DRUG VALUE: EVALUATION OF PHARMACEUTICAL INNOVATION TO IMPROVE RESEARCH AND DEVELOPMENT

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Introduction: in the last years the increase in pharmaceutical expenditure supported by National Health Service (NHS) has led the Italian Ministry of Health to realise control measures, one of which is the introduction of the New Pharmaceutical Formulary (PFN). The PNF aim is to identify a reimbursement value in order to save money by trying to minimise the marked price variability among molecules having comparable efficacy and tolerability. Moreover, as it has been reported in PFN ‘for really innovative medicinal products, ..., a premium price system is introduced which is to be verified the subsequent year in order to confirm or modify the negotiated premium price’.

Objective: the study consists of 2 analysis: a) evaluation of innovation grade in a sample of drugs approved under Centralised (CP) or Mutual Recognition (MRP) Procedures and marketed in Italy; b) evaluation of relationship among innovation, reimbursement and price interventions requested by Health Authorities. Materials and Methods: 117 medicinal products approved under CP or MRP (1995-2000) have been analysed. The criteria formulated by CUF/CIPE Commission (1) and the characteristics reported in each drug EPARs (European Public Assessment Reports) have been considered to evaluate drug innovation. The Italian Ministry of Health web site and the PNF have been consulted to assess the reimbursement and price interventions carried out on those drugs resulted innovative by the first analysis. Results: 46 (including 3 orphan drugs) out of 77 examined CP products and 16 out of 40 MRP products are innovative, respectively. Among the total 62 innovative products, 16% is not reimbursed by NHS and 44% is for Hospital use only. The premium price appears not to be granted to drugs identified as innovative. In addition, 4 products have to reduce their price according to the cut-off fixed by the New Formulary.

Conclusion: a) the number of innovative drugs authorised under CP is significantly higher than in MRP; b) no relationship between innovation grade and price definition has been found; c) research and development of such drugs risk to be not well remunerated.