ADDRESSING IN PART MARKET IMBALANCES IN THE PHARMACEUTICAL SECTOR THROUGH VOLUNTARY JOINT PUBLIC PROCUREMENT

Antoinette Calleja
Overview of the pharmaceutical sector vis-a-vis its interaction with public health care systems

The case for joint procurement

Proposed set up for developing an effective and efficient joint procurement model

Other considerations
OVERVIEW OF THE PHARMACEUTICAL SECTOR VIS-À-VIS ITS INTERACTION WITH PUBLIC HEALTH CARE SYSTEMS
MEDICINES PLAY A VITAL ROLE IN THE DELIVERY OF QUALITY HEALTH CARE
POLICY MAKERS NEED TO BALANCE ACCESS OF PATIENTS TO EFFECTIVE MEDICINES WITHIN LIMITED HEALTH CARE BUDGETS
ACCESS
AVAILABILITY
AFFORDABILITY
SO BASICALLY WHO PAYS?
Across the EU health care is publicly financed on the basis of solidarity and universal access allowing entitlement to a wide range of medicines.

Across the 34 high-income countries in the WHO European Region, public spending on health ranges from 3.3% to 10.0% of GDP.
EU total health care expenditure

- €1 300 billion per year
  - €220 billion (23%) for pharmaceuticals and
  - €100 billion (11%) for medical devices

- 10% of GDP

The figures are forecasted to increase.
AND YET MANY PEOPLE FIND DIFFICULTIES TO ACCESS THE MEDICINES THEY NEED
Gilead Knew Hepatitis Drug Price Was High, Senate Says

Company understood price would put treatment out of reach for many patients, report concludes

By PETER LOFTUS
Updated Dec. 1, 2015 5:28 p.m. ET

Gilead Sciences Inc. knew the $1,000-a-pill launch price for its hepatitis treatment would be out of reach for many patients and cause “extraordinary problems” for government health programs, according to a U.S. Senate report released Tuesday.

The 144-page committee report adds to a chorus of criticism of escalating drug prices from patients, doctors, insurers and some presidential candidates, U.S. congressional committees also have opened inquiries into drug-pricing practices by other companies, including Valeant...
White House Is Pressed to Help Widen Access to Hepatitis C Drugs via Medicaid

By ROBERT PEAR  AUG. 25, 2015

WASHINGTON — Federal and state Medicaid officials should widen access to prescription drugs that could cure tens of thousands of people with hepatitis C, including medications that can cost up to $1,000 a pill, health care experts have told the White House.

Study Shows Medicaid Restrictions for Sofosbuvir Create Barriers for Care


In a new study published in Annals of Internal Medicine, researchers found that Medicaid coverage restrictions for Of the 42 states, 34 restrict sofosbuvir reimbursement on the basis of liver disease stage; 27 restrict sofosbuvir reimbursements; and 15 restrictshell

Report Puts Hep C Price Tag as High as $5 Billion for California

Charles Bacchi, president and CEO of the association, said the report underscores what is to come in the near future when more costly prescription drugs are approved. The high costs aren’t sustainable for health plans, consumers or taxpayers, Mr. Bacchi said.

With a slew of new high-priced drugs set to hit the market this year ... this report really shows how that debate about their outsized bite into health care budgets. The estimated costs have led to policy changes, hearings, lawsuits and ethical debates about who should receive the treatments.

An estimated 3.2 million people nationwide have hepatitis C, the leading cause of cirrhosis and liver cancer.

Gilead Sciences, which won approval for the drug...
Clinton calls for lower price on allergy drug EpiPen

U.S. Democratic presidential nominee Hillary Clinton delivers remarks at a gathering of law enforcement leaders at John Jay College of Criminal Justice in New York, U.S., August 18, 2016. REUTERS/Lucas Jackson

http://www.reuters.com/article/us-usa-election-clinton-mylan-idUSKCN10Z2AV?utm_campaign=trueAnthem:+Trending+Content&utm_content=57bdefdd04d3012a5f0b58b1&utm_medium=trueAnthem&utm_source=twitter
OUT-OF-POCKET PAYMENTS range from 6.3% to 48.7% of total spending on health
Thomson et al 2016, pg. 24
Out-of-pocket payments for outpatient medicines are the most important driver of health care-related financial hardship for households internationally and in Europe

(Saksena et al 2010, Thomson et al 2016)

Medicines are the largest single driver of out-of-pocket payments across OECD countries

(OECD 2015)
The World Health Organisation recognises drug shortages as a global problem. Causes for drug shortages are largely under reported though various plausible explanations have been put forward, such as,

- Mismatches in volume estimations - eg vaccine shortages
- Medicines manufactured outside the EU - non compliance with good manufacturing practices
- Technical issues during manufacturing process
- Parallel trade
- Lack of market attractiveness
PHENYTOIN - a wide range of injected generic medicines:

despite their clinical need manufactures decided that their profit margin did not justify their continued manufacture

( Fox et al, 2014)
Production problems have been identified as the leading cause for shortages in European countries and the U.S.

Improved reporting systems would enable better insights for the reasons behind such shortages.
CONSIDERABLE PRICE DIFFERENCES BETWEEN MEMBER STATES EXIST

- Mainly attributed to differences in:
  - total health expenditure
  - expenditure associated with per capita GDP levels across Members States
  - pricing policies and regulations
PRICE DIFFERENCES COVERED BY PATENTS ACROSS FIVE LARGEST PHARMACEUTICAL MARKETS

- France: 86%
- Italy: 94%
- Spain: 95%
- UK: 100%
- Germany: 123%

- Germany
- UK
- Spain
- Italy
- France
There is evidence of significant variation in the price of generic medicines across EU Member States

(IMS Institute for Healthcare Informatics 2015)
For instance the evolution of prices for generics from 12 months to 24 months:

- **Increases** in France, Italy, Spain, the Netherlands and Portugal, and

- **Decreases** in the UK, Germany and Austria in particular and to a lesser extent Sweden, Greece and Finland
The State or Health Insurance funds are major purchasers for pharmaceutical products.

Article 168 (1) TFEU, holds that, “The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.”
However, according to Article 168 (7) TFEU,

“Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them...”
It is not within the competence of the EU to regulate the market after market authorisation of medicines.

Member States decide which benefits are included in their health care package including the range of medicines that are to be funded through public funds.
GOVERNMENT’S ROLE

- **REGULATOR:**
  - Intellectual property laws
  - tax structures
  - counterfeiting laws
  - safety regulations

- **PURCHASOR**
  - Government serves as pharmaceutical companies’ largest customer
Community law does not detract from the powers of Member States to organize their social security systems and to adopt, in particular, provisions intended to govern the consumption of pharmaceutical preparations in order to promote the financial stability of their health-care insurance schemes”.

(para. 16.)
“...although such systems do not in themselves constitute measures having an effect equivalent to a quantitative restriction, they may have such an effect when the prices are fixed at a level such that the sale of imported products becomes either impossible or more difficult than that of domestic products”.  

(para. 17)
Compliance with the Transparency Directive needs to be respected.


OJ L040/8, 1988
THE PHARMACEUTICAL INDUSTRY IS A COMPLEX AND HIGHLY SENSITIVE SECTOR.
The world pharmaceutical market was worth an estimated €651,500 million at ex-factory prices in 2014.

In 2014, North America accounted for 44.5% of world pharmaceutical sales.

Around a quarter of all pharmaceutical sales globally are from the European Union.

Is a key asset of the European economy.

Directly employs 707,000 people across Europe and generates three to four times more employment indirectly.

In 2014 it invested an estimated €30,500 million in R&D in Europe.
Pharmaceutical companies make use of intellectual property - **a very important asset**

Patents promote innovation to improve human health care

**AND**
- they commercialize it
- create monopolies
GENERIC products authorised pursuant to Directive 2004/27/EC cannot be placed on the market until 10 years have elapsed from the initial authorisation of the originator product.
OTHER extended patent protections:

- *Supplementary Protection Certificate* by way of regulation (EC) No 469/2009 - extended by 5 years
- Orphan medicinal products by way of Regulation (EC) 141/2000 - extended by 10 years
- Medicinal products for paediatric use by way of Article 37 of Regulation (EC) 1901/2006 - extended by 12 years
THE CASE FOR JOINT PROCUREMENT
“How can we provide severely ill people with the medicines they really need? And how can we speed up access for patients that have no time left to wait? Would we be able to afford it? ....... A crucial question as well. Too often, new, innovative drugs come on to the market for skyrocketing prices.”

This poses a threat to the sustainability of our healthcare systems.”

Speech of Minister Schippers at the meeting Innovation for the patient, 1 and 2 March in Amsterdam.
“...increasing number of examples of market failure in a number of Member States, where patients access to effective and affordable essential medicines is endangered by very high and unsustainable price levels, market withdrawal of products that are out-of-patent, or when new products are not introduced to national markets for business economic strategies and that individual governments have sometimes limited influence in such circumstances.”

(Para.16, pg. 5)
EU Health Ministers invited Member States:

- to explore ways of cooperation on a voluntary basis
- to exchange pro-actively information
- to explore the possibility of strategies on voluntary joint price negotiations in coalitions of Member States
Public purchasers are faced with a relatively unusually low degree of bargaining power when it comes to purchasing medicines.
JOINT PROCUREMENT OF MEDICINES CAN HELP OFFSET IN PART MARKET IMBALANCES
PROPOSED SET UP FOR DEVELOPING AN EFFECTIVE AND EFFICIENT JOINT PROCUREMENT MODEL
A functioning pharmaceutical market needs to ensure ACCESS - availability and affordability of medicinal products including innovative treatment solutions for the benefit of patients and consumers.

It clearly calls for a model that embraces at its core the social dimension.

The social dimension needs to be clearly driven by a **PUBLIC INTEREST FUNCTION**
“THE PUBLIC INTEREST”
When a decision is decided on the basis of somebody’s interest,

- What in effect is such interest meant to be?
- How is it determined that it be regarded as important?

Originates from an abstract notion

High level of operational ambiguity therefore allowing a high level of discretion

A notion that is much used and much abused
Important from the outset to instil **CONTENT** within the *PUBLIC INTEREST FUNCTION*

Am NOT concerned with a public interest function that is driven by utilitarian logic:

- aggregative conceptions of *Common Good*
- increasing aggregate individual satisfaction
SERVICES OF GENERAL INTEREST

- Bear a direct impact upon the life of each and every individual citizen

- Reflect values that convey special meanings for each and every Member State

- Member States have a vital task in the delivery of high quality services of General Interest

- Public Sector plays a major role through regulation and government spending
It is a known fact that complete reliance on the market to ensure the delivery of socially desirable objectives is insufficient.

Patients and consumers need to be seen as an end in themselves.

NOT,

The means towards an end or more specifically the means for simply balancing the supply and demand equation.
I am concerned with a public interest function that seeks the interdependent and harmonious flourishing or fulfilment of each individual in the community.
Possible through collaboration:

COOPERATION AND COORDINATION
Collaboration takes place in the COMMUNITY

COMMUNITY is about

- RELATIONSHIPS
- INTERACTIONS
- AN ONGOING STATE OF AFFAIRS
SOCIAL RELATIONSHIPS involve complex exchanges

Public Procurement needs to be viewed through this complex social exchange paradigm

“PUBLIC PROCUREMENT IS A SPECIAL CATEGORY OF CONTRACTS WHEREIN ONE OF THE PARTIES REPRESENTS THE PUBLIC INTEREST AND IS MANIFEST THROUGH COMPLEX EXCHANGES THAT OCCUR IN SOCIAL RELATIONSHIPS AND WHICH IN THE PROCESS ARE SEPERATED IN PART BY THE PASSAGE OF TIME”

No common definition

According to Directive 2014/24/EU

Could range from coordinated procurement

- preparation of common technical specifications following which contracting authorities conduct their procurement separately

To situations where contracting authorities procure collectively either by entrusting one contracting authority with the management of the procurement procedure on behalf of all contracting authorities or by acting together.
Could range from long term institutionalised legal formats such as cooperatives to ad hoc one-time agreements between independent actors in the form of consortia. Kamann et al. (2004)

Barraclough (2002) & The World Health Organisation (2007) identify four levels of collaboration ranging from information sharing to collective purchasing, elaborating as follows:
Informed buying - share information on prices and suppliers but procurement is done individually

Procurement is done individually

Coordinated informed buying - information sharing; joint market research

Procurement is done individually

Group contracting - member countries negotiate prices collectively; and select suppliers; agree to purchase from selected suppliers

Procurement is done individually

Central contracting and procurement - this generally involves a central buying unit established by the member countries to act as their procurement agent in the tendering and award of contracts.

Procurement is done through central buying unit
Broad definitions attached to the concept of Joint Procurement models - compatible when it comes to the purchase of medicines

Customised strategies targeted to meet specific public interest needs are required in order to help mitigate the diverse challenges

Different buyer and supplier groups have different motivations

Scope for countries with quasi similar levels of GDP per capita to team up for the purposes of joint procurement
KEY ELEMENTS FACILITATING JOINT PROCUREMENT

- Strong political commitment
- Trust
- Good governance and transparency in the procurement process
- Effective communications with internal and external stakeholders
- Procurement tailored to meet the needs of the collaborating countries possibly initiated with a limited list of products
- Continuity with expectations for future collaborations
- Clarity as to who will be responsible for managing the joint procurement procedure and against what remuneration
KEY ELEMENTS FACILITATING JOINT PROCUREMENT

- Clarity as to applicable public procurement legislation, including the applicable legislation on remedies and the modus operandi of the joint procurement

  - legal challenges: different experience among the Member States, the question of applicable law, question of jurisdiction, civil law or administrative law, relation between national law and EU law

- Efficient payment mechanisms
KEY ELEMENTS FACILITATING JOINT PROCUREMENT

- Ensuring sufficient capacity with the relative skills and expertise leading the public procurement process
- Sharing of information and experiences
- Developing databases on key issues such as prices, patent status, prequalification of suppliers and medicines registration
OTHER CONSIDERATIONS

- Important to get the balancing act RIGHT

- Research and Development remains a very important factor in the pharmaceutical industry

- Joint public procurement of innovation could serve the needs of research and development

- Separates the research and development costs from medicine prices enabling better transparency on prices

- Risks linked with the innovations could be shared
CONCLUSION

Voluntary joint public procurement in the area of medicines can help in part offset imbalances in the pharmaceutical market as well as better serve the goals of public health
THANK YOU FOR YOUR KIND ATTENTION

Case 238/82 Duphar and Others [1984] ECR 523, para 16.


Speech of Minister Schippers at the meeting Innovation for the patient, 1 and 2 March in Amsterdam available at: https://english.eu2016.nl/documents/publications/2016/03/1/speech-schippers-vws-innovation-for-the-patient
