

First Workshop on Drug Pricing

April, 23rd - 24th, Firenze Campi Bisenzio

Scientific Board

Prof. Pier Luigi Canonico, Direttore, Dipartimento di Scienze del Farmaco, Università del Piemonte Orientale, Novara

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Prof. Claudio Jommi, Professore Associato, Dipartimento di Scienze del Farmaco, Università degli Studi del Piemonte Orientale; Responsabile Scientifico, Osservatorio Farmaci, Cergas, Università Bocconi; Presidente AIES (Associazione Italiana di Economia Sanitaria)

Objective

The Workshop aims at discussing positive and negative aspects of drug pricing in Italy and future options to enhance price regulation. The discussion will be carried out through a multi-stakeholder approach and considering also international experiences.

Topics

- Price negotiation: the role of value (VBP – Value-Based Pricing) , costs (costs-plus), price-corridors, price-volumes trade-off
- How to measure, rank and incorporate added value into price negotiation
- Budget silos and VBP
- Managed market entry (MME) contracts and their effect on actual prices
- Pricing and price-competition in the off-patent market
- Prospective role of the “Programma Nazionale HTA” on price regulation

With the patronage of

- AIES, Associazione Italiana di Economia Sanitaria
- AIFA, Agenzia Italiana del Farmaco
- ISS, Istituto Superiore di Sanità
- ISPOR Italy Rome Regional Chapter
- Università del Piemonte Orientale

AGENDA

APRIL 23rd, 2015

14.00 – 14.15 **Introduction by** *Pier Luigi Canonico, Claudio Jommi, Armando Genazzani*

14.15 – 15.00 **Opening lecture:** Value-based pricing in UK Michael F. Drummond

This opening lecture will provide an overview on issues derived from VBP. More specifically, the British experience, where the introduction of VBP was many times announced and postponed, will be presented.

15.00 – 15.30 **Opening lecture:** Industrial and health policies: should they be considered both in drug price regulation? Roberto Scrivo/Paolo Bonaretti

The second opening lecture will discuss whether price regulation should incorporate industrial issues (e.g. premium price for companies investing in Italy) together with health impact (VBP) or other actions should be implemented for industrial purposes, and how health and industrial issues should be integrated.

15.30 – 17.00 **First session**

Value based pricing

The first session will discuss the application of VBP in Italy and how VBP has been and will be managed within a budget silos approach. Pierluigi Russo will provide some prospects on the assessment of innovativeness and the actual and future role of added value (which endpoints, which comparators, which role of economic impact, which role of budget impact) in price negotiation. Andrea Messori will discuss the actual and future role of regions in collecting evidence on value and costs to support price negotiation. Giampaolo Murri will discuss VBP with the perspective of multinational companies that (i) should reward the investment made on R&D (which are sunk and fixed costs) and (ii) define price-corridors to avoid cross-reference pricing and parallel trade

Coordinator: Armando Genazzani

- Value-based pricing in Italy. Pierluigi Russo
- Value-based pricing in Italy: the role played by regions and health organisations. Andrea Messori
- Value-based pricing and pricing strategies in the big pharma. Giampaolo Murri

17.00 – 18.00 **Discussion**

18.00 – 19.00 **Market Access Award,** Pier Luigi Canonico, Antonio Gaudioso, Armando Genazzani, Claudio Jommi

APRIL 24th, 2015

9.00 – 11.00 **Second session**

Real world evidence: the role of Managed Market Entry contracts

Modera Claudio Jommi

The second session will discuss managed market entry (MME) contracts both volume- and outcome-based. Mondher Toumi will provide an overview of the application of MME contracts worldwide and pros and cons of different options (e.g. population-based and individual-based approach) in the perspective of all stakeholders. Nello Martini will discuss the Italian experience with a particular focus on performance-linked-reimbursement contracts (named in Italy 'payment-by-result') applied to many onco drugs. Jan Weinrich will provide an overview of positive and negative aspects of MME from a multinational company perspective.

- Managed Market Entry Contracts: the European experience. Mondher Toumi
- Drugs Pricing: Clinical Value and Real World Evidence. Nello Martini
- Managed Market Entry Contracts: the experience of Roche. Jan Weinreich

11.00 – 11.15 Coffee Break

11.15 – 13.00 Third session

Price-competition in the off-patent and patent-protected markets

Coordinator: Nicola Salerno

The third session will discuss price-competition on the off-patent and patent-protected markets. Simone Ghislandi will provide an overview of the evidence on the impact of (generic and therapeutic) reference pricing and procurement policies aimed at enhancing price-competition. Francesca Patarnello will discuss the role of "equivalency" in policies aimed at enhancing price-competition. Assogenerici and Lucia Aleotti from Farindustria will discuss if and how price-competition may promote allocative efficiency and enhance access to new and innovative drugs

- Reference pricing, tenders and price-competition: evidence on their effects. Simone Ghislandi
- Equivalence and its use in policy making. Francesca Patarnello
- The role played by generics and biosimilars on price-competition. Assogenerici.
- Price-competition and innovation: how to make them consistent one each other. Lucia Aleotti

13.00 – 14.00 Lunch

14.00 – 16.00 Fourt session

Case-studies

Coordinator: Pier Luigi Canonico

The fourth session will discuss pricing and sustainability issues in three therapeutic areas (diabetes, HCV, and oncology), considering the three aspects discussed in the first three sessions (VBP, MME contracts, Price competition).

- Diabetes. Andrea Giaccari
- HCV. Paola Lanati
- Oncology. Francesco Perrone

16.00 – 17.00 Discussion

17.00 – 17.30 Conclusions *Pier Luigi Canonico, Claudio Jommi, Armando Genazzani*

*Presence not confirmed yet



Faculty

Lucia Aleotti, Vice Presidente Farindustria

Paolo Bonaretti, Ministero dello Sviluppo Economico e Direttore Generale Aster

Mike Drummond, Professor of Health Economics, University of York

Antonio Gaudioso, Segretario Generale CittadinanzAttiva

Simone Ghislandi, Assistant Professor, Università Bocconi

Andrea Giaccari, Professore associato di Endocrinologia, Università Cattolica del Sacro Cuore di Roma

Paola Lanati, Amministratore Unico 3P Solution srl

Nello Martini, Direttore Ricerca & Sviluppo, Accademia Nazionale di Medicina

Andrea Messori, Responsabile HTA, ESTAR (Ente di Supporto Tecnico Amministrativo Regionale) – Regione Toscana

Giampaolo Murri, Market Access & Commercial Operations Executive Director, MSD

Francesca Patarnello, Direttore Value Access & Policy, Amgen

Francesco Perrone, Direttore Unità Sperimentazioni Cliniche, IRCCS Istituto Nazionale Tumori, Fondazione Pascale, Napoli

Pierluigi Russo, Direttore Area Strategia e Politica del Farmaco, AIFA

Nicola Salerno, Economista presso Reforming.it e Research Fellow di Adapt

Roberto Scrivo, Capo della Segreteria Tecnica del Ministro della Salute

Mondher Toumi, Professor at Marseille University and CEO at Creativ-Ceutical

Jan Weinreich, Director Market Access, Roche Italia