Safety First!

A portrait of drivers of growth in the safety syringes market

An Owen Mumford Pharmaceutical Services Report

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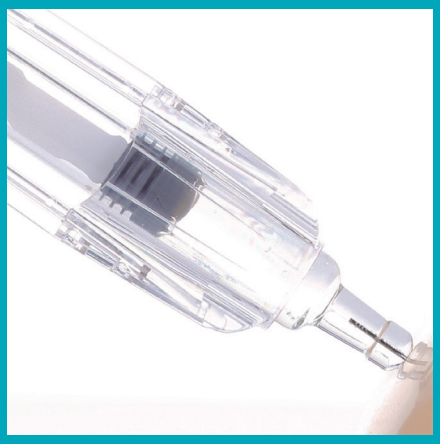

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Summary

- Since the passage of sharps safety legislation in the USA and Europe, use of safety-engineered drug delivery devices has become mainstream
- However, compliance with sharps safety regulations has a considerable way to go to reach mandatory legal levels in the hospital environment, and even more so in non-hospital locations such as homecare and home self-administration, whether in the US, Europe or other parts of the world
- As well as regulatory requirements in primary and acute care locations, other factors are also driving growth in the use of safety devices, including: healthcare worker protection in the home environment; the trend towards homecare; the self-administration requirements of biological therapies; guarding the welfare of carers in non-healthcare settings
- In parallel to the take-up of safety devices, pre-filled syringes are becoming increasingly popular, facilitating the move to home treatment and self-administration, as well as supporting procedural speed and efficiency within healthcare institutions
- The global safety syringe market is experiencing **growth of some 8.96% per year**, according to analysts
- The global pre-filled syringe market is also growing at over 8% per year, and was **valued at over $772 million in 2018**, **rising to some $1.137 billion** in 2023
- Safety-engineered pre-filled syringes dominate the total pre-filled market, with an expected **76% market penetration in 2023 worth over $868 million**

Introduction

It is now almost two decades since the needlestick and sharps safety legislation was implemented in the USA, and over six years since the equivalent implementation in the EU. Yet adoption rates of safety devices, although mainstream, still have some way to grow to meet regulatory compliance penetration levels. This is particularly the case in non-hospital settings, where regulatory compliance levels are lower still, but where the growing trend towards self-administration is pushing up the prevalence of disposable delivery devices, particularly pre-filled syringes for subcutaneous delivery.

This short paper looks at the trends in compliance following the original legislation in the USA and Europe. Drivers of demand for safety devices are then discussed, examining the key factors that are expected to drive strong patient demand and market growth, along with research evidence of the likely scale of that growth through to 2023.

Background
– compliance trends

In the USA, the Needlestick Safety and Prevention Act to revise the Occupational Safety and Health Administration's (OSHA) standard regulating occupational exposure to bloodborne pathogens, including the human immunodeficiency virus, the hepatitis B virus, and the hepatitis C virus, was signed into law on November 6, 2000[1] and became effective in 2001. Modern treatments that eliminate the Hepatitis C virus mean that infection no longer ruins healthcare workers' careers, but expensive and disruptive treatment periods are still required, and no vaccine is available. The passage of this federal needlestick legislation was part of a plan by the American Nurses Association (ANA) and other healthcare worker advocates. Following the introduction of the law, needlestick injuries fell by around 30%[2].

Nevertheless, the Association of Occupational Health Professionals in Healthcare (AOHP) found[3] that healthcare workers are sustaining 320,000 needlestick incidents each year in hospital and non-hospital settings. The Centres for Disease Control and Prevention estimates that about half of sharps injuries may go unreported[4], and the Occupational Safety and Health Administration (OSHA) reckons that 5.6 million workers in the healthcare industry and related occupations are at risk of exposure to bloodborne pathogens[5]. Others assert that more than half of non-hospital healthcare settings are in violation of OSHA law[6]. There is a steady migration of healthcare from the hospital to non-hospital settings with over two fifths of registered nurses now employed in non-hospital settings[7].

In Europe, the EU Directive 2010/52/EU on the prevention of sharps injuries – implemented in 2014 - is aimed at employers, requiring them to make appropriate provisions for healthcare staff in respect of the risk of sharps injuries. It is the employer's duty to ensure the health and safety of workers. The directive reinforces the need for appropriate levels of training and equipment. A risk assessment must be carried out and where there is a risk of exposure, employers need to identify how exposure can be eliminated.

As in the USA, rising EU compliance levels have greatly increased the use of safety devices, but still fall well short of the regulatory requirements. In various countries, regulatory authorities are still serving improvement notices to healthcare establishments because of their lack of compliance, both in the acute sector and in non-hospital locations[8]. The most recent independent survey of European safety device penetration[9], conducted by the European Biosafety Network, revealed a compliance level for safety-engineered injection devices of around 70% across EU economies, which falls to 60% in the homecare environment.

Safety-engineered drug delivery devices
– self administration drives demand

The home environment is worthy of particular focus when considering the current situation on safety devices. The Coalition for Safe Community Needle Disposal estimates that over 7.5 billion syringes are used in the homecare environment every year in the USA[10]. This is broadly and proportionately typical of home healthcare around the world and is likely to increase for a number of reasons.

Ageing populations – a universal global phenomenon resulting from increasing life expectancy – inevitably develop and present a variety of chronic morbidities[11]. With the growing pressure on healthcare systems caused not only by greater life expectancy, but also the rise in obesity[12], diabetes, cancers and heart disease among younger cohorts, most countries are strategically encouraging self-administration of therapies wherever practical and effective[13]. As one commentator notes, "increasingly the focus has been to provide safe, reliable and convenient self-administration for patients, with the goal of minimising the impact on their everyday lifestyle and freeing them from the burden of receiving their medication in a formal healthcare setting[14]."

Secondly, the vast majority of new therapies coming to market are biological drugs. Moreover, the top grossing drugs are now biologics. Access to these therapies has been restricted by their relatively high cost in many instances, but as original biologics come out of patent protection, competitive markets are opening up and are both reducing cost per treatment and increasing usage of these therapies. Between 2018 and 2020 a major 'wave' of original biologics are coming out of patent, representing $100bn revenue of biologics open to competition by biosimilar competitors[15] that are poised to enter the market and likely drive greater uptake of such therapies. The most important aspect of biologic drugs is that they are often the best option for treating medical illnesses and conditions (including inheritable conditions) that have no other treatments. Biologics and biosimilars are mostly administered via subcutaneous injection (due to their larger molecular size), and require regular dosage for chronic conditions such as neurological, cardio-vascular and auto-immune diseases (Crohn's, rheumatoid arthritis, psoriasis, etc).

Self-administration at home is clearly the most economic therapeutic practice, and is increasing the demand for delivery devices that make self-administration accurate and easy for the patient, encouraging compliance with the prescribed medication regime.

As home self-injection increases, so does the importance of managing sharps safety outside of the hospital or the doctor's surgery. Less attention has been paid by groups promoting safety compliance, but that is now changing. For a start, the current legislation covers agency or practice nurses who may be assisting patients, or training them, in the home environment. Both in the USA and Europe, it is the legal duty of the employer or contractor to secure the work environment and protect the staff against the risk of needlestick injury at work. The definition of "at work" will also include visiting an outpatient in their home. This definition would also cover paramedic staff entering the home to take the patient to hospital.

Quite apart from regulatory requirements, in most healthcare systems, from China, to India, to Europe, to the USA, staff shortages are rife[16]. Therefore, the economic benefit of de-risking all working environments is a significant factor to encourage much needed recruitment and job satisfaction. Introducing safety devices is an inexpensive and easy way to remove unnecessary risk from the healthcare professional's working environment, including home visits. Nor is it simply a matter of healthcare workers. If a non-safety sharp causes an injury to any other worker – typically waste disposal – then the issue of legal liabilities arises.

Patient pressures also play a part in this trend towards using safety devices for self-administration. Older patients will often be looked after by a carer – usually a spouse or a family member. The safety of carers also has to be taken into account, from a moral standpoint at least. Even from a practical point of view, it is clearly in the patient's interest that their carer's good health and state of mind be preserved wherever possible.

Safety device growth
– the hard evidence

Are the drivers of growth in safety device usage being borne out in reality? Certainly, research data on market growth supports this view.

Before assembling this evidence, however, two other characteristics of self-administration devices should be highlighted. The first is one of convenience for the patient. Older patients are often less dextrous than their younger counterparts. Therefore, there is a requirement that self-administration devices should be as simple as possible to use, and should require a minimum of force to activate, and operate 'passively' to reduce additional activation steps. In addition, many of the biological drugs mentioned above are making it possible to treat (literally) crippling inflammatory conditions. By definition then, a therapy for rheumatoid arthritis will be self-administered by patients who are debilitated, again requiring the delivery device to be extremely easy to hold securely and operate. This has driven demand for auto-injector devices that fulfil these ease-of-use requirements. In fact, with automatically retracting needle mechanisms, these auto-injectors fulfil both ease-of-use and safety device requirements at one and the same time. The FDA now requires "human factors" data on ease of use and risk reduction as part of the combination drug (drug and device) regulatory submission. The auto-injector safety syringe market is currently estimated to be growing at over 9% per year[17].

In parallel with the increasing demand for safety devices is another trend in drug delivery devices - the increasing popularity of pre-filled syringes. Demand is being accelerated by several of the drivers already discussed in this paper:– the trend towards self-administration as a way of easing the burden on healthcare resources; the need for ease of self-administration, especially for the elderly or infirm; the importance of accurate dosage, especially for biological drugs. Two further factors are also pushing up demand for pre-filled devices: firstly, medication error scandals[18] have resulted in close scrutiny and improved governance from health authorities, and pre-filled syringes are seen as a part of the solution; secondly, clinical studies[19] are beginning to offer evidence that clinical pathways and procedures can be performed more quickly when pre-fills or prefilled syringes are deployed.

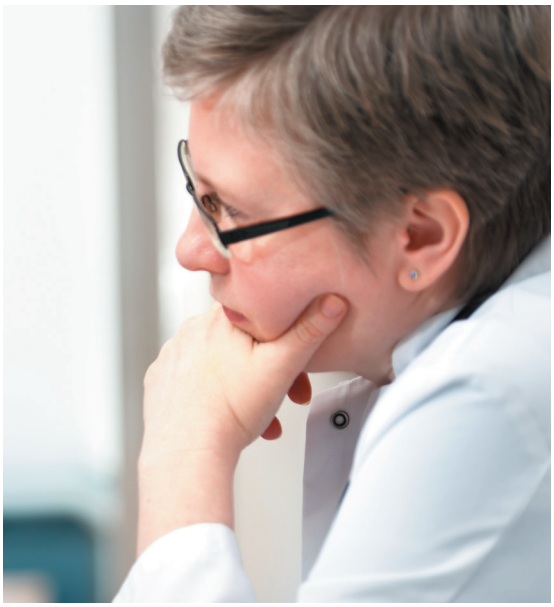
This brings us to the hard evidence of growing demand for safety devices, and in particular safety-engineered pre-filled devices that enable ease and accuracy of drug delivery not just in healthcare organisations, but for the self-administering patient at home.

According to one analyst[20], the global safety syringes market is expected to grow at a compound annual growth rate (CAGR) of 8.9% between 2018 and 2023. Analysis of a range of key research sources[21] reveals that the global pre-filled syringes market was estimated to worth over $772 million in 2018, rising to some $1.137 billion in 2023. This is a growth rate of 8.1%. Looking specifically at safety-engineered pre-filled syringes, the market is projected to grow from $551 million in 2018, to over $869 million by 2023 (9.6% CAGR). This means that safety-engineered pre-filled syringes dominate the market with approximately 76% share of the total pre-filled demand in 2023. This dominance would tend to suggest that pharmaceutical and biotechnology firms consider safety features to be highly attractive to users, whether in clinical environments or in homecare/self-administration, and are favouring their production as a key element for their combination products, as well as a brand advantage.

Conclusions

This paper presents a number of key drivers of increased demand for safety-engineered syringes. In summary, they encompass: improved adherence to regulatory requirements; protection of healthcare workers including in homecare settings; economic pressures on healthcare efficiency that encourage greater patient self-administration/homecare; the drive towards regular self-administration fuelled by new biological therapies and competitive biosimilar markets; increased demand of easy-to-use injectable therapies resulting from ageing populations.

Analysis of market projections clearly points to high expected growth rates in safety device demand across the world. This is paralleled by growing demand for pre-filled syringes in the drive to protect patients through better managed prescription and dosage accuracy. Safety-engineered devices can be seen to dominate the pre-filled market, with three in every four devices offering safety mechanisms, suggesting pharmaceutical firms regard safety features as a positive brand differentiator. In summary, the safety device market presents high and sustainable growth potential in the near-term.



Footnotes

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