22nd Congress of the EAHP
Value Added Medicines Symposium

Why are **Value Added Medicines** relevant for hospital pharmacists?

Challenges and opportunities

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March 22, 2017

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Fresenius Kabi at a glance

High-quality and affordable products for the therapy and care of **critically and chronically ill patients in hospital and outpatient care.**

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Rethink, reinvent & optimise medicines

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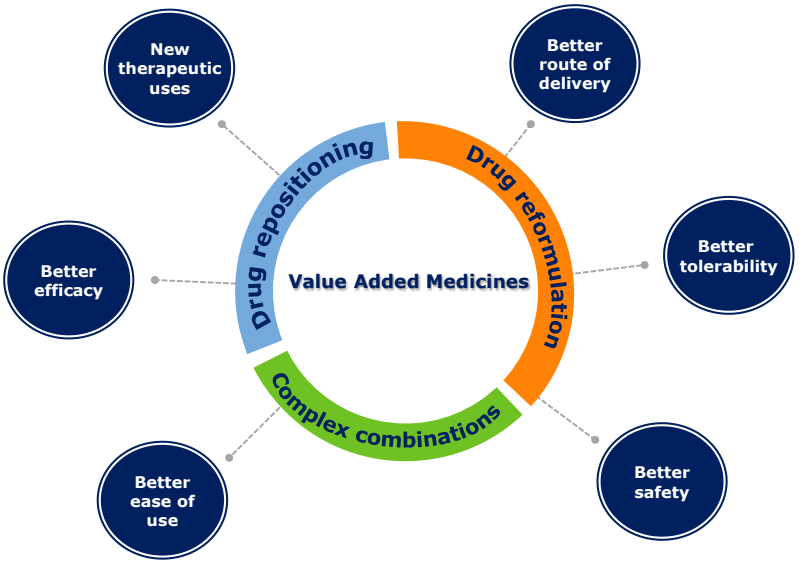

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Let's take post-operative pain for example

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IV PCA
Current challenges

- Impossibility of early mobilization
- Risk of port site infections
- Time-consuming set-up
- Frequent technical issues and nurse intervention
- High over-all costs

1976

"**Cardiff Paliator** – The first commercially available **patient controlled analgesia** (PCA) pump"

i.m. Morphine
- Inadequate pain management

2016
fentanyl iontophoretic transdermal system

"…the only **needle-free**, **patient-controlled**, **pre-programmed** fentanyl delivery system in the EU"

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Addressing evolving needs

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Route of administration unsuitable for certain types of patients (fever, skin irritations)

Cost/benefit ratio

2016
fentanyl iontophoretic transdermal system

?

Patient:
- **non-invasive delivery method**
- **increased mobility in the post-operative period**
- **Easy to use**

Health Care Professional:
- **Effectiveness and reliability as compared to i.v. PCA**
- **Easy and fast set-up**

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Pathway to market for value added medicines

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What are the major hurdles to bringing a medicine with added value on the market to benefit the patient?

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Regulatory bodies recognize medicines with added value

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Hybrid applications
under **Article 10(3)** of Directive 2001/83/EC

REFERENCE MEDICINAL PRODUCT

changes in the
- **active substance(s),**
- **therapeutic indications,**
- **strength, pharmaceutical form or route of administration**

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Regulatory pathway as a cost driver?

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"Regulators should not, for the sake of affordability, yield to pressure to lower standards.

But it's also inappropriate for them to be oblivious to the growing budget pains caused by newly authorized products."

… potentially useful products may not be developed

Source: Hans-Georg Eichler M.D., Drug Regulation and Pricing — Can Regulators Influence Affordability?, N engl j med 374;19, May 12, 2016

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Rewarding regulatory initiatives

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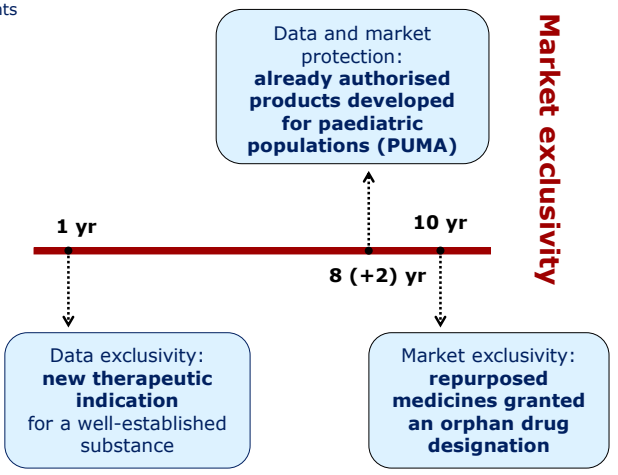
Safe and Timely Access to Medicines for Patients (**STAMP**)

RE-PURPOSING
of established medicines

REPOSITIONING
new therapeutic uses for already known drugs

REFORMULATION
developing different formulations for the same drug

COMBINATIONS
new combinations of drugs previously used as separate products



Source: Background note on re-purposing of established medicines (MHRA) , STAMP Commission Expert Group 10 March 2016

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Pricing and reimbursement systems across the EU

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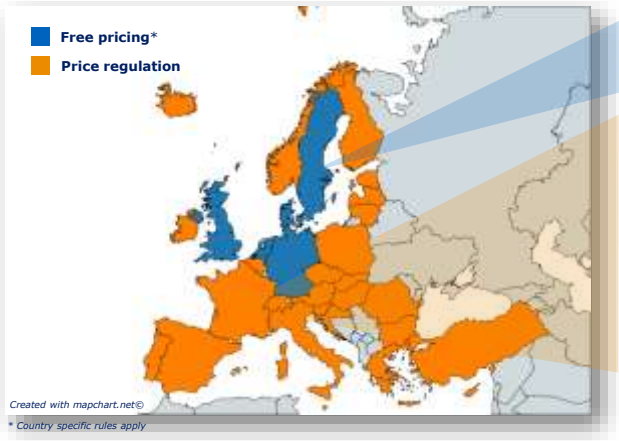

* Country specific rules apply

Free pricing: **DK, DE, NL, UK**
- Different rules in place for cost-containment purposes

Pricing regulation : **AT, BE, BG, EL, CZ, FI, FR, HU, IT, LT, LV, NO, PL, PT, ES, SE, SI, SK, IE, MT, RO, HR, CY**

External reference pricing (ERP): e.g. average price (mean or median), lowest price

Internal reference pricing (IRP): e.g. internal reference pricing groups of active substances, fixed generic price reductions

Source: Market review – European generic medicines markets – Policy Overview 2016, Medicines for Europe

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Strategy focust on reducing costs

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Healthcare cost containment

- Local healthcare needs not in the focus
- Volatile currency exchange rates
- "Proxy prices" of comparison
- "Knock-on effect"
- Tendering criteria
- ●●●

Source: Business Monitor International, The Worldwide Guide to Pharmaceutical Pricing & Reimbursement, July 2016

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Source: Business Monitor International, The Worldwide Guide to Pharmaceutical Pricing & Reimbursement, July 2016

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The M.E.A.T. criterion

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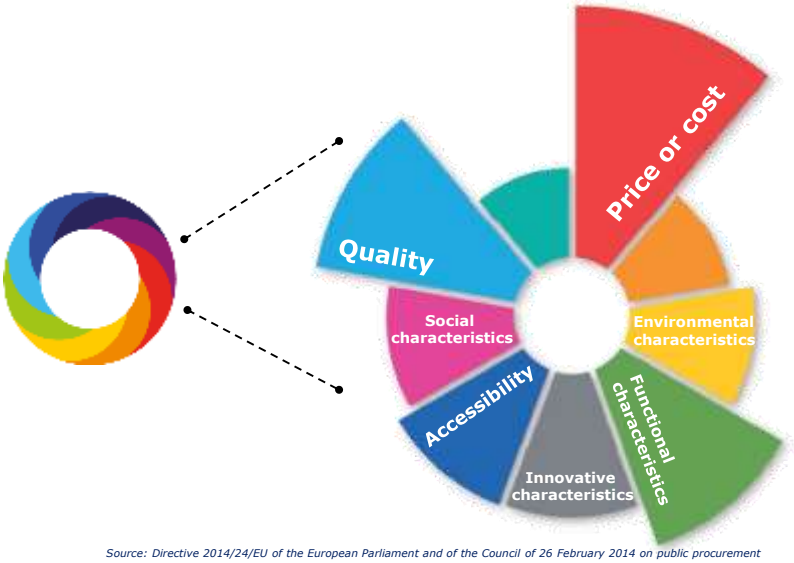
Most
Economically
Advantageous
Tender



Source: Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement

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"Lowest bid" criterion still common practice

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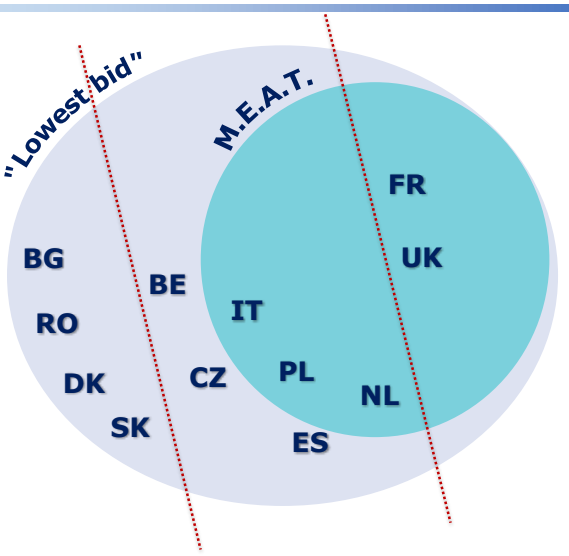

Source: Bird & Bird White paper: Public procurement of medicinal products, 2014

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Holistic view on tenders

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- Foster **competition** and **long-term sustainability** of supply
- Award criteria should go beyond price and **recognize the added value of innovative products** bring to patients and health systems
- Ensure **optimal price-quality ratio rewarding valuable innovation**

HOLISTIC VIEW for the best value for money

Patient

Healthcare systems

Source: AmCham EU Position paper : Implementation of Directive 2014/24/EC on public procurement in the EU healthcare sector, Nov 2015

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What is the impact of pricing policies on value added medicines?

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Some pricing policies might negatively impact value added medicines access, e.g.:

- **By pushing down prices**

  Systematic positioning as **generic medicine** and inclusion in internal reference pricing groups based on active substance

  External reference pricing, especially when value added medicines are considered differently from a pricing and reimbursement perspective (e.g., internal reference pricing, tendering, etc.)

  Tenders/procurement policies with award criteria based exclusively on economic criteria for active substance (lowest price)

- **Single pricing rule across all indications**

Source: Toumi M et al., Value added medicines: what value repurposed medicines might bring to society?, J. of Market Access & Health Policy, Volume 5, 2017 - Issue 1

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What is the impact on patients?

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Pharmaceutical companies might decide...

NOT to invest in
NOT to launch or to
WITHDRAW value added medicines from some countries

Inequities in access to medicines with an added benefit for patients across countries

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Health Technology Assessment

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HTA obstacles
- **Existing stigma**: generic medicines, anti-generic medicines strategy, non-risky strategy
- **Budget silos**
- Current **HTA framework**

Call for Policy Changes

Eligibility for multi-HTA early dialogue and parallel scientific advice

No legislative barriers preventing companies from pursuing HTA for selected value added medicines

HTA decision making framework should take into account the special characteristics of value added medicines not currently captured (e.g., patients' and health care providers' preferences, more weight on quality of life and health economic benefit, accommodate for different time points at which evidence can be assessed)

Source: Toumi M et al., Value added medicines: what value repurposed medicines might bring to society?, J. of Market Access & Health Policy, Volume 5, 2017 - Issue 1

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Let's take Sweden as an example

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Societal perspective assess both costs and benefits of therapies

Free pricing policy

Tendering system compares products based on several criteria – points awarded (medical and pharmaceutical effectiveness, including manageability, labeling and packaging, design of the product etc.)

Reimbursement based on 3 main criteria:
- the human value principle,
- the need and solidarity principle
- the **cost-effectiveness** principle

Source: The Swedish Pharmaceutical Reimbursement System - A brief overview, Pharmaceutical Benefits Board

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The cost-effectiveness principle: How do they do it?

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Total costs associated with using a drug

Benefits from using the drug

Costs for the drug

Costs due to side-effects of the drug

Costs for possible further healthcare measures

Costs related to visits to the doctor

Effects on health
- longer life expectancy
- higher health-related quality of life

Cost savings

Source: The Swedish Pharmaceutical Reimbursement System - A brief overview, Pharmaceutical Benefits Board

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Cost-effectiveness rather than cost-containement

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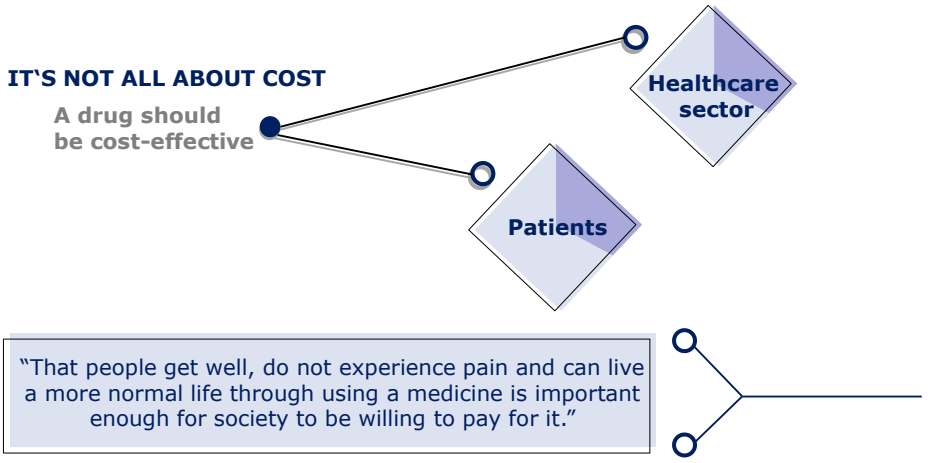

"That people get well, do not experience pain and can live a more normal life through using a medicine is important enough for society to be willing to pay for it."

Source: The Swedish Pharmaceutical Reimbursement System - A brief overview, Pharmaceutical Benefits Board

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Romania: A different system...

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Cost of medicines is set as the **lowest price** within a basket of 12 EU countries

The first generic launched on the market **cannot exceed 65% of the innovative product price**

Claw-back tax

Contracting authorities often use the **lowest price** criterion in tenders

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What has the policy achieved?

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- Medicines under 25 RON (USD 7.10) are reportedly produced at a loss once claw-back taxes are accounted for.
- **2,000 generic drugs** have disappeared from the market within the past four years. In 2015, **850** drugs were discontinued.
- The vast majority of drugs that have been discontinued were costing less than 50 RON (USD 14.20) and were being primarily manufactured in Romania.

- **More out-of-pocket expenses for patients**
- **Lack of appropriate and timely treatment options in hospitals**
- **Patients facing shortage of essential drugs**

Source: Business Monitor International, The Worldwide Guide to Pharmaceutical Pricing & Reimbursement, July 2016

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What about a value added medicine?

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… almost

MISSION: IMPOSSIBLE

1, 2, 3, 4 or 5…

Restrictive market access pathway for value added medicines

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Challenges are opportunities

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The bottom line: patient care

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Imagine you are a patient…

What would be your preferences regarding the care that is delivered to you?

- Access to improved medicines
- Taylored treatment
- Timely and efficient care
- Improved quality of life

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The bottom line: patient care

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… how can you, the decision maker, improve patient outcomes?

Facilitate access to the most appropriate level of care

Healthcare organization

Gained efficiency
Greater effectiveness
Increased productivity

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Let's create value for the patient!

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The role of the pharma industry:

Make available innovative medicines

Innovation can take many forms

… but it should be recognized, facilitated and rewarded

Let's help ease the path of innovation that creates VALUE for the PATIENT!

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Thank you!

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