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Access to new medicines in Europe

Final Draft Report

**Access to new medicines consultation
8 September 2015
UN City, Copenhagen, Denmark**

**Health Technologies and Pharmaceuticals (HTP)
Division of Health Systems and Public Health
WHO Regional office for Europe**

ABSTRACT

This WHO Regional Office for Europe country consultation gathered 74 participants from 25 countries along with participants from WHO Headquarters. The purpose of the consultation was to share the WHO Europe report Access to New Medicines in Europe and encourage policy dialogue between governments and experts on how WHO Europe can facilitate country collaboration on this matter in the 2016-17 WHO HTP work programme.

KEYWORDS

DRUG COSTS
FEES, PHARMACEUTICAL
HEALTH POLICY
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Background

As the number of new medicines introduced in Europe rises, governments are finding it increasingly difficult to afford them. Governments across Europe face similar problems, but the challenge is even greater in countries facing financial pressures. The challenges for national health systems have been illustrated in a recent WHO Europe Health Technology and Pharmaceuticals (HTP) publication, *Access to new medicines in Europe: technical review of policy initiatives, opportunities for collaboration and research* (see <http://www.euro.who.int/en/health-topics/Health-systems/medicines/publications2/2015/access-to-new-medicines-in-europe-technical-review-of-policy-initiatives-and-opportunities-for-collaboration-and-research-2015>). Potential policy directions and choices that may help governments manage or reduce high prices when introducing new drugs are outlined in this publication, and a number of case-studies around specific disease areas are provided. The report suggests that countries need to strengthen cooperation and share their experiences if better transparency in pricing is to be achieved, and differential pricing policies are to be addressed. Having created this evidence base, the natural next step for HTP was to have a first consultation with some Member States on their views and expectations from the HTP Programme in terms of policy initiatives and opportunities for collaboration for 2016-17.

Objectives of the meeting:

Through a mix of presentations from different perspectives involving country representatives, the consultation covered the need for increasing awareness of senior decision-makers and key national stakeholders about medicines policy issues linked to high priced medicines. This consultation provided opportunity to identify areas of work on prioritization in the new medical product access area and specifically how WHO can support this work.

Part I: Key issues around managing the introduction of new medicines in Europe

Whilst the rapid pace of innovation especially regarding non-communicable diseases (NCDs) is very positive particularly from a patient perspective, the introduction of new medicines is adding both to the therapeutic complexity as well as the higher cost of medicines. As a result decision makers, including payers, must increasingly make decisions about which new higher priced medicines to fund, and in which populations, whilst fostering a climate for innovation.

Policy-makers expressed concerns about access and sustainability, especially with high prices of new biotherapeutic medicines. They queried the value-for-money of some of the new medicines given limited data and available evidence at the time decisions had to be made. They were also noting issues regarding pricing especially given the frequent use of external reference pricing (ERP) alongside hidden discounts. Despite the limitations, ERP was seen as an 'easy to use' system (although resource intensive), may offer some short-term savings and information could be used in pricing negotiations.

Some examples of activities in Europe to optimise the entry of new medicines were discussed. In the case of dabigatran for example, in Sweden this included activities to limit the prescribing of this medicine to designated specialists and patient groups in order to minimise the risks of excessive bleeding in the elderly as well as to help manage costs. These were supported by

extensive educational activities. In Slovenia, education of all specialists, with patients principally followed in designated anticoagulation centres and entered onto IT anticoagulation programmes limited the prescribing of dabigatran in practice with only very few patients experiencing minor bleeds.

During the meeting, various country experiences were presented and discussed to illustrate the different challenges and possible solutions:

- The Norwegian experience in managing new medicines: Horizon scanning and timely Health Technology Assessments (HTA) are important tools being used to provide evidence to support decision-making at national and regional levels in advance of decisions regarding the role and value of new medicines. These early assessments help to better manage the introduction of these new technologies into clinical practice and health care systems.
- The Moldovan experience illustrating the "journey" from an EML to a national health insurance system with a reimbursement list and introducing new medicines: The objectives of the health system in Moldova are to increase public expenditure on medicines while introducing reimbursement guidelines for new and existing medicines based on their effectiveness and safety as well as budget impact.
- The challenges small markets face in their negotiations with industry, with the example of Cyprus. This is manifested by the fact that Cyprus faces considerable delay in the introduction of new medicines as well as "no launches" of some products. The consequence is that only a limited number of new medicines are available as compared to countries like Austria, Germany and the UK. Hence, since 2011 only a subset of innovative products is available and reimbursed in Cyprus.
- The initiatives undertaken in Iceland following the economic crisis in 2008 were presented including key areas such as (i) a change in pharmacy mark-ups, (ii) a 10% increase in patient co-payments, (iii) price revisions for medicines every year from 2009 onwards and (iv) changes in the reimbursement of specific groups of medicines. However the costs of new medicines continue to be a concern, necessitating the introduction of a quota system for the number of patients with a particular disease who could be treated (e.g. macular degeneration).
- The Dutch experience with management of new cancer medicines (PD1 inhibitors) was presented. This involved an assessment of the needs for the medicines, as well as assessment of their effectiveness and cost-effectiveness. The limited clinical data available and the high requested prices for the medicines underscore the need for monitoring of the use of these agents in practice. The challenges posed are reflected in the recent introduction by the Ministry of Health of a "lock chamber" for new high priced medicines. To get "unlocked", there needs to be an assessment by the Health Care Institute of its potential role and value followed by successful price negotiations.

Part II: Perspectives on future options for collaboration

A presentation and discussion on the prioritisation and selection principles for the WHO Model List of Essential Medicines (EML) was made. Essential medicines are defined as those that satisfy the priority health care needs of the population, with selection with due regard to disease prevalence, evidence on efficacy and safety, as well as comparative cost-effectiveness data. The Expert Committee on the Selection and Use of Essential Medicines recommended the addition of six oral direct-acting anti-viral medicines for hepatitis C into the 2015 EML based on their comparative efficacy, increased tolerability over existing treatments and the potential public health impact. It is envisaged that the increased number of treatment alternatives will lead to a more competitive market and result in decreased prices. However their potential budget impact at national level will need supportive actions at a global level by the WHO to try to ensure these medicines are accessible and affordable to all (patients and health care systems). Countries need now to consider whether to include these new (expensive) medicines in their national reimbursement lists and which patients might be eligible for treatment, with this selection process being a national responsibility. Selection and reimbursement should be based on the priorities and possibilities within each national health system including diagnostic and treatment capabilities.

The issue of price transparency was also discussed as a potential tool to improve affordable access to new medicines in the WHO Europe Region. With increased use of external reference pricing across Europe, payers are aware of the ex-factory list prices. These list prices can be used in price negotiations however they do not reflect the actual prices paid. Should countries with considerably lower GDP per capita pay less than those European countries with higher GDP per capita? This leads into discussions regarding the role of differential pricing. Significant progress towards differential pricing will require a consensus between countries and pharmaceutical companies as well as procedures to prevent product leakage from lower cost to higher cost countries. This dialogue needs to continue in a relevant forum and will be an important stakeholder consultation for the future likely best taken forward within the economic collaboration structures with Europe. It was also important to recognise the concerns among manufacturers that price transparency will adversely affect pricing and reimbursement negotiations at the country level if low prices in some markets are revealed, as well as a risk of price cartels developing.

The presentations were followed by group work to discuss areas of potential collaboration in greater detail.

- **Strengthening collaboration on HTA & prioritization:** There is already a number of existing HTA and similar networks, such as networks on pricing and reimbursement, across Europe. These include ISPOR, EUnetHTA, Advance-HTA, the PPRI network, the Piperska group, etc. Countries can use the methodological guidance from these networks and learn from each other as their HTA capacities grow to inform decision making within their country. Currently, activities among a number of European countries are fragmented. With growing concerns about the high cost of a number of medicines and their budget impact, there are important questions about funding these medicines versus funding cheaper medicines for all. There were also active discussions in the group regarding who should fund HTA agencies and how to address issues of conflict of interest that might compromise assessments. Different stakeholders can be consulted to help reduce any potential bias and improve the acceptance of any deliberations. WHO

- Europe can provide direction in this area mostly through facilitation of country collaboration. Country collaboration can help countries introducing HTA to ensure that common mistakes are not repeated and furthermore bring potential efficiency on process and use of resources including human resources.
- **Strengthening supply side collaboration – including procurement:** Strategic procurement is a growing area of interest across Europe especially with growing budgetary pressures. However, there is a need for greater collaboration in this area between countries, especially countries with smaller populations as they can have limited powers to negotiate with industry. In this regard, there are a number of barriers to address. These include variation of reimbursement processes between countries making joint purchasing difficult, different ‘willingness to pay’ thresholds and currently limited experience within Europe on common procurement of medicines. There are also issues in terms of different packaging, labelling and indications for use that will affect joint procurement.. However, this should not preclude countries with similar characteristics from collaborating on strategic procurement, within the limits of what current regulations allow (especially for EU countries).. These initiatives will be led by Member States with WHO playing a role in enhancing collaboration across countries. There may also be a role for WHO Europe to assist with information regarding medicine prices, and their transparency, that can be shared among countries. This recognises that obtaining data on discounts will be challenging.
 - **Strengthening demand side collaboration – including how to encourage appropriate use of high cost medicines and monitor use against agreed guidance.** Discussion in this group was based on two scenarios. The first scenario involved potential ways to limit the prescribing of a new high priced medicine for patients with advanced lung cancer that offered limited increase in overall survival. Potential methods to limit its prescribing and/or budget impact include negotiating price-volume agreements at a national level. Guidelines should also be developed with key stakeholder groups to define patient populations eligible for treatment based on clinical value and effectiveness and budget considerations. This could include development of treatment algorithms ahead of launch, e.g. limiting prescribing to third or fourth line treatment regimens or defined populations based on clinical characteristics. Patients could also be included in registries to monitor the effectiveness and safety of use of the medicine in routine clinical care, potentially such registries could be sponsored by the pharmaceutical company. The second scenario involved new treatments to reduce cholesterol levels with anticipated medicine costs of over US\$8,000/ patient/year. The group discussed the clinical data with concerns that cholesterol levels are a surrogate marker and there are currently no outcome data available for the new medicines. As a result, the group suggested that the prescribing of these new medicines could be restricted to second or third line therapy as well as being subject to price-volume agreements for reimbursement given no clinical outcome data to date and the high requested prices. In addition, the group considered the use of higher patient co-payments for these new medicines versus existing therapies as a mechanism to try to limit demand. As the second scenario reflects an emerging problem for countries, the situation should be closely monitored to provide guidance to countries.

Next steps

Based on this country consultation, it was suggested that two working groups should be set up and facilitated by WHO, HTP:

- One working group should focus **on horizon scanning and HTA collaboration across countries**
- Another one on **strategic procurement and capacity development within countries through regional networking activities.**

HTP will prepare for these working groups to be established and initial consultations to take place early 2016.

Annex 1

PROVISIONAL PROGRAMME

09:00 – 10:30 Part I: Key issues around managing the introduction of new medicines in Europe

Moderation/Chair

The session will be moderated by Professor Brian Godman, Karolinska Institute, Sweden and Strathclyde Institute of Pharmacy and Biomedical Sciences, Glasgow, UK

- Key note: Challenges and experiences in managing new medicines in the Norwegian health system, Øyvind Melien, Norwegian Directorate of Health (15 minutes);
- Presentation of the WHO report *Access to new medicines in Europe: technical review of policy initiatives, opportunities for collaboration and research*:
 - Overview of the report, presentation by Hanne Bak Pedersen, HTP (10 minutes)
 - *Optimizing decisions- Horizon Scanning & HealthTechnology Assessment (HTA) – its role and place in prioritization and decision making*. Presentation by Jane Robertson, WHO Consultant & Prof University of Newcastle, Australia (15 minutes)
 - *High price medicine as a challenge for public pricing and reimbursement*. Presentation by Sabine Vogler, Gesundheit Österreich (15 minutes);
 - *How to encourage and ensure appropriate use of new medicines?* Professor Brian Godman, Karolinska Institute, Sweden and Strathclyde Institute of Pharmacy and Biomedical Sciences, Glasgow, UK & Nicola Magrini, Secretary of the Expert Committee on the Selection and Use of Essential Medicines Policy, Access and Use Team, WHO Geneva (15 minutes)

Questions and discussion

10:30 – 11:00 Coffee Break, lounge area, finger 7

11:00 – 12:30 Experiences and constraints - country perspectives relating to introducing new medicines

Moderation/Chair

The session will be moderated by Hanne Bak Pedersen, Programme Manager, HTP, WHO Europe

- Experiences and constraints - country perspectives relating to introducing new medicines:
 - Country perspectives - moving from an essential medicine list to a national health insurance system with a reimbursement list and introduction of new medicine, Zinaida Bezverhni and Ala Ulianoschi, WHO country office in Republic of Moldova (15 minutes)
 - New innovative medicines procurement in the context of small markets, Dr Louis Panayi, Director of Pharmaceutical Services, Ministry of Health, Cyprus (15 minutes);

- Impact of the economic crisis on the procurement of new innovative medicines: the case of Iceland, Einar Magnússon, Director of Pharmaceutical Affairs Ministry of Welfare, Iceland (15 minutes);
- The introduction of nivolumab in the Netherlands (Lydia de Heij, Manager, Pharmaceutical Department, MoH, the Netherlands) (15 minutes)

Discussion

12:30 – 13:15 LUNCH, lounge area, finger 1

13:15 – 15:00 Part II: Perspectives on future options for collaboration

Moderation/Chair

The session will be moderated by Jane Robertson, WHO Consultant & University of Newcastle, Australia

- WHO perspectives, Evidence-based selection /decision making criteria/ prioritization, Nicola Magrini, Secretary WHO EML, EMP/PAU, WHO Geneva (20 minutes)
- Price transparency as a tool to achieve access to new medicines in the WHO Euro Region, Alessandra Ferrario, LSE Health (20 minutes)

Discussion

15:00 – 16:30 Group work (3 groups) including coffee break (lounge area, finger 7) - Potential Collaboration Agenda:

- Strengthening collaboration on HTA & prioritization- moderated by (Alessandra Ferrario, LSE Health, Press room)
- Strengthening supply side collaboration – including procurement related - moderated by (Francisco Blanco, UNICEF, Auditorium 1)
- Strengthening demand side collaboration – including how to encourage appropriate use of high cost medicines and monitor use against agreed guidance– moderated by (Brian Godman, Auditorium 1)

16:30 – 17:30 Feedback from group work, discussion and next steps for virtual continuation of Working Groups

17:30 – 18:00 Summing up and next steps: Brian Godman & Hanne Bak Pedersen

Annex 2

PROVISIONAL LIST OF PARTICIPANTS

Albania

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Lilit Ghazaryan, Deputy Director of the Medicines Agency of the Republic of Armenia

Azerbaijan

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Rashida Abdullayeva, Main Specialist of the Department of the Rational Use of Medicines in the Center of Innovation of the Republic of Azerbaijan

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