Comment on: "Disinvestment and Value-Based Purchasing Strategies for Pharmaceuticals: An International Review"

Angelo Claudio Palozzo & Andrea Messori

PharmacoEconomics

ISSN 1170-7690
Volume 34
Number 4

PharmacoEconomics (2016) 34:419-420
DOI 10.1007/s40273-015-0376-6

Springer

PharmacoEconomics (2016) 34:419–420
DOI 10.1007/s40273-015-0376-6

LETTER TO THE EDITOR

Comment on: "Disinvestment and Value-Based Purchasing Strategies for Pharmaceuticals: An International Review"

Angelo Claudio Palozzo[1,3] · **Andrea Messori**[2,3]

Published online: 29 February 2016

In Italy, the reimbursement of medicines is managed by the national health system (NHS), and our national medicines agency (Agenzia Italiana del Farmaco [AIFA]) is responsible for making all reimbursement decisions. Hence, the Italian context (including reimbursement approvals for new treatments and disinvestment of previously reimbursed treatments) is very similar to that of the UK, France, Canada, Australia, and New Zealand. However, Italy has not been taken into consideration in the study by Parkinson et al. [1], which was recently published in *PharmacoEconomics*. In Italy, both passive and active approaches to disinvestment do not substantially differ from those of the above-mentioned countries; however, there are two peculiarities of the Italian scenario that deserve to be mentioned.

First, most innovative drugs employed in Italian hospitals are assigned to nationwide patient-level registries in which clinical indications and outcomes are electronically recorded [2–4]. These registries, which are managed by the AIFA and are part of a mandatory surveillance program, were designed both as the data source for nationwide effectiveness and appropriateness evaluations and as an administrative tool for handling the reimbursement of innovative treatments. For example, in 2014 these registries included a total of 352,872 patients [3] in terms of vital statistic information and physiopathological and outcome data. Evidence is accumulating that the real-world effectiveness, as measured by these registries, tends to be less than that suggested by pivotal clinical trials [5]. This information is the basis for undertaking disinvestment interventions that essentially consist of a reduced payment for agents showing less effectiveness than that initially expected. For example, erlotinib as second-line treatment for lung cancer has recently been demonstrated to be less effective than standard chemotherapy with docetaxel in wild-type epidermal growth factor receptor (EGFR) bearers [6, 7]. Excluding this condition from reimbursement has been proposed, which could save millions of Euros all over Europe. Likewise, bevacizumab has proved to be less effective in recent studies compared with the outcomes observed in pivotal trials [5]. In addition, these registries represent the operative tool whereby treatment failures registered on an individual basis are associated with paybacks from the drug companies to our NHS. In fact, these large databases also have the purpose of managing price–volume agreements and performance-based reimbursement (including capping, cost-sharing, payment-by-results and success fee models, particularly in the field of oncology [2, 4]).

Second, there is a national regulation regarding equivalence between treatments (the so-called Balduzzi Law) that in past years has had quite a profound impact on disinvestment in the field of pharmaceutics [8, 9]. The Balduzzi Law was approved by the Italian Parliament at the end of 2012. Accordingly, local tenders for drugs belonging to the same pharmacological class were no longer allowed within the NHS unless certification is requested and obtained from the AIFA that the agents are therapeutically equivalent. Unfortunately, this regulation proved to

✉ Andrea Messori
andrea.messori.it@gmail.com;
andrea.messori@estar.toscana.it

[1] Veneto Oncology Institute IRCCS, Padua, Italy

[2] HTA Unit, Regional Health Service, Florence, Italy

[3] SIFACT, Italian Society of Clinical Pharmacy and Therapeutics, via Farini 81, 20100 Milan, Italy

be a hurdle to disinvestment interventions in our NHS, mainly because selecting a single drug in a pharmacological class for use in our hospitals became much more problematic than in the past. On the other hand, this law fostered a constructive debate on which criteria could be used for these equivalence certifications, and consequently improved the methodological quality of the decisions made by our NHS in running competitive tenders. In particular, evidence-based methods (including formal demonstrations of equivalence and/or non-inferiority) were recognized to be the most intuitive and rational tool to address this issue. Interestingly enough, most of the analyses accompanying the launch of competitive tenders took the form of a scientific report, and this regulatory requirement was therefore translated into the generation of original scientific findings [8, 9].

In conclusion, the experiences described herein show that Italy has some peculiarities that have improved the accumulation of real-world effectiveness evidence for some innovative agents (particularly in the area of oncology). On the other hand, a more evidence-based approach has been promoted regarding the assumptions of therapeutic equivalence for managing competitive tenders.

Compliance with Ethical Standards

Conflicts of interest Angelo Claudio Palozzo and Andrea Messori declare that they have no conflict of interest that are directly relevant to the content of this letter.

Funding No funding was received for the preparation of this letter.

References

1. Parkinson B, Sermet C, Clement F, Crausaz S, Godman B, Garner S, et al. Disinvestment and value-based purchasing strategies for pharmaceuticals: an international review. Pharmacoeconomics. 2015;33(9):905–24.
2. Palozzo AC. New drugs—how much are they worth? the Italian registries: a model to evaluate appropriateness and effectiveness. Eur J Hosp Pharm. 2012;19:398–403.
3. Rapporto Osmed 2014 (annual nationwide report). http://www.agenziafarmaco.gov.it/it/content/rapporti-osmed-luso-dei-farmaci-italia. Accessed 8 Jan 2016
4. Messori A, De Rosa M, Pani L. Alternative pricing strategies for cancer drugs. JAMA. 2015;313(8):857.
5. Messori A, De Rosa M, Fadda V, Pani L. Effectiveness and cost effectiveness of bevacizumab in metastatic colorectal cancer. J Clin Oncol. 2015;33(32):3838–9.
6. Trojniak MP, Jirillo A. Does chemotherapy have a role after erlotinib treatment in NSCLC? Lung Cancer. 2012;75(1):136.
7. Garassino MC, Martelli O, Broggini M, et al. Erlotinib versus docetaxel as second-line treatment of patients with advanced non-small-cell lung cancer and wild-type EGFR tumours (TAILOR): a randomised controlled trial. Lancet Oncol. 2013;14(10):981–8.
8. Messori A, Fadda V, Maratea D, Trippoli S. The Italian way to evidence-based demonstration of equivalence as a prerequisite for conducting procurement tendering within the NHS. 1 July 2014. http://www.bmj.com/content/347/bmj.f4951/rr/759376. Accessed 8 Jan 2016
9. Messori A, Trippoli S, Fadda V, Maratea D. Producing evidence in support of disinvestment: the experience of the Tuscany region in Italy. Eur J Intern Med. doi:10.1016/j.ejim.2015.10.021 **(Epub 9 Nov 2015)**.