

Aktualnosti pri pakiranju proizvoda u farmaceutskoj industriji



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Sajam ideja 2017

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Sveučilište u Zagrebu, Zagreb, 23.10.2017.

“Between 44,000 to 98,000 people die from medical errors each year in US hospitals alone. According to a 1999 report issued by the US National Academy of Sciences, ‘To Err is Human’, this is more than the number killed in the US by highway accidents, breast cancer or AIDS.”



Što učiniti kako bi se smrtnost uzrokovana nepravilnim uzimanjem lijekova smanjila na minimum?

Rizična populacija

- Djeca
- Starije osobe
- Osobe s problemom vida
- Osobe oboljele od Parkinsonove bolesti
- Osobe oboljele od reumatoidnog artritisa...



Što učiniti kako bi se smrtnost uzrokovana nepravilnim uzimanjem lijekova smanjila na minimum?

Problemi

- Veličina slova/znakova na ambalaži
- Boja znakova
- Kontrast između boja prenizak
- Zaboravljanje uzimanja lijeka
- Ne uzimanje lijeka u određeno vrijeme...



Karakteristike „consumer friendly” ambalaže

Atraktivna

Praktična i robusna

Ekološki prihvatljiva

„Tamper evident”

„Child resistant”

Mogućnost nesmetanog korištenja

Sukladna potrebama proizvoda

U skladu s regul.; Uredba (EU) br. 10/2011, Uredba (EZ) br. 1935/2004, Ph. Eur.



„Safety Considerations for Product Design to Minimize Medication Errors”

Safety Considerations for Product Design to Minimize Medication Errors Guidance for Industry

Additional copies are available from:

Office of Communications
Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg.
Silver Spring, MD 20993-0001
Phone: 855-343-3784 or 301-796-3400, Fax: 301-796-3400
Email: druginfo@fda.hhs.gov
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation>

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research

April 2016
Drug Safety

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2. Points to Consider During Development of the Container Closure Design

The container is defined as the immediate unit, bottle, vial, ampule, tube, or other receptacle containing the product (see 21 CFR 600.3(bb)). The closure is the cap, stopper, or seal. For drug-device combination products, the container closure can be the physical device.

Selection of the container closure should be based not only on stability and manufacturing considerations, but also on the ability of the design to protect against improper use.

The best container closure designs are those that do not require extensive end-user training and that make sense for the dose, route, and method of administration. Improper container closure system designs have contributed to medication errors including wrong routes of administration, wrong doses, and incorrect use. Especially problematic container closure systems include those that are (1) incongruent with the intended dosage and administration of the product or are (2) atypical for similar products marketed with a different type of container closure. These types of container closure systems should be redesigned because they cannot be remedied with additional label/labeling statements or health care provider and patient education.

„Connected devices”

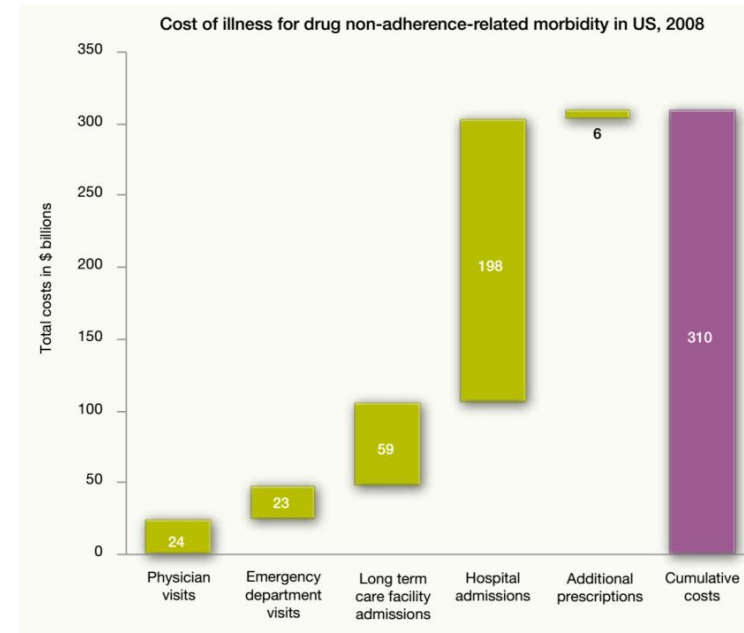
Posljedice uzrokovane nepridržavanjem upute o lijeku

„U.S. Centers for Disease Control and Prevention”

- ❑ Oko 20% - 30% propisanih Rx lijekova nikada nije podignuto
- ❑ Nepridržavanje propisane terapije:
 - 30% - 50% neuspjelih liječenja
 - 125,000 smrtnih slučajeva godišnje

Nepridržavanje upute o lijeku manifestira se na:

- ❑ Pacijente
- ❑ Osiguravajuće kuće
- ❑ Farmaceutske kompanije
- ❑ Rezultate kliničkih ispitivanja



Je li moguće „pratiti trag” lijeka?

Istraživanja nad tržištem:

- ❑ Slanje upitnika pružateljima zdravstvene zaštite
- ❑ Praćenje baza podataka

Konvencionalne metode prikupljanja podataka:

- ❑ Analogni dnevnicu pacijenata
- ❑ Digitalni dnevnicu pacijenata



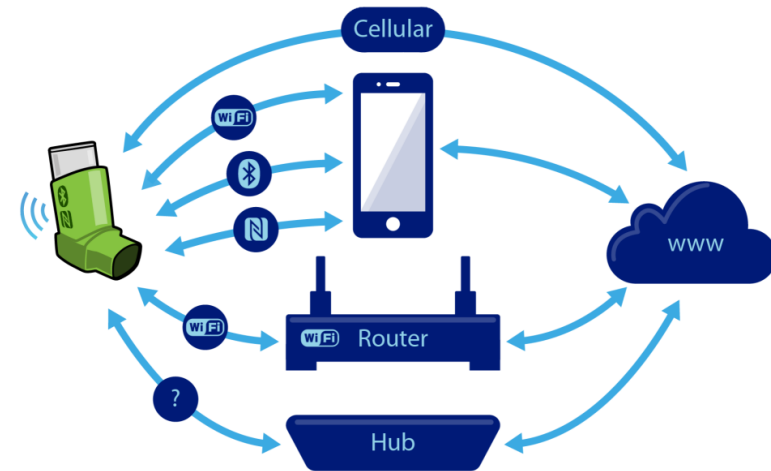
Mogućnost prikupljanja podataka direktno sa spremnika za doziranje lijeka?

Odgovor: DA!

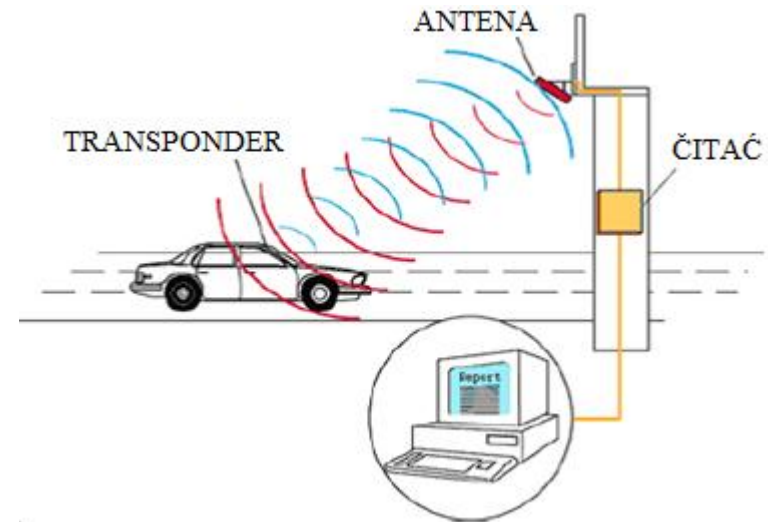
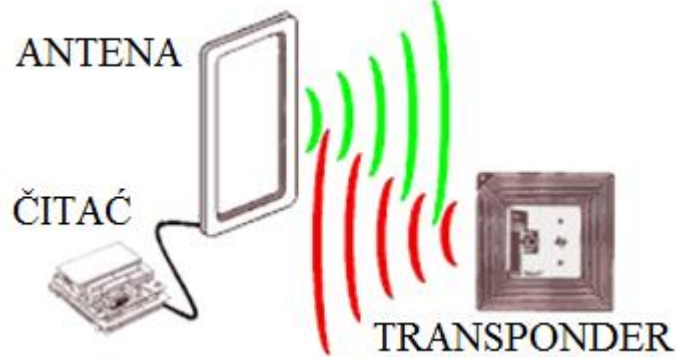


„Connected device” - Što je to?

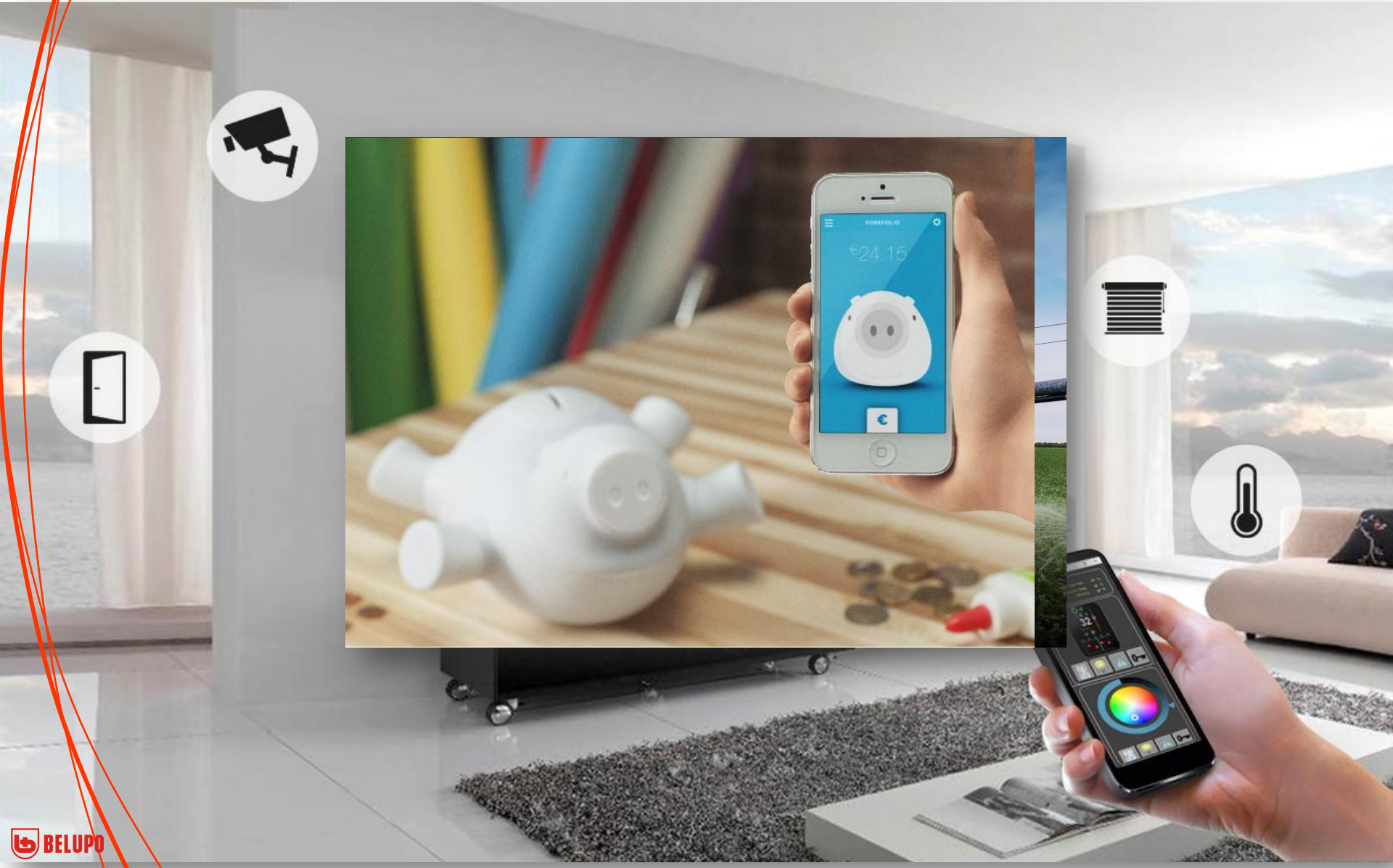
- Uređaj koji je povezan s drugim uređajem
- Veza je gotovo uvijek bežična
- Uređaj je najčešće povezan sa smartphoneom
- Primarna veza može posredovati daljnju vezu
- Daljnja veza; putem interneta
- Veza omogućuje razmjenu ili kontrolu podataka



RFID: identifikacija pomoću radio frekvencije



„Connected devices” – primjeri iz svakodnevnog života



Zašto „povezati” spremnik za doziranje lijeka?

- ❑ Podsjetnik o uzimanju lijeka
- ❑ Prikupljanje podataka o uzimanju lijeka
- ❑ Razmjena podataka s medicinskim stručnjacima
- ❑ Informiranje pacijenta
- ❑ Zaštita od krivotvorenja
- ❑ Farmakovigilancija – sigurnosna upozorenja

Informacije moraju biti relevantne i korisne!!!



„Connected drugs” – primjeri spremnika za opremanje lijekova

„PhutureMed™ Memo Solution,
Patient-friendly Packaging Design”; Palladio Group



„Smart Packaging for Patient Compliance”;
Medicodose Systems

<http://www.palladiogroup.com/it/innovazione/phuturemed/>

<http://medicodose.com/>

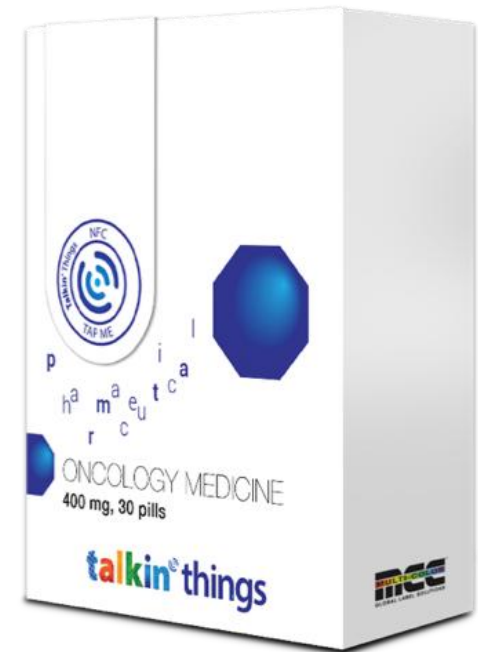
„Connected drugs” – primjeri spremnika za opremanje lijekova

„Intuity® Ject medical device”; EVEON



„Connected drugs” – primjeri spremnika za opremanje lijekova

„SMART Packaging Solution, Talkin things”; Multi-Color Corporation





The Most Advanced Smart Packaging System in the World



❑ Uloga ambalaže

- Očuvati izvornu kvalitetu proizvoda tijekom roka valjanosti
- Pružiti pacijentu informaciju o lijeku
- Omogućiti upotrebu lijeka na ispravan način
- „Spona” između proizvođača i potrošača

❑ „Connected drugs”

- Podrška pacijentu pri poštivanju propisane upute/terapije
- Farmaceutске kompanije zainteresirane za tehnologiju „connected drugs”



Sajam ideja 2017



Hvala na pažnji!