The role of economic evaluation in the P & R in Italy

Marcellusi A[1], Ragonese A[2], Manetti S[3], Mucherino S[4], Viti R[5], Ferrario M[6], Moreno C[7], Di Laura D[8], Carletto A[9], Bortolami A[10], Marinozzi A[11], Canonico PL[12] and The ISPOR Italy Rome Chapter Study Group

CEIS TOR VERGATA Centre for Economic and International Studies
Economic Evaluation and HTA (*EEHTA*)

[1]Faculty of Economics, Centre for Economic and International Studies (CEIS)-Economic Evaluation and HTA (EEHTA), University of Rome Tor Vergata, Rome, Italy, [2]Clinical Psychologist, Italy, Italy, [3]Sant'Anna School of Advanced Studies, MeS Lab, Pisa, Italy, [4]CIRFF, Center of Phamacoeconomics and Drug utilization Research, University of Naples; Department of Pharmacy, Univeristy of Naples Federico II, Naples, Italy, [5]Takeda, Rome, Italy, [6]Roche S.p.A., Monza, Italy, [7]Regulatory Pharma Net, Pisa, Italy., Pisa, Italy, [8]MA Provider, Milano, Milano, Italy, [9]Health Economic Evaluations Office, Italian Medicines Agency, Rome, Italy, Rome, Italy, [10]Rete Oncologica del Veneto, Istituto Oncologico Veneto IRCCS Padova, Padova, Italy, [11]Hospital Pharmacist, Clinical Pharmacy, Department of Health Servis, AO University United Hospitals of Ancona, Italy, Ancona, Italy, [12]University of Eastern Piedmont, Novara, Italy

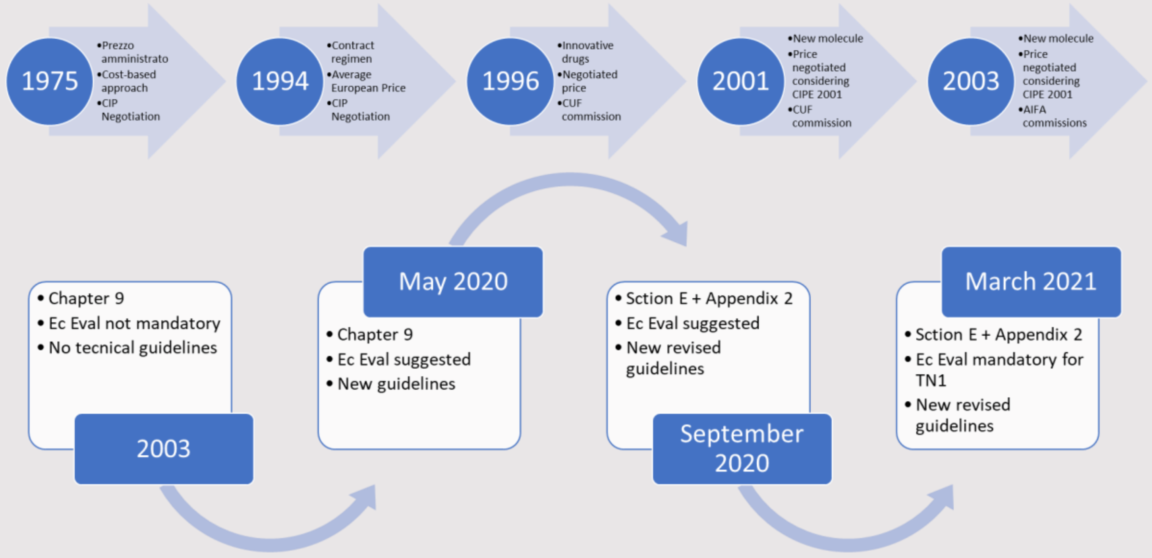
OBJECTIVES: The present work aims to discuss the role of the economic evaluation in the new guidelines for pricing and reimbursement (P&R) of medicines adopted by the Italian Medicines Agency (AIFA) in March 2021.

METHODS:

A multidisciplinary scientific group were enrolled from Academia (2 researchers), Regulatory Agency (1 expert from AIFA), Regional Entities (2 pharmacists), Pharma Companies (2 access managers) and Healthcare Consultancy Firms (2 access leads). A systematic review of the literature was conducted in order to collect the main documents available in Europe about the role of economic evaluations in the P&R process. All the records were analysed in qualitative terms according to a pre-specified analytical framework. At the end of the analysis, a consensus questionnaire was developed to establish agreed approaches and possible solutions to any critical issues.

The questions were divided into 7 sections:

Figure 1. Economic Evaluation background in the P/R process in Italy



RESULTS:

A common analysis framework was applied to all countries, and the results were narratively summarized and presented in evidence tables. The main document was structure in 5 sections: 1) Review of the European and UK guidelines on the use of Economic Evaluation in the P&R process, 2) History of the role of Economic Evaluation in P & R in Italy (Figure 1), 3) comparison of the EU/UK with the new Italian guidelines, 4) Results of the public consultation of the Italian guidelines (Table 1) and ISPOR Italy Rome Chapter consensus and recommendations.

The consensus process allowed to collect many experts' opinions on the main issues relating to P&R approaches. All affiliated members of ISPOR Italy Rome chapter will complete the consensus questionnaire during Q4 2021.

Table 1. Summary of the main comments received from AIFA during the evaluation period

	Perspective	Population	Comparators	Time horizon	Discount rate	Model description	Model input	Transition probabilities	Efficacy data and extrapolation	Utility values	Cost parameters	Model output	Model validation	Sensitivity analysis	Results
Association															
AFI															
AIM															
AISM											tipologie costi				
APMARR															
ASSOBIOTEC					Stabilire un range										
ASSOGENERICI			Specifiche bios/gener												
Fondazione GIANNI BENZI															
FARMINDUSTRIA			Dare priorità allo SoC		range										
Scientific society and association															
ISPOR Italy Rome Chapter			Dare priorità allo SoC		Riduzione					tariffe locali per QoL					Fissare soglie WTP
OSSFOR	prospettiva sociale		Specificare lo SoC						costi indiretti						
SIARV															
SIF			Dare priorità allo SoC												
SIFEIT	prospettiva sociale														
SITHA															
Pharmaceutical companies															
GMM FARMA S.r.l.															
MERCK SERONO															
ROCHE			SoC secondo LG di Rif												
University research group															
ALTEMS															
CERGAS	Importanza prospettiva sociale		Richiesti maggiori dettagli			Aggiornamento dei Software	Modifiche minori	Specifica di half-cicle	Richiesti maggiori dettagli					Maggiore rilevanza a PSA	
Consultatn society															
MA Provider															
Pharma Value															
Researchers															
Dr. Carlo Lazzaro	Importanza prospettiva sociale			Aumentare		Specifica di half-cicle	Modifiche minori	Richiesti maggiori dettagli			Modifiche minori			Maggiore rilevanza a PSA	
Prof. Stefano Capri						Specifica di half-cicle							Modifiche minori		

CONCLUSION: The new AIFA guidelines provide an opportunity to improve the use of economic evaluations. Comparison with the guidelines used in other European countries demonstrates the importance of a standardised and transparent approach to economic analysis in healthcare for improving transparency of the economic modelling approach during the P&R process.