World Health Organization

FAIR PRICING FORUM

2017 Meeting Report

Amsterdam, The Netherlands

11 May 2017

Report on the Fair Pricing Forum 2017

Beurs van Berlage, Amsterdam, the Netherlands

11 May 2017

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Introduction

The main aim of the Forum, held on the 11th May 2017 in Amsterdam, was to enable stakeholders to discuss options for a fairer pricing system that is sustainable for both health systems and the pharmaceutical industries.

The Forum sought to address three questions:

- What can governments do to ensure fairer medicines prices and greater access?
- What can industry do?
- How can WHO support the process?

Key issues addressed included: developing alternative approaches for research and development (R&D) and business models for innovation; facilitating collaboration among payers by expanding current networks to include other relevant stakeholders and countries; increasing exchange of information, for example to assess the value of new products; promoting transparency of prices paid, R&D costs, production costs, and profit margins.

The Forum was hosted by the Dutch Ministry of Health, Welfare and Sport together with WHO, and attended by representatives from non-governmental and patient organizations and Member States (Annex A) and the pharmaceutical industry. The forum was divided into two parts – an interactive plenary session in the morning, based on a series of four short films addressing different aspects of the pricing/access issue, followed by breakout sessions in the afternoon covering related themes (Annex B).

Summary of proceedings

The forum was opened by Martin van Rijn, Dutch State Secretary of Health, Marcel van Raaij, Director Pharmaceuticals and Medical Technology Department, Dutch Ministry of Health, Welfare and Sport, and Dr Marie-Paule Kieny, Assistant Director General for Health Systems and Innovation, WHO.

It was noted that medicines pricing is a complex issue that affects rich and poor alike. The need to balance the interests of the health sector and businesses was emphasised as well as the need for access to medicines for all as part of the right to health. It was acknowledged that the different stakeholder groups have different priorities but there was consensus around the overall objective: that there should be effective care, accessible care and affordable care. There is little value in a new innovative medicine if severely ill people cannot access it or it is not affordable. At the same time, there need to be adequate economic incentives for manufacturers. The current situation with respect to medicines prices highlights two problems: high prices causing access issues on the one hand, and low prices leading to shortages on the other.

The need for new and sustainable business models was raised. Instead of focusing only on the current model, which is primarily based on intellectual property and a high return on investment, greater collaboration is needed in order to ensure R&D meets public health needs and to reduce barriers to accessing essential medicines, particularly price.

The potential for countries to come together to have a stronger voice at the negotiating table was identified. However, effective negotiation requires understanding of the real costs of R&D for new products and anticipated profit margins. While no pharmaceutical company can operate without a fair profit, and innovation should be rewarded, there 'must be a balance'. In other words, there must be fair prices.

Interactive plenary discussion.

Dr Suerie Moon moderated the plenary discussion based on film clips illustrating different aspects of medicines pricing, using structured questions and audience polling exercises.

The first session focused on the question of "what is a fair price?" Discussion began around value for money. Issues raised included therapeutic value, individual preference and need, especially with respect to medicines for life-threatening illnesses. The relationship between 'value' and 'price' was questioned: depending on the situation, consumers may be prepared to pay whatever they can afford. A price that all patients can afford reflects the moral obligation to make medicines available to everyone who has a need. The need for a sustainable return on investment to ensure companies remain viable was highlighted.

It was recognised that affordability is often discussed in the context of people in low-income countries paying personally for medicines (out-of-pocket payments) and it was debated whether dysfunctional health systems should be supported by industry. Universal health coverage is intended to enable risk-pooling and make medicines more affordable. Importantly, this shifts the ability to pay for medicines from the capacity of individuals to the fiscal capacity of countries.

It was suggested that pharmaceutical companies are making a significant contribution to affordability based on a recent G-FINDER survey, describing industries' contribution of around 15% ($471m) of total R&D funding for neglected diseases in 2015, making it comparable to the contribution made by philanthropic funders[1].

What is driving the high price of medicines?

The role of appropriate action from governments was discussed. It was suggested that governments needed to be more involved in the R&D investments or ensure publically funded research into certain conditions. Government action and regulation also contribute to the difference between prices in European and American markets. The need for transparency was noted, without which, stakeholders will be unable to understand the dynamics or the real costs of bringing products to market.

The discussion focused on mechanisms for increasing bargaining power of purchasers, including transparency of inputs into price setting. It was recognised that in many countries the published prices for medicines are not the actual prices paid. It was suggested that governments generally do not realise the bargaining power they have, and could negotiate more effectively if they shared information on prices and joined together to reduce transactional costs and place more emphasis on price-volume negotiations. It was suggested that WHO could play a key role to facilitate awareness and train negotiators. Other suggestions included the need for innovative financing solutions, as well as agreeing on what constitutes fair pricing. The importance of making full use of TRIPS flexibilities, including the use of compulsory licenses was also raised.

What is the most promising solution to the problem of shortages?

The discussion focussed around issue of price-related shortages, noting that if prices are too low, production costs are not covered or potential return is insufficient, manufacturers may drop out of the market. This has occurred with established older drugs, including antibiotics and generic cancer medicines.

However, it was recognised that price is not the only cause of shortages; the supply of active pharmaceutical ingredient is an issue for production of many medicines. An effect of globalisation is greater concentration of manufacturing, so that for some medicines there is only a single supplier. This increases the risk of shortages.

It was considered that ensuring market intelligence to inform production planning is critical to reduce the risk of shortages. This is particularly important for certain essential medicines. WHO could potentially play a role in identifying vulnerable products and opening a pathway for prequalification. A alternative solution is to increase prices to levels that cover producers' costs.

The need for improved tendering practices was discussed. It was suggested that 'winner-takes-all' tendering in many countries has led to poor-quality manufacturers winning large markets based on lowest price. These practices may drive higher quality manufacturers out of the market or cause them to switch to more profitable production lines. It was pointed out that some countries structure tenders so that 70% of the tender award goes to a winner, while the additional 30% is distributed among the other bidders.

The impact of substandard/falsified (SF) drugs was recognised. Strong regulatory authorities are needed to ensure quality, otherwise SF medicines enter the market and can cause price decreases that drive quality manufacturers out of the market.

What are alternative business models?

'Push' and 'pull' mechanisms were discussed. One example proposed was a $3 billion prize for new HIV drugs. There was also discussion of the need to consider the role of intellectual property provisions and the current emphasis on this as an over-arching solution. Examples of new business models, such as Drugs for Neglected Diseases initiative, the Medicines Patent Pool, and Global Antibiotic Research & Development Partnership, were highlighted and accepted as having potential impact for specific therapeutic areas. However, for de-linkage models to be effective, hundreds of millions of dollars may be required up front with no guarantee of success.

The challenge of mobilizing funds was identified as the largest barrier to progress. There was a broad call for public policy to drive prioritized innovation. However, this requires governments to be proactive in investing in R&D either directly or through public-private partnerships. It was pointed out that Ministries of Health provide finance to deliver health care, and may not control R&D funding. It was also suggested that inter- and intra-governmental collaboration is needed to mobilize funds and achieve better priority setting including with other funders. The challenge is achieving cross-sectoral dialogue and mobilizing financial resources. It was suggested that further research is needed to help establish national priorities on medicines so that countries can work together, pool resources, and avoid duplication of efforts.

Intergovernmental collaboration for development of medicines would require significant specialist technical input. It was suggested that one of the benefits of Product Development Partnerships (PDPs) is that health care sector players can partner with private companies to make the R&D process more effective to ensure the needs of the global community are being met.

Breakout sessions conclusions.

In the afternoon, there were four break-out sessions to discuss ideas, and exchange best practices. Four thematic areas were covered: availability of generic medicines; transparency regarding R&D costs and price; voluntary cooperation of payers; and alternative business models.

Availability of generic medicines

It was concluded that there is an urgent requirement for collaboration between authorities to establish an inventory of needs and to develop policy option to address these needs. The establishment of a structured discussion between competent regulatory authorities, payers, and industry to identify which molecules are needed, at what price and how to ensure the future stability of the market was suggested. The need to set rules for tendering, taking into account not just price, but also liability, quality, and sustainability was highlighted. The value of pooled procurement in order to achieve adequate volumes was also emphasised.

Transparency of R&D costs and pricing

Particular attention was drawn to the need for greater transparency on R&D costs. However, it was acknowledged that this should take into account the complexity of the different elements that require costing, including failed drug development attempts, and decisions not to proceed with drug development on commercial grounds. With regard to achieving greater transparency on prices, a first step could be that governments agree to acknowledge or 'flag' where the published price is not the actual price paid while noting that the commercial nature of these agreements may mean that it is not possible to identify the price paid for individual products. However, it was emphasised that achieving greater transparency has the potential to result in additional benefits, for example, targeted rewards for needed innovation. It was suggested that the obstacles to achieving greater transparency are considerable and that governments have an important role to play in driving reform.

Voluntary cooperation of payers

It was concluded that voluntary cooperation of payers could increase access to medicines and innovative products, but that this is more likely to happen across countries with similar health systems. It was suggested that WHO should play a key role in bringing people together in activities such as health technology assessment (HTA) and joint horizon scanning for new products. It was also proposed that WHO should support new global voluntary collaborations for sharing of information.

With respect to joint negotiation of prices, the objective would be to strive for a more homogenous HTA/pricing process. Existing formal and informal networks should be maintained and enhanced.

Alternative business models

The implications and consequences of the current business-based R&D model, and possible alternatives were discussed. Currently, incentives lead to the development of medicines that generate returns on investment that are similar or greater to returns on investment in other industries. This has led to a focus on specialty medicines affecting older populations that are covered by insurance systems. Achieving fairer pricing for new medicines will challenge the current model of market-driven R&D. If PDPS are to be a viable alternative, governments would need to enlarge these partnerships. To enable government risk-sharing, it was proposed that public funders might be able to support the clinical trial phase in health care systems. Such risk-sharing models could potentially result in lower prices. It was suggested that governments should attach conditions to research funding so that the public funding is explicitly taken account of in pricing discussions and the results are made publically available.

Summary

The multi-stakeholder discussion was seen as a first step towards identifying an actionable agenda towards fair pricing, and reiterated the message that by "fair" pricing, WHO does not mean "low" pricing. Fair pricing means pricing that allows for a reasonable return on investment in exchange for an affordable price, which is to say one that does not bankrupt health systems and other payers. It is with such 'sustainable pricing' that the growth of the pharmaceutical sector will be supported and universal access to essential medicines and other health technologies will be ensured.

Governments need to be enabled to play a stronger role in negotiating prices and where appropriate, incentivising needs-based R&D. More cooperative approaches would be helpful, for example with governments sharing information on pricing, and gaining greater leverage when negotiating prices. Governments should see funding for health as an investment that will contribute to greater economic benefits, for example by enabling more health sector jobs in the public and private sectors, in addition to keeping the population healthy. Greater investment in R&D prioritization should result in development of products that respond to public health needs.

With regard to pricing drivers and strategies, a 'value-based' pricing model is not viable in many countries because it does not take into account affordability and total cost. Used in isolation, it also has the potential to exclude other valuable price-negotiation tools such as tendering and price-volume agreements.

There is a need to fully understand the concept and consequences of 'de-linkage' with respect to development of medicines. At present, there is little transparency on what inputs actually feed into decisions about medicines prices, and there is very little evidence regarding many elements such as the actual R&D investment or the public sector contribution. For example, the cost of acquisition of a start-up company is often conflated with R&D costs. Before de-linkage models are pursued, better definitions of the inputs into price setting are needed, noting that R&D has to be paid for in order to have the necessary medicines and health technologies.

The need for greater transparency was a recognised as a recurring theme. More transparency on pricing is needed from all stakeholders: from public research entities, defining how much public money is spent on discovery research; from companies, on how much they spend on clinical trials and other

development activities, and how much on production costs; and from countries, on how much each one pays for a medicine.

Finally, there is a need for further discussion, in order to find solutions to the many different facets of the prices/access issue, to develop a constructive and concrete action plan that can be implemented.

Annex A

Participants

Fair Pricing Forum 2017 – List of Participants

Affiliation	First name	Last name
Access to Medicine Foundation	Jayasree	Iyer
Access to Medicine Foundation	Tara	Prasad
Akin Gump	Alan	Yanovich
Argentina	Rubén Agustín	Nieto
Association of non-profit health insurers	Menno	Aarnout
Astellas Pharma B.V.	Daan	Muris
Australia	Karen	Binnekamp
Australia	Madeleine	Heyward
Austria	Clemens Martin	Auer
Austria	Vinzent	Rest
Belgium	Ronse	Ignace
Belgium	Raphael	Mertens
Belgium	Inneke	Van de Vijver
BEUC	Francesca	Cattarin
Bill & Melinda Gates Foundation	Greg	Widmyer
Biotech Industry Association	Annemiek	Verkamman
Bosnia and Herzegovina	Sanja	Custovic
Brazil	Leonidas	Coelho
Brazil	Lara	Pereira
Brazil	Leandro	Safatle
Burkina Faso	Nacoulma	Aminata P.
Canada	Elena	Lungu
Canada	Tanya	Potashnik
Changemaker	Lisa Esohel Ogbei	Knudsen
CoachMan Consultancy	Henk	den Besten
Colombia	Álvaro Gutiérrez	Botero
Colombia	Javier	Guzmán
Commons Network	Sophie	Bloemen
Consultant	Abigail	Jones
Council on Health Research for Development	Janis	Lazdins
Croatian Health Insurance Fund	Tomislav	Javor
Czech Republic	Jan	Badura
Czech Republic	Lukas	Zahalka
Danish Cancer Society	Jes	Sogaard
Department of Pharmacology, University of Delhi	Anita	Kotwani
Deutsches Medikamenten-Hilfswerk Action Medeor	Christoph	Bonsmann
DNDi	Pascale	Boulet
DNDi	Spring	Gombe-Götz
DNDi	Anita	Staud
Dutch Association Innovative Medicines	Ida	Haisma
Dutch Cancer Society	Eveline	Scheres
EHA	Robin	Doeswijk

Estonia	Alice	Kivistik
European Cancer Leagues	Wendy	Yared
European Commission	Jo	De Cock
European Commission	Dimitrios	Florinis
European Commission - EuropeAid	Kevin	McCarthy
European Patients Forum	Marco	Greco
European Public Health Alliance	Yannis	Natsis
European Society for Medical Oncology	Josep	Tabernero
EURORDIS	Yann	Le Cam
Fair Medicines	Anne	Dankert
FIP	Luc	Besancon
France	Elise	Anger
France	Catherine	Dauphin
France	Adrien	Dozol
Gesundheit Österreich GmbH / Austrian Public Health Institute	Sabine	Vogler
Gilead	Neil	Mulcock
Global Antibiotic R&D; Partnership	Jean-Pierre	Paccaud
Global Health Centre, Graduate Institute	Suerie	Moon
Graduate Institute of International and Development Studies	Gaelle	Krikorian
Greater Paris University Hospitals	Claire	Biot
Greece	Georgina	Tzanakaki
Guyana	Glendon	Fogenay
Health Action International	Margaret	Ewen
Health Action International	Tim	Reed
Health Technology Assessment	Brent	Fraser
Healthcare Consultancy	Andrea	Corazza
HERA Mongolia	Wilbert	Bannenberg
Hungary	Gergely	Németh
i+ solutions	Marcel	van Valen
IAVI	Ardi	Voets
IFPMA	Eric	Cornut
IFPMA	Thomas	Cueni
IFPMA	Fumie	Griego
IFPMA	Ansgar	Hebborn
IFPMA	Haruhiko	Hirate
IFPMA	Erin	Huntington
IFPMA	Andrew	Jenner
IFPMA	Petra	Laux
IFPMA	Mark	Legault
IFPMA	Noritsune	Miura
IFPMA	Danielle	Rollmann
IFPMA	Adrian	Thomas
IFPMA	Richard	Torbett
IFPMA	Erica	Whittaker
IGBA	Adrian	van den Hoven
Ireland	Ross	Hattaway
Johnson & Johnson	Adrian	Thomas
Knowledge Ecology International	Thirukumaran	Balasubramaniam
Knowledge Ecology International	James	Love
Latvia	Daina	Murmane-Umbrasko

Latvia	Janis	Zvejnieks
License to Heal	Dominiek	Veen
Lithuania	Neringa	Bernotienė
Lithuania	Vilma	Meldziukaitė
Malta	Anne Marie	Grima
Malta	Mark	Zammit
Mauritania	Abdellahi	Kebd
Medicine Patent Pool	Esteban	Burrone
Medicines Law & Policy, University of Groningen	Ellen	't Hoen
Médecins Sans Frontières	Katrien	Coppens
Memorial Sloan Kettering Cancer Center	Peter B.	Bach
MfE	Sergio	Napolitano
Morocco	Adil	Brigui
Morocco	Laila	Ibnmakhlouf
Netherlands Antibiotic Development Platform	Kees	de Joncheere
Nicaragua	Claudia Valeria	Rodezno
Norway	Marit	Måge
Norway	Kristin	Svanqvist
Norwegian Cancer Society	Anne Lise	Ryel
NVZA	Tjalling	Van der Schors
OECD	Valerie	Paris
Oman	KH	Husaini
Open Society Foundations	Kiti	Phillips
Oxfam	Mohga	Kamal-Yanni
People's Health Movement - UK	Brenda	Nsambateshi
PFSCM	Wesley	Kreft
Philippines	Jeffrey	Castro
Philippines	Abdullah, Jr.	Dumama
Pillango Development	Ard	van Dongen
Praksis	Apostolos	Kalogiannis
ReAct	Helle	Aagaard
Republic of Korea	Kyungho	Choi
Researcher	Melissa	Barber
Researcher	Dzintars	Gotham
Royal Dutch Pharmacists Association	Doerine	Postma
Saudi Arabia	Abdullah	AlAhmari
Saudi Arabia	Fahad	Aldossari
Saudi Arabia	Jameel	Alharbi
Saudi Arabia	Ibrahim	Aljuffali
Saudi Arabia	Fahid	Alnutafy
Saudi Arabia	Hajed	Hashan
Slovakia	Elena	Jablonická
Slovakia	Alexandra	Turkovicova
Sri Lanka	Hithanadura Asita	De Silva
Stichting Fair Medicine (Foundation)	Hans	Büller
Stichting Fair Medicine (Foundation)	Frans	de Loos
STOPAIDS, UK	Tabitha	Ha
Sweden	Pontus	Johansson
Sweden	Ylva	Kalin
Sweden	Fredrik	Moen

Sweden	Michael	Schenkenberg Van Mierop
Switzerland	Guido	Barsuglia
Switzerland	Jörg	Indermitte
Switzerland	Simon	Schmid
The Netherlands	Herbert	Barnard
The Netherlands	Andrea	Beelen
The Netherlands	Irene	Blok-de Vries
The Netherlands	Marcel	Canoy
The Netherlands	Pieter	de Coninck
The Netherlands	Tim	De Jager
The Netherlands	Roland	Driece
The Netherlands	Marit	Elenbaas-Thomas
The Netherlands	Marja	Esveld
The Netherlands	Frank	Flier
The Netherlands	Maurice	Galla
The Netherlands	Tidde	Goldhoorn
The Netherlands	Aldo	Golja
The Netherlands	Lili	Guo
The Netherlands	Fabienne	Jol
The Netherlands	Huib	Kooijman
The Netherlands	Patrick	Kruger
The Netherlands	Eveline	Lankhorst
The Netherlands	Mascha	Meijer
The Netherlands	Tessel	Mellema
The Netherlands	Maike	Nellestijn
The Netherlands	Bart	Ooijen
The Netherlands	Daphne	Paleari
The Netherlands	Mieke	Put
The Netherlands	Gert-Jan	Rietveld
The Netherlands	Martine	Rutten
The Netherlands	Priscilla	Schoondermark
The Netherlands	Ad	Schuurman
The Netherlands	Diederick	Slijkerman
The Netherlands	Bente	Sturm
The Netherlands	Evert Jan	van Asselt
The Netherlands	Philip	van Dalen
The Netherlands	Frank	van de Looij
The Netherlands	Tessa	van der Velden
The Netherlands	Karin	van der Velden
The Netherlands	Loukie	van Lennep
The Netherlands	Rivka	van Mastrigt
The Netherlands	Marcel	van Raaij
The South Centre	Viviana	Munoz Tellez
The South Centre	German	Velasquez
Timor-Leste	Santana	Martins
TWN International Geneva	Sangeeta	Shashikant
UNCTAD	Christoph	Spennemann
Union for International Cancer Control	Guy	Muller
UNITAID	Karin	Timmermans

United Kingdom	Jacoline	Bouvy
United Nations Development Programme	Tenu	Avafia
United States of America	Emily	Bleimund
United States of America	Steve	Sheingold
Universities Allied for Essential Medicines	Jeffrie	Buckle
Universities Allied for Essential Medicines	Thilo	von Groote
Universities Allied for Essential Medicines	Victoria	von Salmuth
University of British Columbia	Steve	Morgan
University of Groningen	Hans V.	Hogerzeil
University of KwaZulu-Natal	Fatima	Suleman
University of Liverpool	Andrew	Hill
University of Michigan Law School	Nicholas	Bagley
University of Newcastle	David	Newby
University of Tokyo	Isao	Kamae
Wemos Foundation	Ella	Weggen
WHO Headquarters	Daniela	Bagozzi
WHO Headquarters	Peter	Beyer
WHO Headquarters	Tania	Cernuschi
WHO Headquarters	Sarah	Garner
WHO Headquarters	Suzanne	Hill
WHO Headquarters	Gary	Humphreys
WHO Headquarters	Swathi	Iyengar
WHO Headquarters	Marie-Paule	Kieny
WHO Headquarters	Ruediger	Krech
WHO Headquarters	Ryoko	Miyazaki-Krause
WHO Headquarters	Andrew	Rintoul
WHO Headquarters	Inthira	Yamabhai
WHO Regional Office for Europe	Hanne	Bak Pedersen
WHO Regional Office for Europe	Guillaume	Dedet
WHO Regional Office for Europe	Janice	Lam
WHO Regional Office for Europe	Jeanne	Riqué
WHO Regional Office for the Americas	Francisco	Caccavo
WHO Regional Office for the Western Pacific	Uhjin	Kim
Youth Stop AIDS	James	Cole
ZS Associates	Ed	Schoonveld

Annex B

Programme

11 May 2017

08:00	-	09:00	Arrival and registration
09:00	-	09:05	Welcome by Marcel van Raaij, Director Pharmaceuticals and Medical Technology Department, Dutch Ministry of Health and Marie-Paule Kieny, Assistant DG - Health Systems and Innovation WHO
09:05	-	09:15	Introductory Speech by Martin van Rijn, Dutch State Secretary of Health
09:15	-	12:00	Introduction of the Scenario based policy discussion by Moderator Suerie Moon Director of Research, Global Health Centre and Visiting Lecturer, Graduate Institute of International and Development Studies, Geneva, and Adjunct Lecturer, Department of Global Health and Population, Harvard T.H. Chan School of Public Health.
12:00	-	12:15	Instruction for Break out sessions
12:15	-	13:30	Lunch
13:45	-	15:00	Break out session round 1 - brainstorm
15:00	-	15:30	Coffee Break
15:30	-	16:45	Break out session round 2 - review of outcome brainstorm
16:45	-	17:00	Family photo
17:00	-	17:45	Plenary report from break out sessions by moderators
17:45	-	18:00	Closing remarks by the WHO (Marie-Paule Kieny, Assistant DG - Health Systems and Innovation WHO)

[1] GFINDER Annual Report 2016.