PMU57: Analysis of the evolution in the access to medicines in Italy in the last 5 years (2014-2018)

Authors: Prada M, Candolera L, Mantovani M
Intexo, Rome, Italy, MEDAVANCE Italy, Milan, Italy

Introduction

In Italy the price setting of medicines reimbursed by the NHS is regulated at the central level by the Italian Medicines Agency (AIFA). The Agency provides, with its scientific authority and autonomy, the clinical, scientific, and economic evaluation of medicines. AIFA’s activities are supported by two commissions consisting of well-established experts: the CTS (Technical Scientific Commission), which assesses the national marketing authorisation applications, delivers a consultative opinion on them, and provides a classification for reimbursement; and the CPR (Pricing and Reimbursement Committee), which carries out negotiations with pharmaceutical companies for setting prices of medicinal products considered for the reimbursement by the NHS according to transparent methods, timelines, and procedures established by the resolution of the Interministerial Committee for Economic Planning (Comitato Interministeriale per la Programmazione Economica – CPR) of February 1, 2001.

For a non-onor drug, companies are allowed to submit a Price and Reimbursement Dossier for the AIFA CTS and CPR evaluation after the European Commission Decision on its marketing authorisation. In the case of an orphan drug, the dossier related by the company could be submitted immediately after a positive opinion of the CHMP (Committee for Medicinal Products for Human Use) of the EMA.

After the dossier submission, the AIFA CTS issues a binding opinion on the therapeutic value of the drug, defining its place in therapy, its delivery regime, and its possible innovative status. The AIFA CPR assesses the economic part, evaluating: cost-effectiveness ratio compared with other available treatments, the lowest price of the medicine in all other EU Member States, price of similar products within the same pharmacotherapeutic group, market share, and the expected impact on NHS expenditure for the next three years, economic models (e.g., BIM). If there is no agreement on the price between CPR and the applicant, the medicine is classified as not-reimbursable and listed in Class C.

Objective

This study aims to assess the changing dynamics of the Italian market access (negotiation conditions, time to reimbursement (TTR)) pathway for all the new active substances recommended for authorization by the EMA between January 2014 and December 2018.

Methods

We reviewed the EMA’s Human Medicines annual Highlights referred to the last 5 years (2014-2018) in order to build our panel, by selecting all the new molecular entities approved by the EMA between January 2014 and December 2018. We then collected all the information about authorization and reimbursement in Italy, throughout the AIFA’s websites and the Italian Official Journal (DOI). The received data were carefully analysed in order to evaluate TTR for different drug categories (negotiation conditions, DO/non-DO, Innovation status, publication year on DOI).

Results

Between January 2014 and December 2018, 432 drugs, of which 184 represented new active substances, were recommended for the authorization by the EMA.

In September 2015, 109 drugs (59%) out of these 184 obtained the reimbursement in Italy, with a medium TTR (i.e. days between CHMP positive opinion and P&R publication) of 15 months (446 days, median 516, range 97-1,260). Out of these 109 drugs 36/62 (58%) orphan drugs (ODs) and 73/122 (60%) non-ODs achieved a reimbursement. Median TTR for ODs was slightly shorter (5%) than for non-ODs (428 vs. 452 days, mean 495 vs. 526, ranges 122-995 vs. 97-1,260, respectively).

Medium TTR for drugs reimbursed through the MEA (383 days, mean 419, range 19-994) was shorter than for drugs reimbursed through other negotiation conditions (461 days, mean 541, range 204-1,260) and for drugs reimbursed without specific conditions (475 days, mean 528, range 160-1,128). In particular, reimbursement through the MEA reduced TTR by 17% compared to those reimbursed through other negotiation conditions and by 19% compared to drugs reimbursed without specific conditions.

Conclusions

This analysis allows to observe trends and dynamics in the access to new active substances in Italy in a consistent timeframe. Even if our results don’t show a clear time trend in reduction or increase of time to reimbursement, they clearly show that the adoption of the MEA, helping to manage possible uncertainties, leads to a quicker completion of the negotiation procedure. Likewise, the innovation status granted by the AIFA CTS allows drugs to be made available in a shorter time than non-innovative drugs (mainly when a “full” instead of a “conditional” innovation status is recognized). Despite the increasing interest in MEAs, in the last months hidden discounts seem to be preferred to those - more sophisticated - regulatory tools. This may depend on the complexity of their management. It will be extremely interesting to observe the future development of the performance based schemes, which role will be essential in granting access to the new coming innovative medicinal products. Unexactly, the drug’s orphan status does not seem to have a significant impact on the time to reimbursement, even if the Italian regulation allows P&R Dossier to be submitted immediately after the CHMP positive opinion (instead of waiting for the European Commission Decision, as for the non-orphan drugs).

References

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