Safety First!

A portrait of drivers of growth in the Indian safety syringes market

An Owen Mumford Pharmaceutical Services Report

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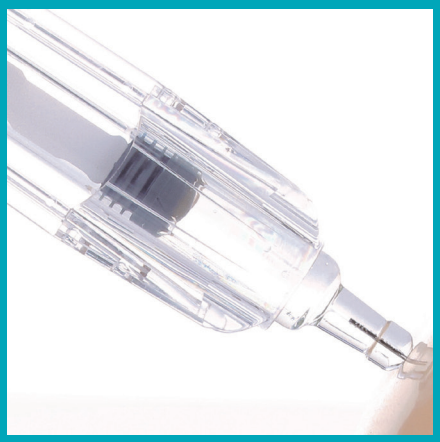

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Summary

- A new regime promising tighter and wider regulation of medical devices may well signal future recommendation of the use of safety-engineered devices in India to help avoid needlestick injury and infection for healthcare workers. This is underlined by pre-emptive initiatives to mandate safety devices in some states.
- In the meantime, awareness of the need to avoid needlestick injury is clearly high in mind for Indian healthcare managers, especially to attract and protect scarce healthcare professionals in a system that is suffering from an acute shortage of doctors and nurses
- 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.
- Data on the rapid growth of sales of safety-engineered syringes in the Indian market (CAGR of 19%) provides hard evidence that healthcare managers are increasingly specifying safety device options to protect healthcare workers and home carers.

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. The situation in India, on the other hand, is somewhat different.

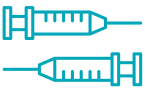
For a start, the regulatory regime in India for medical devices has been under-developed for many years. Until recently there were just 22 categories of notified medical devices under the Drugs and Cosmetics Act 1940, which need to be registered with Indian regulatory body the CDCSO. This is about to change radically.

India's health ministry announced in October 2019 its plan to register and regulate all medical devices in the same way as drugs – prompted by a long history of concerns over their safety and quality. The government's decision comes after media investigations into long-term concerns[1] over a poorly regulated medical device industry that was, in some instances, actually causing harm to patients.

India's Drugs Technical Advisory Board recommended earlier in 2019 that the government improve its system to track devices and report adverse events, with meeting minutes reported by the media[2] revealing that the health ministry considered "many medical devices are not yet regulated and are available in the market without any certification or regulatory control, putting patient safety at risk."

This marks a major and rapid move forward for medical device regulation. Having begun to register syringes and infusion sets in 1980, the country has only added just over twenty types of medical products to the list of controlled medical devices up to now. However, from here on in, all devices will have to be registered and comply with official standards. The Ministry of Health has been quite explicit on the issue[3], noting that, "…the Drugs Technical Advisory Board, hereby specifies the following devices for use in human beings or animals ***as drugs*** with effect from the 1st day of December, 2019…. All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination…." The recently announced regulation will gradually apply to all device categories, including those used to diagnose, monitor and treat diseases and disabilities, as well as life-supporting and birth-control devices.

This stepping up of the regulatory regime in India may well indicate a future where safety devices – which largely eliminate risk of needlestick injury, become at least recommended, if not mandatory. In fact, syringes are one of the few products among the current 22 categories of device that are already regulated. This list[4] includes disposable hypodermic syringes, catheters and IV cannulae. Category 119 specifies syringes with needle shielding safety mechanisms, Category 118 talks about Re-use Prevention Syringes (RUP) for therapeutic injections, and Category 115 specifically cites Auto-Disable (AD) syringes.



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These last two categories are important as they often (but not always) double up as safety mechanisms, and therefore overlap with the specific safety category. Recent press reports[5] have noted that the Health Ministry is reflecting on a proposal to limit government hospitals' purchase of syringes to 'reuse prevention' (RUP) or 'auto-disable' (AD) ones as part of efforts to contain the spread of infections. Indeed, regional authorities have taken the initiative in advance of national legislation. For instance, Andhra Pradesh has become the first Indian state to pass an order to use Auto-Disable Syringes for all clinical purposes, with the state government declaring itself "Safety Injection Use State"[6]. The benefits are clear, as one Head of Infection Control in Kolkata notes: "When you adopt safety devices you can reduce needlestick injury by eighty percent.[7]"

This short paper looks at the trends in safety syringe demand in India, and the likely drivers of that demand.

Background
– compliance trends

Needlestick injury exposes healthcare workers to bloodborne pathogens, including the human immunodeficiency virus, the hepatitis B virus, and the hepatitis C virus. 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 problem is one of major proportions. Needlestick injuries and other healthcare worker exposures to bloodborne pathogens have received more attention in the literature than other nosocomial illnesses and injuries in India. Researchers have reported that 33% to 75% of Indian hospital staff sustain at least one needlestick injury annually[8].

Indian institutions are clearly becoming aware, and concerned, about needlestick injury and its adverse effects on staff and hospital reputation. Private hospitals are especially keen to present a best-practice brand image to the increasingly lucrative medical tourism market.

One recent paper[9] also notes that "Increasingly, healthcare facilities are applying for the National Accreditation Board for Hospitals and Health care Providers (NABH) and Joint Commission International (JCI) accreditation. All accrediting bodies give emphasis on the implementation of NSI protocols and occupational safety of the HCW. Thus, policies and processes are clearly established in such NABH and JCI accredited facilities."

Safety device usage figures regularly in the recommended methods to bring needlestick injury under control. For instance, one paper[10] notes that, "There is much room for improvement in protecting the HCWs from NSI, which can be accomplished through a combination of comprehensive programs, including stress on institutional behavior and device-related factors, that contribute to the occurrence of these injuries, seeking alternatives to the use of needles wherever possible, [and] using newer devices with safety features." A leading specialist in Ahmedabad[11] has been quoted as saying – on the needlestick prevention issue – "Treatment is a… thousand times costlier than prevention."

In India, the importance of keeping healthcare workers safe from avoidable harm – in the form of needlestick injury and other dangers – is critical to a functioning health system. India has a crippling shortage of nurses, with only 1.7 nurses per thousand population, compared with the WHO recommended level of 2.5 nurses per thousand. This represents an absolute shortage of 2.5 million nurses across the country[12]. Similarly, there is a shortage of doctors amounting to some 600,000 positions nationwide[13].

The economic impacts of not addressing the needlestick issue, and failing to implement usage of safety devices is well rehearsed. They embrace: treatment costs; loss of workforce time during treatment and recovery; work stress causing increased absenteeism; and so on[14]. Quite apart from the moral position – that workers should not be exposed to avoidable risks in the workplace – there is the issue that in an environment where there are too few healthcare workers, making their jobs less attractive to the employment pool by failing to take safety measures is clearly poor practice. This is especially the case in India, where the Government is committed to universal healthcare coverage through the Ayushman Bharat initiative, and where consequently the healthcare infrastructure is undergoing rapid expansion[15] (and therefore need for healthcare professionals).

Use of safety devices is clearly a priority strategy in the minds of Indian experts. One NABH assessor in New Delhi[16] has been quoted as saying, "Injuries from blood-filled needles is the major reason because of which healthcare workers become vulnerable to blood borne pathogens and life-threatening diseases…. The good news is that majority of the infections through needle stick injuries are preventable…. focusing on education and training of healthcare workers pertaining to needle stick injury prevention and use of safety engineered devices can go a long way in bringing down the incidence of infections."

The experience in the Western world underlines this outlook. Following the introduction of the law mandating the use of safety syringes in the USA, needlestick injuries fell by around 30%[17]. The most recent independent survey of safety device penetration[18] in Europe, 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

– both acute care and self-administration drive demand

The home environment is worthy of particular focus when considering the current situation on safety devices. Ageing populations – a universal global phenomenon resulting from increasing life expectancy – inevitably develop and present a variety of chronic morbidities[19]. With the growing pressure on healthcare systems caused not only by greater life expectancy, but also the rise in obesity[20], diabetes (India has the highest number of diabetes patients in the world[21]), cancers and heart disease among younger cohorts, most countries are strategically encouraging self-administration of therapies wherever practical and effective[22]. 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[23]."

Secondly, the 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. An Associated Chambers of Commerce of India 2017 report reports that the biosimilars market in India was worth $2.2B in 2017 and is expected to reach an astonishing $40B by 2030[24].

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. This short paper has already remarked that 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, one other characteristic 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 deliver the medication, and ideally provide 'passive' needle shielding and needlestick protection. For instance, a therapy for any condition to be self-administered by patients who are debilitated, requires the delivery device to be extremely easy to hold securely and operate. This has driven demand for auto-injector devices and prefilled safety syringes that fulfil these ease-of-use requirements. In fact, with automatically retracting needle mechanisms, these devices fulfil both ease-of-use and safety device requirements at one and the same time. The emerging Indian medical device regulation regime is expected to accept product accreditation from regulatory systems like those in the US or Europe. It is therefore significant that, for instance, 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 market numbers reveal that safety syringe deployment is growing fast in India. One study[25] tells us that Auto Disable (AD)/safety syringes and needles currently control the second largest market share in terms of revenue in Indian market. According to this analyst's estimates, the Indian Auto Disable (AD)/safety syringes and needles market is expected to grow at a CAGR of 19% till 2020 and maintain its market share position. Another analyst[26] confirms this picture noting that "China and India are expected to witness a huge surge in retractable needle industry, as the market value is expected to double itself in India shortly."

Conclusions

This paper presents a number of key drivers of increased demand for safety-engineered syringes in the Indian healthcare environment. In summary, they encompass: a new drive to build a widespread regulatory regime for medical devices; protection of healthcare workers including both acute care and homecare settings; economic pressures on healthcare efficiency that encourage greater patient self-administration/ homecare; increased demand of easy-to-use injectable therapies resulting from ageing populations; and the rapid growth of biologic drug markets in India.

Analysis of market projections clearly points to high expected growth rates in safety device demand across the country. Safety-engineered devices can be seen to dominate the market, by value. In summary, the safety device market presents high and sustainable growth potential in the near-term.

Footnotes

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