcare providers due to its ability to reduce pressure on hospital facilities and doctors, relies on a partnership between a Homecare Service Provider (often out-sourced) and the parcels delivery company.

The global home healthcare market is anticipated to reach \$368 Billion by 2020 according to CyberMedia Research. If the logistics element of the market accounts for 5% of total costs, this would indicate a value of around \$18 bn for the storage, handling and final delivery of the products direct to patient.

Services have been classified as below⁹:

Homecare Service Complexity

Low tech homecare service

Activities include:

- self-administration of oral therapy or medicinal products for external use only excluding oral oncology
- products are licensed medicines or uncomplicated medical devices
- product storage conditions are 15-25 C and/or 2 -8 C suitable for storage in the patient's own fridge
- homecare team members are expected to identify and report obvious misuse of medicines and noncompliance

Mid tech homecare service

Activities include:

⁸ <https://www.forbes.com/sites/angelicamarideoliveira/2018/09/27/cvs-boosts-innovation-investment-to-reinvent-pharmacies-in-brazil/#2064b7697c6e>

⁹ Adapted from <https://www.eocph.nhs.uk/What-are-Homecare-Medicines-Services.htm>

- products that are unlicensed medicines
- therapy that requires significant clinical support or diagnostic testing such as blood level monitoring as part of the homecare service e.g. oral oncology
- patient training and competency assessment relating to self-administration
- self-administration needing basic aseptic technique and standard ancillaries e.g. pre filled syringes
- medications with special storage requirements
- provision of refrigeration equipment

High tech homecare service

Activities include:

- intravenous infusion
- self-administration needing advanced aseptic technique and / or portable equipment / specialist ancillaries
- administration by healthcare professional

Complex homecare service

Activities include:

- provision of bespoke homecare solutions
- permanent or semi-permanent adaptation of the home environment required as part of the service
- permanent or semi-permanent installation of equipment in the home
- clinical responsibility delegated to a third party
- clinical trials including homecare services

Homecare services are already provided to over 200,000 patients in the UK¹⁰. In the UK, the biggest provider of homecare services is Healthcare at Home (HaH) which has out-sourced its logistics to Movianto, a specialist provider to the pharmaceutical sector and which uses its own vans, external couriers and Royal mail for delivery.

In theory, very reliable services are required to pick, pack and deliver the right medication to the patient just-in-time for the healthcare professional to either administer or oversee the self-administration. Value added services, such as ensuring product integrity is maintained, unpacking deliveries, rotating stock and removal of waste should indicate higher margin services.

However, the last mile delivery part of the supply chain has, anecdotally, been neglected at least in the UK. Feedback on the logistics services provided in the UK in the past include¹¹:

- interface problems between logistics providers and Homeservice providers
- no track and trace services
- poor proof of delivery processes

¹⁰<https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/Professional%20standards%20for%20Homecare%20services/homecare-services-handbook.pdf>

¹¹ https://www.pharman.co.uk/imagelib/pdfs/A_Helicopter_View_of_Homecare_-_Philip_Aubrey.pdf

This suggests that the service has been underfunded with cost-cutting measures leading to poor quality services in what is regarded, however misguided, as the least important part of the operation.

In the US, the provision of these services is often undertaken by smaller regional providers regulated by the U.S. Department of Labor's Occupational Safety and Health Administration. However, UPS has also recognised the opportunity saying in its latest communication to the market that a strategic imperative for the company was:

'...Further penetration of the Healthcare and Life Sciences logistics market, given the increasing shift toward home healthcare, where UPS's trusted residential delivery network will provide new value for healthcare companies and consumers.'

The market in India for home care is booming, according to one report¹² due to a lack of hospital beds, digital adoption, increasing elderly population and the fact that homecare is 30-70% cheaper than hospital care. The market is forecast to grow to \$6.2 billion by 2020 at a CAGR of 18% from 2016.

CONCLUSION

Centralized on-line pharmacies offer a cost-effective service which given the pressures placed on bricks-and-mortar pharmacies, will grow fast over the coming years.

Online pharmacies will require reliability, speed and tracking from their parcels operators. In some countries this will benefit the postal operators (such as Royal Mail). In the US, UPS and FedEx are benefiting, whilst in emerging markets it is likely that a range of private sector operators will be the main beneficiaries.

The delivery of medicines to patients within homecare programmes will also become extremely important. Being encouraged by healthcare providers who face pressure on budgets from increasing costs of care in hospitals, the sector will grow not least facilitated by digitization which will allow patients to be monitored effectively remotely. However, it must be recognised that the last mile of the operation must be funded appropriately to maintain quality of service provision.

¹² <https://www.entrepreneur.com/article/316069>

About Ti Insight

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