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Agenzia Italiana del Farmaco

AIFA

# UFFICIO STAMPA

## Direttore generale Prof. Guido Rasi al 15° meeting annuale "International Society for Pharmacoeconomics and Outcomes Research"

Il Direttore generale dell'Agenzia Italiana del Farmaco Prof. Guido Rasi è intervenuto oggi ad Atlanta al simposio "Finding common requirements and endpoints for licensing and reimbursement agencies" organizzato dall'ISPOR.
Di seguito un abstract del suo intervento:

"An ageing population with growing needs for chronic care and the introduction of new technologies (in the period 2009-2013 over 50 new cancer medicines will be submitted for approval and presented to reimbursement committees seeking market access) have consistently contributed to the increase of pharmaceutical expenditure.

This rise in pharmaceutical expenditure is challenging health care budgets and patient access to new medicines, especially the most expensive and those with a limited benefit. As a result, payers in both the US and Europe are not only making efforts to control pharmaceutical expenditure through price and/or price and utilisation control by means of formularies, but are also starting to consider denying coverage of an increasing number of new medicines or other rationing measures.

As a political response to the growth in pharmaceutical and health care expenditure, the US Administration has established a federal council to coordinate and support Comparative Effectiveness Research. The European Commission has also agreed to fund a European-wide project on HTA and relative effectiveness of drugs. Both these initiatives are aimed at learning how to spend in a "smarter" way, make the best use of limited available resources and optimise the value of health care expenditure.

This global need for further data on comparative effectiveness further burdens the current clinical development process, which at any rate requires a larger number of patients to be studied over longer times of observation than in the past, resulting in a substantial increase in

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R&D costs. Paradoxically, the high volume of data generated by this costly R&D process is proving more and more frequently not to satisfy information needs of reimbursement agencies.

Thus, rising health care costs, rising R&D costs and political decisions on funding comparative effectiveness research bring up new questions to be addressed together by licensing authorities, reimbursement agencies and industry in order to promote innovation and assure access to high quality care.

Licensing of new medicines is a well established process with its own legislation, procedures and standards publicly defined in EMA and FDA documents and, at a global level, in ICH guidelines. Licensing agencies are traditionally devoted to assess safety, quality and efficacy of new medicines using the results of RCTs, often comparing the new medicine with a placebo.
Pricing and reimbursement (COVERAGE) procedures are not harmonised between the US and Europe or between the single countries or States within the US and Europe as they relate to the different local health care systems.
Reimbursement agencies base their decisions on the efficacy and safety data resulting from pre-marketing clinical trials but also need information on effectiveness, comparative effectiveness, comparative costs, cost-effectiveness, health outcome and societal impact. The absence of well defined and agreed criteria and endpoints, and a shortage of comparative data are an obstacle to the evaluation for coverage decisions.

Thus, in a life cycle perspective, there is an evident need to reduce the so called “firewall” between licensing and reimbursement agencies and to bring current European and US comparative effectiveness assessment practices closer.

This might be achieved by:
1) better coordinating existing initiatives
2) learning from each other’s best practice
3) clearly defining the different perspectives and data requirements making decisions more predictable
4) finding ways to include through scientific advice common data models in the R&D process, which are useful in pricing and reimbursement decisions as well
5) stimulating an early dialogue between industry, regulators and payers
6) reflecting on future developments such as the impact of personalised medicine on the definition of target populations.”