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EDITORIAL

Reimbursable drug classes and ceilings in Italy: why not only one?

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Introduction

Since the beginning of the second millennium, reimbursable drugs have been classified into two classes in Italy: (1) class A, which includes essential drugs and drugs for chronic diseases; and (2) class H, for drugs dispensed only in hospital and thus unavailable in community pharmacies. Starting from 2008, this classification relates closely to pharmaceutical expenditure control since the two classes are capped under different ceilings subject to paybacks in case of overspending.

Trying to interpret class H meaningfully, since there is no technical definition, we might guess that the drugs included should be limited by the hospital setting, typically the routes of administration (e.g. intravenous), which can seldom be delivered in the community, and/or for patient safety reasons during their administration. These criteria should reflect the indications in the European Public Assessment Reports (EPARs) for drugs approved through the centralised procedure [1]. Another overlapping criterion that might help explain which reimbursable drugs are listed in class H is the 'delivery regimen' of drugs, defined by the Italian medicines agency (*AIFA*, *Agenzia Italiana del Farmaco*) as 'the different modality by which drugs can be delivered to the public' [2]. These modalities, revised in 2006 [3] to be harmonised with the European Directive 2001/83 [4], mainly reflect the classification laid down in article 70 of the Directive, envisaging specific restrictions to drug prescription (e.g. drugs subject to non-renewable medical prescription, and/or limited to specialist's prescriptions) and hospital setting.

The two national ceilings on community and hospital pharmaceutical expenses (for classes A and H, respectively), both estimated as proportions of the whole National Health Fund (NHF), are agreed between the central Government and the 20 Italian regions. *AIFA* worked out two different types of payback [5] to cover potential regional deficits. All 'players' in the supply chain (pharmaceutical industry, wholesalers and pharmacies) are accountable for the community budget, mainly on the basis of their fixed proportions on retail prices [6], while only the pharmaceutical industry and regions (roughly '50–50') have to cover overspending for the hospital budget.

Here we analyse, by administration route and delivery regimen, the mix of drugs listed in class H compared to those in class A. Then, we analyse ceilings and expenses for the two classes. Finally, we discuss whether this dual classification still makes sense for drug reimbursement in Italy, and widen the discussion on pharmaceutical reforms for a possible policy agenda.

Analysis

Products in class H are mainly for intravenous (66.1 % of the total) and oral (11.5 %) use (Fig. 1), the majority of the latter being antiinfectives and neoplastics, while drugs in class A are mainly oral (76.2 %) and only a few of them intravenous (2.7 %) forms, as expected. Almost all products in class H (90.7 %) are subject to delivery restrictions, mainly limitations to the hospital setting (77 %). Almost all products (89 %) in class A have no restrictions (i.e., renewable prescriptions), although a negligible proportion

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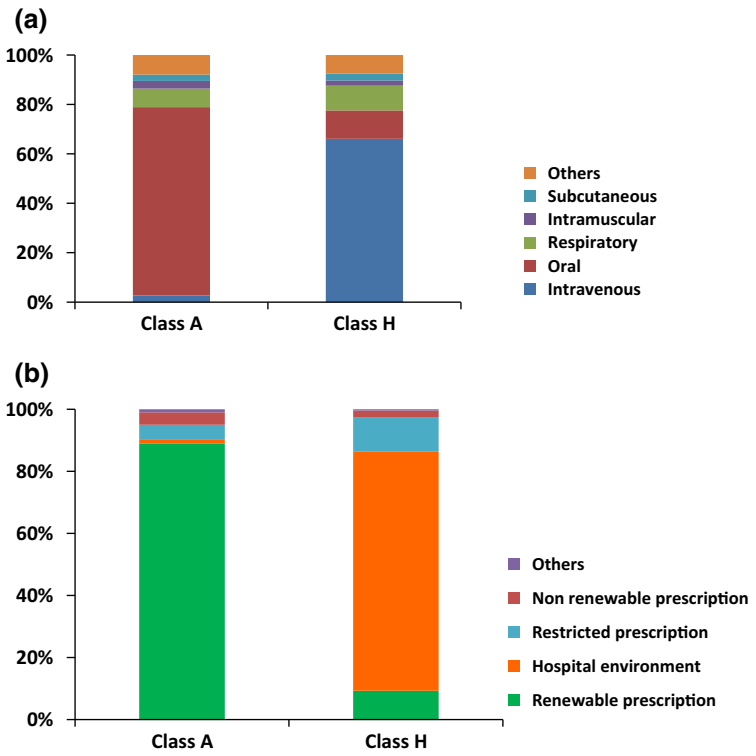

Fig. 1 Reimbursable products in classes A and H by **a** administration route and **b** delivery regimen (2015)

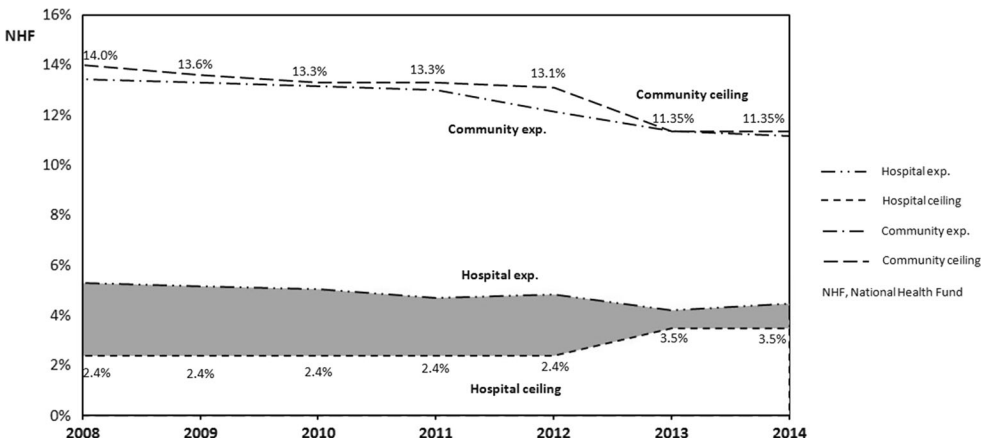

Fig. 2 National community and hospital pharmaceutical expenditure and related ceilings

(1.1 %) are limited to the hospital environment. The average price to the public per package was around nine times higher in class H (€835.79) than class A (€93.67) in 2015.

Figure 2 shows the patterns of national pharmaceutical ceilings and expenditure for the two classes since 2008. The community ceiling (14.0 % of the NHF in 2008) was gradually lowered (11.35 % in 2014). However, the decrease in the last 2 years is due mainly to a change in accounting criteria, since the budget was previously calculated on gross pharmaceutical expenditure including co-payments by patients [7]. In contrast, the hospital ceiling was steady until 2012 (2.4 %), and then rose in the last 2 years (3.5 %). Despite the fact that many regions (especially in Southern Italy) often overspent, the national community budget was always respected as a whole, whereas the hospital budget was largely breached every year in most regions and at national level too, even after the latest increase.

Finally, the Regional Administrative Court of Latium (the region of which Rome is the capital) recently upheld various appeals filed by the whole pharmaceutical supply chain against the two AIFA paybacks [8–10], mainly because of a lack of transparency in calculation methods and uncertainty in expenditure data. Accordingly, it is now hard to assess the real pharmaceutical expenditure and predict what will happen with ceilings and paybacks in the near future.

Policy implications

Unlike other major European countries, where drugs are classified at registration with approval for different settings, Italy has two classes of fully reimbursed drugs: class A for community and class H for hospital care. The criteria for inclusion in class H are not clear-cut, although they probably overlap those for drug prescription limitations set at European approval. This leads to some apparent inconsistencies, such as a few products limited to hospital setting but listed in class A, presumably included in the subset of packages that can be purchased directly by regions and delivered either by hospital or by pharmacies [11], another Italian peculiarity aimed at cost-cutting of the traditional distribution margins (still related to prices charged to the public).

The dual classification of reimbursable drugs is also (if not especially) important for the control of pharmaceutical expenditure, being related to two different ceilings and types of payback. The national trends in the two pharmaceutical expenditures have tended to differ in the last few years, the community budget being under control, and the hospital one out of control. The main reason seems to be related to the continuous shift by health authorities (aimed at cost containment) of prescription patterns from primary care towards medical specialists [12]. This has led to more and more new, sky-high priced products being listed in class H, while expenditure in class A has not risen, mainly due to off-patent drugs and the consequent low-cost generics. As a consequence, deficits have been recorded for the hospital budget every year, despite the recent increase. Moreover, the straightforward payback system on the hospital budget is partly a 'clearing entry' for public pharmaceutical expenditure, since overspending regional authorities have to cover half the deficit.

In the long run, accountancy of pharmaceutical expenses in Italy has become very uncertain—even puzzling—for various reasons. Here we can cite the dual drug delivery system [11] and the so-called 'managed entry agreements' [13] as two further emblematic examples. So it is not surprising that the most important regional administrative court has upheld all appeals raised by the supply chain so far. Pharmaceutical expenditure in Italy has become a 'jigsaw puzzle' and class H is an integral part of the confusion, although not necessarily the most important.

Accordingly, we believe it is high time to simplify pharmaceutical policy in Italy. Here, we put forward a very general proposal, open to debate.

A first step in the right direction would be to eliminate class H and merge all drugs into a single class for reimbursement. A second step would be to reform the distribution margins and convert them into 'fees for service' unrelated to retail prices [6]. This would also make private pharmacists more credible in their role as health professionals providing a public service, besides being shopkeepers in their own interest, which makes this category one of the richest in Italy according to tax declarations. A third step would be to estimate a national budget still on a yearly basis, but according to the historical trend of pharmaceutical expenditure (instead of a NHF proportion) and planned over a short-term perspective (e.g. 3 years). The forecasts should take account of the budget impact induced by the imminent launch of potentially innovative drugs identified thanks to 'horizon scanning' [14]. As a logical fourth step, a payback could be applied only to industry (e.g. proportional to the turnover of each company) in case of overspending the national budget, limited to in-patent drugs delivered through community pharmacies, and possibly agreed with domestic industrial associations. We would highly recommend excluding from payback calculation (1) off-patent drugs under reference price [15], to avoid further penalising low-cost drugs in case of deficit; and (2) drugs purchased directly by local health authorities and hospital trusts, to make their managers more accountable for their own expenses.

To conclude, these changes, as easy as they are radical, should help make it easier to keep pharmaceutical expenditure under control, although major changes are needed to make it sustainable, starting with drug pricing, which could be dealt with better at European level [16]—not only for Italy, of course. We believe it is high time for a more concrete European pharmaceutical policy too.

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