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EDITORIAL

‘Appropriateness’ in Italy: A ‘Magic Word’ in Pharmaceuticals?

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1 Appropriateness in Italy

Appropriateness is the term largely used in Italy in the debate on efficient allocation of health-care services. Various domestic laws mention it, stressing its importance for enhancing the performance of the Italian National Health Service (INHS). The latest finance law even introduced a ‘Commission for the Promotion of Appropriateness in the INHS’, aiming at ‘leading a continuous evaluation of existing and forthcoming health care services and assessing their economic impact’ [1].

Focussing on drug therapies, a recent triennial planning law [2] described various measures to improve prescription appropriateness and control of pharmaceutical expenditure, such as updating the National Medicines Formulary (the Italian positive list) on the basis of efficacy and cost-effectiveness criteria and redefining the rules for patients’ access to reimbursement. During the last few years several regional health authorities approved measures aimed at improving prescription appropriateness [3].

At central level, *AIFA* (*Agenzia Italiana del Farmaco*), the main authority for drugs in Italy, adopted four tools for the appropriateness of drug prescriptions [3]: (1) the so-called ‘*AIFA* notes’, which define the reimbursement regimens for many drugs and encourage physicians to limit prescriptions to the indications with proven efficacy; (2) price caps for single drugs or therapeutic classes within managed entry agreements [4] contracted with pharmaceutical industry; (3) ‘therapeutic plans’, which state the clinical conditions for reimbursement and limit it only to labelled therapeutic indications; (4) ‘monitoring registries’, which track the eligibility of patients and the complete flow of treatments according to approved indications. To measure the appropriate use of medicines, *AIFA* has recently identified a set of indicators focussed on prescription behaviours, consumption of medicines, and compliance to prescribed therapies [3].

Finally, *AIFA* has issued a formal definition of appropriateness, describing it as the ‘adequacy of the actions adopted to manage a disease, concerning both the patient’s needs and the correct use of resources’ [5], a far-reaching definition indeed.

2 Appropriateness in the Literature

With the aim of clarifying the meaning of appropriateness in the context of pharmaceutical prescription and find a justification for its recent mention in the INHS, we conducted an international literature search on the PubMed international database[1] and identified six studies containing a theoretical definition of this term [6–11].

Broadly, these definitions incorporate five key issues: drug safety, efficacy, cost effectiveness, prescription patterns (mis/over/under-prescribing) and patient choices. Drug safety (relating to risk-benefit) was mentioned in five [6–8, 10, 11] of the six studies selected; among these, three

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[1] We used the MeSH terms ‘inappropriate prescribing’ for the search. From the 359 studies published in English on the subject up to December 2015, 353 were discarded, being: (1) reviews focused on specific medicines (182) or prescriptions in older patients and/or polypharmacy (84); (2) studies on methods, evaluation criteria and guidelines (16) or other topics (71).

each included drug efficacy [7, 10, 11] and cost effectiveness [7, 8, 11] as further issues, and only two each considered prescription patterns [8, 10] and patients' choices [7, 11]. The remaining study [9] mentioned only prescription patterns.

Kaufmann et al. [7] and Lexchin (the most dated among the studies reviewed) [11] considered all the key issues except prescription patterns, underlining the importance of maximizing efficacy and minimizing risks and costs while still respecting patients' preferences. O'Connor et al. [8] and Gallagher et al. [10] attributed inappropriate prescribing mainly to safety and prescription patterns; the latter pointed out the role of efficacy too, while the former added the issue of cost-effectiveness. The remaining two studies included only one of the five key issues. Dimitrow et al. [9] focused fully on prescription patterns and deemed pharmacotherapy inappropriate if not consistent with medical evidence; Santos et al. [6] based their definition of inappropriate prescription only on the drug risk-benefit profile, thus referring to safety.

To complete the historical picture, in a WHO workshop report [12] issued 15 years ago and focussed on the evidence of appropriate and inappropriate services, appropriateness was described as a 'complex and fuzzy issue' for defining effective and efficient health care, including ethical values and patient priorities. In practice, the concept of appropriate prescribing has most recently often been more associated with prescription patterns in the elderly, because of their higher prevalence of illnesses and poly-pharmacy [13, 14].

3 Policy Implications

Our literature search suggests that appropriateness still lacks a fully shared international theoretical definition. Since the first publication that defined it was published at the end of the second millennium [11], the notion of appropriateness does not seem to have evolved so much at the beginning of the third as to justify the recent (ab)use of this term in the INHS, particularly in pharmaceuticals. At best, appropriateness can be interpreted as a practical application to prescription patterns of the evidence on a specific drug stemming from health-technology assessment [15], a multidisciplinary approach in which *AIFA* has produced very scant evidence so far despite claims of intensive activity on its website [16].

We might therefore speculate that the frequent mention of prescription appropriateness has become politically fashionable in Italy to pass many piecemeal measures that make Italian pharmaceutical policy simply increasingly puzzling, instead of tackling the most important unresolved issues through political reforms. Here it is worth mentioning at least one major issue that remains in the INHS despite recent attempts of reforms [17], which undermines the containment of public pharmaceutical expenditure in primary care and concerns its major 'player', i.e. the general practitioner (GP). Italian GPs are still self-employed physicians (mainly paid on a capitation basis) who have historically worked single-handed and are still somewhat isolated within the INHS. Although some experience has encouraged group practices, patients are still registered with one doctor and this *ad personam* system is a major hurdle to working in groups. Moreover, the aging professional workforce (around half the Italian GPs are over 55 years old) is becoming a further barrier to cultural change, making any general effort to enhance rational prescribing in general practice hard to push through.

This chronic weakness has probably induced health authorities to shift pharmaceutical expenditure controls on very expensive new drugs towards medical specialists, specifically the hospital setting, in order to constrain potential over-prescribing by GPs. However, this policy has implied a huge mass of administrative data required by the central level to be collected at local level, particularly by specialists. Managed entry agreements and, more extensively, registries and therapeutic plans on single drugs are good examples of burdensome and time-consuming activities, to the detriment of clinical work centred on patients.

Here we wonder whether this burden, closely related to cost containment despite claims about contributions to scientific evidence [18], could not be mainly devolved to hospital pharmacists, in line with the concept of prescription appropriateness. Once medical specialists have made their diagnosis and prescribed a drug therapy (if necessary), why not assign to public pharmacists, in respect of the central 'rules of the game' (e.g. *AIFA* notes), the task of selecting the most appropriate drug to improve prescription patterns according to safety, efficacy and cost effectiveness at local level? Then, in a public service such as the INHS, patient preferences (the fifth key issue) could be limited to the choice of the most appropriate route of administration and/or form for reimbursable drugs, an easy issue to sort out together with specialists.

Public pharmacists (around 2500 employees in 2012) [19] currently work on drug cost accounting, warehousing and delivering inside the INHS, all activities for which a scientific degree is not strictly necessary. Improving appropriateness at local level inside the INHS—easier to monitor in terms of performance once assigned to public pharmacists—should also allow them to exploit to the best their pivotal role as health professionals in the pharmaceutical sector, and could potentially generate considerable savings in public pharmaceutical expenditure (e.g. by

selecting the cheapest option among copies of off-patent drugs). This shift could also indirectly help free-up work time for medical specialists, to the advantage of their clinical activity (e.g. helpful for reducing waiting lists, another growing issue in the INHS).

In conclusion, while awaiting the radical reforms still hard to pass in Italy despite the current period of unprecedented crisis, we do believe that any effort is at least worth making to exploit the role of health professionals appropriately inside the INHS.

Compliance with Ethical Standards

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