Tumori, 97: 442-448, 2011

Disparity in the "time to patient access" to new anti-cancer drugs in Italian regions. Results of a survey conducted by the Italian Society of Medical Oncology (AIOM)

Stefania Gori[1], Massimo Di Maio[2], Carmine Pinto[3], Oscar Alabiso[4], Editta Baldini[5], Enrico Barbato[6], Giordano Domenico Beretta[7], Stefano Bravi[8], Orazio Caffo[9], Luciano Canobbio[10], Francesco Carrozza[11], Saverio Cinieri[12], Giorgio Cruciani[13], Angelo Dinota[14], Vittorio Gebbia[15], Lucio Giustini[16], Claudio Graiff[17], Annamaria Molino[18], Antonio Muggiano[19], Giuliano Pandoli[20], Fabio Puglisi[21], Pierosandro Tagliaferri[22], Silverio Tomao[23], and Marco Venturini[24] on behalf of AIOM Working Group "Interaction with Regional Sections" (2009-2011)

[1]Medical Oncology, "SM della Misericordia" Hospital, Azienda Ospedaliera, Perugia; [2]Clinical Trials Unit, National Cancer Institute, "G Pascale" Foundation, Napoli; [3]Medical Oncology Unit, "S Orsola-Malpighi" Hospital, Bologna; [4]Azienda Ospedaliero-Universitaria "Maggiore della Carità", Università degli Studi del Piemonte Orientale "A Avogadro", Novara; [5]Medical Oncology, "Campo di Marte" Hospital, Lucca; [6]Ospedale "SG Moscati", ASL CE, UOSD, Oncologia, Aversa (CE); [7]Medical Oncology, Istituto Clinico Humanitas Gavazzeni, Bergamo; [8]UO di Oncologia, Asl 1, Città di Castello (Perugia); [9]Medical Oncology Department, "S Chiara" Hospital, Trento; [10]Medical Oncology, PA Micone Hospital, ASL3 Genovese, Genova Sestri P; [11]Medical Oncology, "A Cardarelli" Hospital, Campobasso; [12]Medical Oncology & Breast Unit, PO Senatore Antonio Perrino ASL Brindisi, via Appia, Brindisi, and Medical Department, Istituto Europeo di Oncologia (IRCCS) Milano; [13]Medical Oncology, Umberto I Hospital, Lugo di Romagna (RA); [14]Medical Oncology, Azienda Ospedaliera S Carlo, Potenza; [15]Medical Oncology, La Maddalena, Palermo; [16]Medical Oncology, Zona Territoriale 11 Fermo; [17]Medical Oncology, Central Hospital ASDAA/SABES, Bolzano/Bozen; [18]Oncologia, Ospedale Civile Maggiore, Azienda Ospedaliera Universitaria Integrata, Verona; [19]Oncology Department, "A Businco" Hospital, ASL 8, Cagliari; [20]UO di Oncologia, ASL di Pescara, Pescara; [21]Department of Clinical Oncology, University Hospital, Udine; [22]Medical Oncology Unit, Tommaso Campanella Cancer Center and Magna Graecia University, Catanzaro; [23]Dipartimento di Scienze e Biotecnologie Medico-Chirurgiche, Università degli Studi di Roma "Sapienza"; [24]Medical Oncology, Ospedale Classificato Sacro Cuore Don Calabria, Negrar, Verona, Italy

ABSTRACT

Aims and background. In 2009, the Italian Society of Medical Oncology (AIOM) conducted a survey to describe the impact of regional pharmaceutical formularies on the disparity of access to eight new drugs among cancer patients treated in Italian regions. The survey documented some regional restrictions for some anti-cancer drugs. In the study, we analyzed the "time to patient access" to new anti-cancer drugs in Italian regions.

Methods. In March 2010, we analyzed the availability of 17 new anti-cancer drugs at a regional level, specifically the coherence of regional authorizations compared with national authorizations approved by the Italian Medicines Agency (AIFA). In the regions with pharmaceutical formularies, we analyzed the characteristics of technical-scientific committees for the evaluation of inclusion of hospital drugs in these formularies. We also analyzed the time from EMA (CMPH) authorization to AIFA marketing authorization, the time from AIFA marketing authorization to patient availability, and the total time from EMA (CMPH) authorization to patient availability of the drugs in all Italian regions, for 11 of these drugs.

Results. Some drugs were included in all the regional pharmaceutical formularies, without restrictions, whereas other drugs were not included in one and others were

Key words: anticancer drugs, disparity, time to patient access.

Conflict of interest statement: The authors declare no conflict of interest relevant to this work.

Correspondence to: Dr.ssa Stefania Gori, Oncologia Medica, Ospedale Santa Maria della Misericordia, Azienda Ospedaliera di Perugia, Via Dottori 1, 06122 Perugia, Italy.
Tel +39-075-5784212;
fax +39-075-5279082;
e-mail stefania.gori@tin.it

Received November 5, 2010;
accepted January 17, 2011.

not included in more than one formulary. Median time from EMA to AIFA was 11.2 months (range, 2.9-17.1). Median time from AIFA to patient availability was 1.4 months (range, 0.0-50.5) in regions with drug formularies *versus* 0.0 months in regions without drugs formularies. Median total time from EMA to patient availability was longer in regions with formularies (13.3 months; range, 2.9-65.3) than in regions without formularies (11.2 months; range, 2.9-24.0), where drugs are immediately available after AIFA marketing authorization. Moreover, the interval was very long (range, 2.9-65.3) for some drugs in regions with formularies.

Conclusions. The analysis confirmed that the presence of multiple hierarchical levels of drug evaluation can create disparity in drug availability for Italian citizens.