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The story of innovation in healthcare may be told in many ways. A scientist will describe innovation as a triumphal march towards the emancipation of men from illness: a series of breakthrough discoveries and small incremental improvements, inevitably leading to better life and health conditions for the population. An expert in management of the healthcare system, such as Prof. Jommi, knows that managing public healthcare in practical terms means to face difficulties that a pure scientific mentality might just not get. The introduction of a new drug, of a new diagnostic-therapeutic path, or even just of an advanced-technology version of an already marketed device can lead to the definition of a new healthcare treatment or, more simply, of an enhanced quality standard of an existing one. From the point of view of the National Healthcare Service, the enlarged scope of healthcare assistance and the improvement of its quality will entail an increase in costs, if access to care is to be made available to every citizen. In a time when the concern for the sustainability of public finance tends to overshadow the concern for the safeguard of universality of welfare programmes, innovation in healthcare might turn from a friend of health, in the sense of the human condition defined as freedom from suffering, into an enemy of health, in the sense of an individual right to care. Can public healthcare address this paradox? Or must we accept the notion that public healthcare granted to every citizen and funded through taxation is the legacy of an unrepeatable time? Jommi calls for a change of mentality: raising the awareness of decision-makers at every level of Government and making them responsible for an efficient and sustainable allocation of (scarce) resources in the long run, instead of binding them to an annual spending containment target. We found his remarks on across-the-board cuts illuminating: it is not just a matter of non-selective spending cuts, operated on the basis of an a-posteriori budget control. Above all, those cuts stem from a way of conceiving and managing each single intermediate input in healthcare and social assistance (drugs, hospital/ambulatory treatments, assistance to non self-sufficient people) as a single category for budget control, without taking into account the virtuous interrelations that access to innovative care may generate among different components of public spending. Let us take the easiest example: the admission to reimbursability of an innovative drug may make it harder for the NHS to stay within the budget for the provision of pharmaceuticals, but in the medium-long run that treatment, should it prove effective, will perhaps mitigate the expenditure for hospital treatments, for social assistance to non self-sufficient people as well as invisible costs, like the time and energy spent by the patient's relatives to take care of him. In addition, let us not forget that spending more, and more wisely, to encourage technology transfer from basic science research to industrial application means to stimulate both scientific research and industrial development. To sum up: healthcare spending means investing in our future, not just bearing a cost. We should never forget that.

Mariella Palazzolo

Telos is a member of the FIPRA network

JOMMI

MANAGING HEALTHCARE SPENDING IN THE AGE OF AUSTERITY: BETTER VALUE FOR MONEY IS WHAT WE NEED.

> *"Healthcare planning should acknowledge that different types of intermediate inputs within the healthcare service (e.g. drugs and hospital services) and within public spending more generally (e.g. healthcare and social assistance) are related to each other: this could lead to an efficient allocation of resources"*

Telos: Contrasting the decline of the manufacturing sector is widely felt as a priority. Biomedical and pharmaceutical research might be one of the pillars of an innovation-driven growth pattern. What are in your view the most effective incentives for research and development at the national level? To what extent does the localisation of investments respond to the efficiency of the institutional framework (certainty and stability of the rules, synergies between Universities and the industry), to the reimbursement price of pharmaceuticals or to other aspects?

Claudio Jommi: It is important to make a clear distinction between research and pre-clinical development on one side, and clinical development on the other side. Tax incentives and subsidies are very important tools to encourage research and pre-clinical development, as is any initiative stimulating technology transfer, facilitating the relations between Universities/other research centres and the industry, improving a transparent and merit-driven allocation of funds for public research. As regards clinical development, crucial factors to attract investments include streamlining the process of approving trials, standardising contracts, developing advanced systems for the planning and management of studies within local healthcare units. Indeed, the post-marketing phase may influence the localisation of clinical investments, but it only has an indirect impact, which is more related to a general assessment of our country's attractiveness.

The sovereign debt crisis in the Eurozone has led several Member States to adopt non-selective cuts to social spending. In Italy, the crisis strengthened a pre-existing tendency to a reduction of the financial resources allocated to the National Healthcare Service, including the budget for pharmaceutical spending. Are there any feasible alternative options to this strategy? Could an increase in funding for innovative treatments generate, in the medium run, a structural reduction of the healthcare spending, thanks to an enhanced prescribing appropriateness and reduced hospitalisation rates?

Unfortunately, across-the-board cuts stemming from *a posteriori* controls and the Budget Silo mentality (*i.e. the policy of categorising spending by type of intermediate input, e.g. drugs, hospital services etc. for budgetary control purposes)* according to which healthcare spending is planned entail the only benefit of allowing short-term cost control, which is precisely the goal that the public decision-makers are made sensitive to. There are several examples of technologies, clinical

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Jommi was born in Milan and he is 48 years old.

procedures and also social services which entail higher costs in the short run and decreased need for treatments in the medium-long run, even though the relevant savings can hardly balance the higher costs already borne. The final outcome is an overall increase in costs, combined with enhanced benefits for patients and for the population as a whole. Healthcare planning should acknowledge that different types of intermediate inputs within the healthcare service (e.g. drugs and hospital services) and within public spending more generally (e.g. healthcare and social assistance) are related to each other: this, coupled with an appropriate use of technologies and a focus on ensuring that incremental costs are consistent with incremental benefits could lead to an efficient allocation of resources.

Regulatory authorities, such as Aifa in Italy, are increasingly challenged by the need to evaluate the therapeutic efficacy of innovative treatments, e.g. personalised medicine, whose incremental costs are very high but whose incremental benefits are difficult to measure. Hence, the urgency of developing Health Technology Assessment models for the evaluation of the therapeutic value-added of new treatments. Have significant steps ahead been taken in Europe and Italy on this front? In your opinion, to what extent are conditional reimbursement schemes effective?

The issue of comparative evaluation between different drugs, as well as between drugs and other technologies addressing the same health problem, is on the agenda of several international decision-makers. On the one hand, the need is felt to harmonise the criteria for evaluation (e.g. the choice of comparators, the role of different efficacy indicators, the role of the so-called patient reported outcomes), while on the other hand it would be unconceivable to have the same conditions for admission to reimbursability and the same price level in every Country, given the structural variety in their respective ability to pay. Conditional reimbursement mechanisms (commonly known as risk-sharing agreements or managed market-entry contracts) represent one of the possible options to address the uncertainty about the efficacy of a given product when the latter is launched, by allowing to gather post-marketing evidence: it is essentially a way to launch a product at the price requested by the manufacturer, as an alternative to hidden rebates. Such mechanisms should therefore be encouraged, provided that they do not become too pervading (otherwise they would be unmanageable) and they do not aim primarily to contain the spending.

More than 10 years have passed since the Italian Constitution was reformed to devolve the management of healthcare to the Regions. The case is widely advanced for a rationalisation of competences, reinforcing the central level. In our view, is the regional dimension of the NHS just a source of undue costs and inequalities in the provision of healthcare or is it rather a valuable way of preserving local autonomy?

We are dealing with a very sensitive topic. The pair autonomy/responsibility of the Regions and, above all of the Local Health Units is technically a positive one, since these are the bodies which are closer to both patients and health professionals than any other. The questions we should ask ourselves is whether inequality in access to care was lower before the 2001 reforms or not, and whether access is more equal in other centralised systems or not, in a context where resources are increasingly scarce. The combination of autonomy and responsibility of local levels of Government can generate a virtuous circle, provided that (i) the framework of rules preserving equality in access to care is well defined, where the notion of equality should be interpreted not only horizontally (equal access for equal need) but also vertically (diverse access for diverse need), since it is unfair that access is granted in some Regions in a context of inappropriate use of resources; (ii) the system is managed in a context of transparency and trust among the different levels of the NHS, meaning that, for example, the rationale of the decisions on prices and admission to reimbursability, negotiated at the central level, is made explicit and is sustainable for the Regions. Obviously, this may only happen if the Regions then use the available resources appropriately, if they are made truly responsible for their spending and if an undue proliferation of assessment activities at the local level is avoided.

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