Procurement and tenders: What, when and how

Presenter

James Kent, NHS, UK [1]

Linked to EAHP Statements

The following statements are covered by the Synergy Masterclass:

Section 1 - Introductory Statements and Governance: Statements 1.1, 1.3, 1.5, 1.6

Section 2 - Selection, Procurement and Distribution: Statements 2.1, 2.2, 2.3, 2.4, 2.5, 2.6

Section 4 - Clinical Pharmacy Services: Statement 4.1

Section 5 - Patient Safety and Quality Assurance: Statement 5.1

Section 6 - Education and Research : Statement 6.2

Abstract

Medicines procurement usually aims to ensure availability of the most effective medicines at the best possible prices. During the last 10-15 years the cost of medicines has risen dramatically throughout Europe which has been driven by the emergence of innovate hospital only treatments such as the monoclonal antibodies, and new therapies for hepatitis C. However, the budgets allocated to these medicines have not always increased at the same rate. This has placed even greater pressure on the procurement processes in place to deliver as much value as possible. What does hospital pharmacy procurement really look like? How is it done and how are the contracts awarded?

Procurement for medicines can be run at a local, regional or national level. There are pros and cons with each of these arrangements. The advantages of national procurements include a reduction in the level of resource required to run the tender as well increased leverage due to the size of the market being tendered for. Disadvantages can be that the market can become dominated by one supplier which in turn reduces competition in the market and could increase the chance of shortages. How do you decide if local or regional procurement is the better option? Higher prices may result but could be worth paying is market stability and maintenance of supply is assured.

To ensure that the medicines procured meet the needs of the patients, doctors and nurses it is beneficial to involve other healthcare professionals in the procurement process, usually at the tender design and adjudication stages. In some countries there may also be national bodies responsible for the assessment of innovative branded medicines so that key decisions over what is funded are taken centrally.

Regardless of what stage of the product lifecycle a medicine is it is vital to have knowledge of the existing competition, other medicines in the pipeline as well as new indications for existing products so that the ideal procurement process can be put in place and the best financial outcome achieved. This lecture will describe the various procurement and tender structures currently in place within the English healthcare system. The various considerations regarding timing, duration and structure will be explored and the potential benefits and drawbacks described.

Learning objectives

At the end of this lecture, participants will be able to:

- Recall the various tender structures utilised in the English Healthcare system
- Recognise the pros and cons of the various models deployed
- Discuss the roles of the key stakeholders in the procurement processes
- List the purchasing strategies deployed at all stages of a product's lifecycle

Educational needs assessed

To ensure the best possible drug treatment within the available budget it is necessary for the participants to understand how procurement and tendering are managed to address the increasing medication costs throughout Europe.

Keywords

Procurement procedures, tender content, legislation compliance, rational drug use

National assessment and procurement of new hospital drugs

Presenter

Dorte Glintborg, The Danish Medicines Council, Denmark [2]

Linked to EAHP Statements

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Abstract

Some countries in Europe assess new drugs and/or perform procurement at a national level. The reasons for performing national assessment/procurement are usually to save administrative cost and ensure equity in drug availability and treatment throughout the respective country.

The assessment of new drugs is based on added clinical value and costs. Some countries are expressing the value in OALY´s with a threshold for how many costs per QALY is acceptable for the drug to be recommended and funded by the healthcare service. I Denmark the process for assessment and procurement of new drugs is divided in two separated parts. A clinical part and a health economic part. The aim of this separation is to secure full transparency in the decision-making whether a new drug should be recommended or not is based on lack of efficacy, low evidence or expensive costs.

To ensure optimal implementation of the negotiated tenders, prediction of use of the individual drugs and information dissemination is essential, and this can only be done in close collaboration with healthcare professionals throughout the countries.

A certain area of drug treatment; biosimilars, has drawn significant attention during the preceding years. Biosimilars do not smoothly fit into the existing procurement systems, and confusion about when and how to use them, has been discussed vigorously.

Learning objectives

At the end of this lecture, participants will be able to:

- Address reasons for performing national national assessment and procurement of new hospital drugs
- List elements to be considered when performing national procurement of new hospital drugs
- Discuss issues related to introduction of biosimilars to a market

Educational needs assessed

Healthcare professionals need to be familiar with the drug assessment and procurement process and methods, when making decisions at national level on the introduction of new drugs into the market.

Keywords

Clinical assessment, health economic assessment, biosimilars

International collaboration: Experiences from The BeNeLuxA Initiative

Presenter

Francis Arickx, The Belgian Social Insurance Institute INAMI, Belgium [3]

Linked to EAHP Statements

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Section 2 - Selection, Procurement and Distribution: Statements 2.1, 2.2, 2.3, 2.4, 2.5, 2.6

Abstract

The BeNeLuxA Initiative seeks to “ensure sustainable access to innovative medicine at affordable cost for our patients” (1). The initiative was announced in 2015 by the health ministers of Belgium and the Netherlands at the informal meeting of European Ministers for Employment, Social Policy, Health and Consumer Affairs (1). Later on, the Grand Duchy of Luxembourg, Austria and Ireland joined the initiative (1).

The countries of The BeNeLuxA Initiative collaborate about horizon scanning of new drugs, new indications etc., share information on medicine policies, cooperate in Health Technology Assessment (HTA) by using expertise from theEuropean Network on Health Technology Assessment (EUnetHTA), and work closely together on pricing and reimbursement when e.g. negotiating drug prices with the industry.

The BeNeLuxA Initiative has initiated pilot projects on the above mentioned subjects. One of these pilot projects was conducted by Belgium and The Netherlands with the aim of negotiating the reimbursement of Spinraza, a drug for Spinal Muscular Atrophy (SMA). This first pilot project proved successful with Belgium and the Netherlands reaching an agreement on the pricing of Spinraza

Learning objectives

At the end of this lecture, participants will be able to:

- describe the background and aims of The BeNeLuxA Initiative
- recall pilot projects conducted by The BeNeLuxA Initiative
- recognise pros and cons by collaborating on market access for new drugs between countries

Educational needs assessed

With the goal of ensuring timely access and affordability of medicines for patients, it is important for participants to assess various possibilities of achieving more balance in the pharmaceutical market by e.g. collaborating between countries. One of these initiatives is BeNeLuxA.

Keywords

HTA, international collaboration, price negotiation, horizon scanning

International collaboration: Experiences from The Valetta Declaration

Presenter

John Yfantopoulos, Greece [4]

Linked to EAHP Statements

The following statements are covered by the synergy masterclass:

Section 1 - Introductory Statements and Governance: Statements 1.1, 1.2, 1.3, 1.6

Section 2 - Selection, Procurement and Distribution: Statements 2.1, 2.2, 2.3, 2.4, 2.5, 2.6

Abstract

The Valletta Declaration is an alliance of southern EU member states, which aims to explore joint strategies to negotiate drug prices with the industry. The declaration was initially signed in 2017 by the health ministers of Malta, Cyprus, Greece, Italy, Spain, and Portugal, and, later on, Ireland, Romania and Slovenia also joined, while Croatia has “observer status”.

The Declaration was establishedto address the rising price of drugs in Europe, which prevent drugs from reaching patients in need of treatment .

Currently, the ten countries have agreed to (1):

- continue their work on identifying candidate products for joint assessment and negotiation
- explore new areas of activity e.g. negotiation on products already assessed
- reinforce the exchange of information on areas of common interest e.g. biosimilars
- analyse therapeutic areas of growing expenditure such as the i-DPP-4 (oral antidiabetics) and oral anticoagulants

Members of The Valletta Declaration have identified initiatives to be explored in practice.

Learning objectives

At the end of this lecture, participants will be able to:

- describe the background and aims of The Valletta Technical Committee
- recall initiatives planned by The Valletta Technical Committee
- recognise pros and cons by collaborating on market access for new drugs between countries

Educational needs assessed

With the goal of ensuring timely access and affordability of medicines for patients, it is important for participants to assess various possibilities of achieving more balance in the pharmaceutical market by e.g. collaborating between countries. One of these initiatives is The Valletta Declaration.

Keywords

International collaboration, price negotiation, HTA, horizon scanning

Differentiated procurement strategy based on specific drug types – The Danish Model

Presenter

Dorte Glintborg, The Danish Medicines Council, Denmark [2]

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Abstract

From time to time procurement officers may ask, how competition of new, expensive drugs may be increase without compromising quality and accessibility of drugs. In Denmark, an attempt to address this question is done by the Danish Medicines Council by developing therapeutic guidelines, where drugs are categorized into groups of similar effect. Assessment of the drugs is performed using an evidence-based approach assisted by clinical experts. This is supported by a thorough understanding of the market and drugs in the pipeline. Various criteria and thoroughmethodology are used in the process.

Based on the categorisation of the drugs, procurement is performed.

Learning objectives

At the end of this lecture, participants will be able to:

- describe the Danish model of differentiated competition
- recall criteria used for categorising drugs
- recognise pros and cons by using the Danish model

Educational needs assessed

To create competition between new drugs, it is necessary for participants to consider untraditional concepts of procurement, and an example of this is the Danish model of assessing drugs for therapeutic purposes.

Keywords

Procurement, creating competition, horizon scanning, therapeutic guidelines

Managed Entry Agreements: How can they be used in practice?

Presenter

John Yfantopoulos, Greece [4]

Linked to EAHP Statements

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Abstract

Managed entry agreements (MEAs) are mechanisms, which have been developed to limit the reimbursement of medicines, facilitate access to the market and to generate further clinical evidence of innovative, expensive drugs.

A variety of MEAs exist, and they may be categorized into “economically based agreements” (EBAs) and “performance-based agreements” (PBAs). EBAs, such as price-volume based agreements and capping agreements, are based on drug use at an aggregated level, while PBAs, such as risk sharing agreements, are based on use of the drug at patient level.

Most of the agreements require close monitoring of the drug use to ensure correct reimbursement of the drugs, and especially PBAs may be challenged by the level of information needed for monitoring. Predefined, objective, clinical criteria to measure effect of the drug need to be available, and data should to be valid and quickly accessible for reimbursement. Otherwise it may be necessary to provide clinicians or hospital pharmacies with an administration burden to ensure availability of data.

The MEAs require an agreement between the payer and the industry, which may be difficult, since the various types of MEAs may not seem to have a balanced benefit for both parties. On the other hand, MEAs may give hospitals the opportunity to offer patients new, expensive drugs at a lower cost for a period of time.

The lecture will give an overview of existing MEAs and provide advice on when the individual MEAs are feasible for use in practice.

Learning objectives

At the end of the lecture participants should be able to:

- list types of MEA
- understand the benefits and limitations of MEA from the perspective of hospitals, regulators and the industry.

Educational need addressed

Managed entry agreements may be used when introducing new, expensive medicines into a market. As a consequence, it is important for health care professionals procuring, prescribing or administering drugs to understand the mechanisms behind using managed entry agreements including risks and benefits for the hospital when implementing MAEs.

Keywords

Managed entry agreements, drug cost reimbursement, new expensive drugs

Procurement of drugs in the hospital setting

Presenter

António Gouveia, Portugal [5]

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Abstract

Appropriate drug use at a hospital, and consequently procurement of hospital drugs, requires a multidisciplinary approach shared by physicians, nurses, pharmacists, support personnel and administrators . Drug and Therapeutic Committees (DTCs) are responsible for developing policies and procedures to advise on rational use of drugs and develop formularies . The DTCs also monitor the drug used and assess adverse drug reactions. Physicians prescribe the drugs, nurses administer the drugs and hospital pharmacists are responsible for procuring, storing and distribution of drugs assisted by support personnel (1). Finally, the hospital administrators are responsible for the hospital budgets including budgets available for drug procurement. All of these procedures have an impact on, which drugs would be most

optimal for use at the hospital.

The drugs are usually procured through the hospital pharmacy or in some cases provided through small-scale hospital pharmacy production. In both cases forecast of drug consumption is necessary to ensure the best possible delivery of drugs. This forecast may be determined through drug use evaluations and close collaboration with e.g. the prescribers.

When procuring drugs, a fruitful collaboration with the drug companies is essential irrespective of whether the tenders are on new, expensive drugs or drugs available on the market for a longer time period. Drug tenders are negotiated between the hospital and the drug company based on various criteria and complying with current legislation. Tenders vary in length and different criteria are used depending on drug type, competition etc. This lecture will consider these aspects.

Learning objectives

At the end of the lecture participants should be able to:

- list participants and their roles in the drug procurement process
- discuss the processes involved in procurement
- understand the complexity of the procurement process in the hospital setting

Educational need addressed

Drug procurement in the hospital setting is a complex procedure. As a consequence, it is important for health care professionals to understand the mechanisms involved in procuring drugs for a hospital to ensure the best possible drug treatment in practice within budget limitations.

Keywords

Drugs and Therapeutic Committees (DTCs), procurement, hospital, multidisciplinary collaboration, forecast

Procurement of medical devices and medicinal gasses

Presenter

Jo Swartenbroekx, University Hospital Antwerp, Belgium [6]

Linked to EAHP Statements

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Abstract

Not only the costs of new drugs have resulted in increased health care costs, but also innovative medical devices apply pressure on the health care budgets throughout the world. This has resulted in considerations of “value-based purchasing”, which is the concept of spending well rather than spending less, leading to “most economically advantageous tender” (MEAT). This may be the medical device concept comparable to HTA, since healthcare outcomes are introduced in the tendering procedure. However, medical devices comprise a large array of products, and detailed knowledge of the treatment is required to ensure the best possible procurement procedure. In addition to healthcare outcomes, other aspects may be necessary to consider: technical issues such as compatibility withexisting equipment and power supply, compliance with EU directive, requirement of special skills to use the medical device, cost of e.g. operating, maintenance, cleaning and disposal etc.

Indeed, the complexity of purchasing medical devices has led to development of five principles of best practice of purchasing medical devices :

1. Evaluate the total cost of care
2. Ensure clinical input
3. Use flexible contracts
4. Encourage supplier diversity
5. Fair and transparent procurement processes

Learning objectives

At the end of this lecture, participants will be able to:

- describe procurement procedures for medical devices
- list specific aspects necessary to consider regarding medical device tenders
- recognise similarities and differences between procurement of drugs and medical devices

Educational needs assessed

Some hospital pharmacies may procure other treatment products than drugs, e.g. medicinal gasses and medical devices. To ensure the best possible procurement of these devices, it is important to understand how this differs from purchasing drugs to ensure best value for money.

Keywords

Procurement, tenders, medical devices, medicinal gasses, MEAT

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Links

[1] http://www.eahp.eu/http%3A//www.eahp.eu/synergy-masterclass/events/procurement/Speakers-James-kent [2] http://www.eahp.eu/http%3A//www.eahp.eu/http%253A//www.eahp.eu/synergy-

masterclass/events/procurement/Speakers-dorte-glintborg#overlay-context=congresses/acpe [3] http://www.eahp.eu/http%3A//www.eahp.eu/http%253A//www.eahp.eu/synergy-masterclass/events/procurement/Speakers-Francis-arickx [4] http://www.eahp.eu/http%3A//www.eahp.eu/synergy-masterclass/events/procurement/Speakers-john-yfantopoulos [5] http://www.eahp.eu/http%3A//www.eahp.eu/synergy-masterclass/events/procurement/Speakers-antonio-gouveia [6] http://www.eahp.eu/http%3A//www.eahp.eu/synergy-masterclass/events/procurement/Speakers-jo-Swartenbroekx