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RECENT TRENDS IN PACKAGING SYSTEMS FOR PHARMACEUTICAL PRODUCTS

Renata Dobrucka

Poznan University of Economics, Poznań, Poland

ABSTRACT. Background: In recent years, pharmaceutical packaging market was one of the fastest growing areas of the packaging industry. At the same time the packaging manufacturers put high demands on quality and safety.
Methods: Review of innovations in packaging systems for pharmaceutical products was made including newest information of researches and achievements of recent years.
Results and conclusion: Observed in recent years the development of pharmaceutical packaging market expanded due to with the huge technological advances that allow introduction of new packaging. Also, in this study presented intelligent packaging in pharmacy and innovation in child-resistance packaging.

Key words: pharmacy, packaging, intelligent packaging.

INTRODUCTION

Pharmaceutical packaging may be defined as the science, art and technology of enclosing or protecting products for distribution, storage, sale and usage including printed material, employed in the finishing of a pharmaceutical product [Mehta et al., 2012]. According to World Health Organization (WHO), global pharmaceuticals market is worth US$300 billion a year, a figure expected to rise to US$400 billion within three years. The 10 largest drugs companies control over one-third of this market, several with sales of more than US$10 billion a year and profit margins of about 30%. Six are based in the United States and four in Europe. It is predicted that North and South America, Europe and Japan will continue to account for a full 85% of the global pharmaceuticals market well into the 21st century. Also, the development of the pharmaceutical market has led to the growth of the market for medicinal product packaging. In 2010, the value of the global pharmaceutical packaging market amounted to USD 47,8 billion. According to the data provided by Global Business Intelligence Research, until 2017 it should increase by 7,3% per year on average, and by the end of the forecasted period, it should approach the amount of USD 80 billion. Although the packaging for the medical and pharmaceutical sector constitutes only a small part of the world packaging industry (about 5% of production), due to the dynamic development of this sector in the last few years, medicinal and pharmaceutical packaging is becoming one of the driving forces behind the growth of the whole packaging industry. Because of the unchangeable demand for drugs, the pharmaceutical packaging industry is highly resistant to macroeconomic factors. Therefore, it is a particularly attractive niche that has been penetrated relatively superficially [Mrówczyński, 2011].

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The use of packaging systems not only intended for passive protection against humidity, light and oxygen, but also designed to improve the overall quality characteristics of their contents, e.g. to extend shelf-life and enhance safety, is a well-known concept for medical products [Rooney, 1995, Vermeiren et. al. 1999, Ahvenainen, 2003]. The packaging for medicinal products has to satisfy certain requirements. Above all, the packaging is designed to protect the product against the external effects of all actions that may change the properties of the product, e.g. humidity, light, oxygen, temperature and changes in temperature. Moreover, its role is to protect the product against biological contamination and mechanical damage, as well as enable the correct information and identification of the product. The type of packaging and the materials used have to be chosen in such a way as to exclude the adverse effect of the packaging on the product (through chemical reactions, the rinse of packaging materials, or absorptions). The safety aspect must also work reversely, i.e. the product cannot have negative effect on the packaging; it cannot change the properties of the packaging and affect its protective function [Dobrucka, 2012]. Moreover, packaging should give clear identification of the product at all stages. The life of the patient may depend upon rapid and correct identification in emergencies. Packaging also serves as a mean to identify the manufacturer of the product. Besides, packaging should carry the information on the correct usage of dosage forms, their contents, their provenance, side-effects and warnings [Chirag et al., 2012]. Package should assist in patient compliance [Aulton, 2005, Mehta, 2001].

Also, packaging is also of great importance during the examinations of the stability of medicinal products in various conditions related to temperature and humidity, performed in line with GMP requirements. The scope of examination includes the packaging of a given product. Thus, the stability of the drug in given packaging in various climatic conditions is an indicator of safety and quality, very important both to the manufacturing company and the patient.

INTELLIGENT PHARMACEUTICAL PACKAGING

Constant innovations in the pharmaceuticals themselves (such as prefilled syringes, blow fill seal vials, powder applications and others) also hale a direct impact on the packaging. Traditionally, the majority of medicines (51%) have been taken orally by tablets or capsules, which are either packed in blister packs (very common In Europe and Asia) or fed into plastic pharmaceutical bottles (especially in the USA). Powders, pastilles and liquids also make up part of the oral medicine intake. However, other methods for taking medicines are now becoming more Widery used. These include parenteral or intravenous (29%), inhalation (17%), and transdermal (3%) methods. Oral tablets themselves are also now available in a wide range of different shapes and sizes. These changes have made a big impact on the packaging industry and there is an increasing need to provide tailored, individual packaging solutions, which guarantee the effectiveness of medicines [Kunal et al., 2012]. For this reason, one of the packaging that has been introduced in the pharmaceutical industry is intelligent packaging. At present, this packaging system is growing rapidly. In pharmacy, intelligent packaging is designed to facilitate communication within the whole medicinal product chain, as well as to ensure its better quality and safety. The role of the intelligent drug packaging is also to increase the effectiveness of the taken drug, which has a direct effect on the improvement of the patients' health and brings considerable savings. An example of this type of packaging is system based on conductive ink on a carton board based blister inlay, which is connected to a cellular module embedded in the package. This enables the tracking of one pill at the time on removal from the blister, whereby data is sent to the cellular module and then forwarded wirelessly, even instantaneously if required, using GSM or GPRS cellular networks, to electronic health record systems. This allows real-time tracking and intervention by a physician and also enables physicians to make timely changes to patients' medication. The principal benefits derive from the numerous possibilities that this solution provides to healthcare service providers:

sending voice-call reminders or text messages (SMS) to patients, or making personal visits when important prescribed medication has not been taken in time. Another type of intelligent solution is packaging system, designed for topical treatments. This technology measures the right amount of topical cream or ointment to simplify the application process. Besides, this system allows patients to scan a digitally embedded watermark in the packaging with their smartphones to access extra product information.

In the pharmaceutical market there is also the "talking packaging". There are for patients who have problems with regularity in the use of drugs. System the "TalkPack" can be invisibly integrated into any printed image on any packaging material. This technology needs a special scanning pen. The method used by "TalkPack" is not limited to the packaging material but can be used by any printed material. No other composite elements are used which could influence the recycling qualities. A special pen-shaped reader is used to retrieve the stored information and to replay it as audio files. Talk Pack does not require any RFID or microchips; the dot code is simply printed on top of images and texts using a special varnish. This technology can be used with all printing technologies and package types. For example, NFC (Near Field Communication) tags can be added to any packaging so a consumer could touch the code on the packaging with their NFC-enabled mobile phone to download text, audio or web page product information, which can be played back on his handset. The medical and pharmaceutical industry could use the technology to display detailed information and instructions in a small area.

The huge changes relate to aerosols. In the pharmaceutical market there are systems of aerosols with indicators of dose. One example is nebulizer designed to operate in-line with standard ventilator circuits and mechanical ventilators. This system is operated without changing patient ventilator parameters. Besides, this nebulizer is refilled without interrupting ventilation. In order to remind the patient about the dose or to take the drug, special packaging was introduced to the market. It has a special closing equipped with electronic microcircuits, which strictly monitors the date and time of each opening and closing of the packaging. The packaging closing is equipped with an LCD screen, which shows the number of the drug doses administered within 24 hours, as well as the time that has elapsed since the last pill was taken. All the actions connected with opening and closing the packaging are saved, and later they can be read and analysed during a medical appointment. This solution makes it possible to determine whether the patient complied with the chosen therapy, as well as to assess its effects. Another type, the Slide Pack packaging, ensures that the medicinal product is not separated from its packaging and it constitutes its integral part. Moreover, the packaging ensures that both the blister pack with pills and the patient information leaflet are packed together and are easily available to the client. In order to open the packaging, you grab the shorter sides of the rectangular box and pull out the compartments. From one side, you pull out the blister pack with pills/capsules, while from the other - the patient information leaflet, from which the patient can read the application instructions at any time.

As the pre-filled syringes become more popular on the pharmaceutical market, the packaging with a security mechanism has been introduced. The mechanism prevents injuries, and it is integrated with the safety label [MedPack, 2011]. It is related to the fact that the pre-filled syringe contains a needle, which poses the risk of an accidental prick with an already contaminated needle. In the new pre-filled syringe, next to the needle there is a special mechanism - Needle Trap, thanks to which the patient may administer the drug independently, without running the risk of microbiological contamination. Moreover, to reduce the possibility of microbial contamination and the risk of disease transmission dry as hepatitis or HIV developed new syringe design. This syringe turns dark red after use and warning doctors and patients that it may be contaminated. The ABC Syringe is impregnated with an ink that's sensitive to carbon dioxide and then sealed in a protective atmosphere so that it remains transparent until it is ready for use. After the seal is broken, the shell of the syringe starts to turn a dark red,

alerting both doctors to the risk that the syringe may already have been used.

INNOVATION IN CHILD-RESISTANCE PACKAGING

Since its introduction in the late 60s and early 70s, child-resistant packaging has led to a significant reduction in the number of children admitted to hospital for accidentally ingesting poisonous substances. However, recent statistics show accidental poisoning is still a serious problem worldwide, even in heavily regulated, developed countries.

USA was the first country in the world that introduced the requirement of securing the child of chemical substances and drugs. To be able to say that the packaging is sufficiently well protected against children, at least 85% of the 200 children tested could not cope with opening the package within 5 minutes of testing. The result is positive if at least 85% of the children did not open the package (opened less than 8 for packaging unit doses of pharmaceutical products) during the first test, and if at least 80% of the children did not open the package (opened less than 8 for packaging unit doses of pharmaceutical products) during the first and second attempt. An article published in 2011 in the Journal of Pediatrics reported the number of children admitted to hospital in the US after swallowing inappropriate medication has been increasing in recent years. The most popular used packaging to protect the child is close to a 'push - turn "or " squeeze- turn ". This type of closure requires the use of two hands to open the package . Many pharmaceutical companies in the world conduct research on packaging safe for children. One example is blisters with the necessary puncture resistance and specialized peelability to meet both American standards and European testing criteria. Broad range of lidding structures that suit all opening mechanisms: push-through, peel-push, peel-open and tear-open. Also, one of the pharmaceutical companies introduced printed tear indicator, accompanied by text explaining how to open it as opposed to other packaging options on the market which use a notch to signify where to tear open the sachet. The level of child resistance can be further increased by incorporating Amcor's tear system with "fold first" or "squeeze first" instructions. Child resistant packaging must strike a balance between being too hard for children to open but easy enough for invalids and the elderly to access.

Spray products, both cosmetic and pharmaceutical, are particularly challenging for packaging designers to protect against curious children. A spray top is much easier and more intuitive for a child's mind to grasp than a screw-top bottle. In recent years, sliding lock systems have become popular for many spray cans. Developed specifically for a new anesthetic spray being launched by a major US pharmaceutical company, the design's opening mechanism requires a tab to be pushed at the same time as the cap is being twisted, an action that requires the wrist and fingers to work together, something that is beyond most young children.

SUMMARY

Packaging in the pharmaceutical industry has gone through major changes in the past decade. This is undoubtedly due to the fact that they are placed high demands. The advent of new drug delivery systems and the development of new biochemical compounds have resulted in a need not only for enhanced protection against factors such as moisture, light, oxygen and mechanical forces, but also for packaging forms to play a more integral role in the drug delivery process.

The protective and safety function of the product gains a special meaning here and it must be guaranteed in each type of packaging used, with no exceptions. However, the wide range of materials used in the pharmaceutical packaging industry does not impose any limitations on the manufacturers, and the dynamic development of the plastic industry leads to new opportunities and solutions related to packaging. Therefore, the innovations that are now inventions will soon be generally accessible, and they will be replaced with other novelties. Everything that is being created aims at achieving the highest product quality and thus the safety of the potential patient.

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NOWE ROZWIĄZANIA W SYSTEMACH PAKOWANIA PRODUKTÓW FARMACEUTYCZNYCH

STRESZCZENIE. **Wstęp:** W ostatnich latach rynek opakowań farmaceutycznych należał do najszybciej rozwijających się obszarów przemysłu opakowaniowego. Jednocześnie wyznaczał producentom opakowań duże wymagania w zakresie jakości i bezpieczeństwa.
Metody: Przegląd innowacji w systemach pakowania dla produktów farmaceutycznych został dokonany z uwzględnieniem nowości ostatnich lat.
Wyniki i podsumowanie: Obserwowany na przestrzeni ostatnich lat rozwój rynku opakowań farmaceutycznych związany jest przede wszystkim z ogromnym postępem technologicznym, który umożliwia wprowadzenie na rynek nowych opakowań. W związku z tym, w pracy przedstawiono inteligentne opakowania dla farmacji oraz innowacje w opakowaniach chroniących przed niepożądanym otwarciem przez dzieci.

Słowa kluczowe: farmacja, opakowanie, opakowania inteligentne.

NEUE LÖSUNGEN IN VERPACKUNGEN FÜR PHARMAZEUTISCHE PRODUKTE

ZUSAMMENFASSUNG. Einleitung: In den letzten Jahren war der Markt für pharmazeutische Verpackungen einer der am schnellsten wachsenden Bereiche der Verpackungsindustrie. Gleichzeitig hat er den Verpackungsherstellern hohe Anforderungen an Qualität und Sicherheit gestellt.
Methoden: Es ist eine Übersicht von Innovationen innerhalb der Verpackungen für pharmazeutische Produkte unter Berücksichtigung der Neuheiten der letzten Jahre gemacht worden.
Ergebnissen und Fazit: Die in den letzten Jahren auf dem Markt für fharmazeutische Verpackungen beobachtete Entwicklung ist in erster Linie mit den großen technologischen Fortschritten, die die Einführung von neuen Verpackungen ermöglichen, verbunden. Im Zusammenhang damit wurden intelligente Verpackungen für die pharmazeutische Industrie sowie innovative Lösungen in Verpackungen, die vor unbefugtem Öffnen durch die Kinder zu schützen vermögen, dargestellt.

Codewörter: Pharmazie, Verpackung, intelligente Verpackungen

dr Renata Dobrucka
Uniwersity of Economy in Poznań
al. Niepodległości 10
61-875 Poznań
ph. 508 145 440
e-mail: renata.dobrucka@ue.poznan.pl