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)

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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

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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.