NATIONAL COUNCIL OF ETHICS FOR THE LIFE SCIENCES

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OPINION ON A DECISION MODEL FOR FINANCING THE COST OF MEDICINES

(September 2012)

A. Introduction

The request made by His Excellency the Minister of Health concerns the drafting of an Opinion on the ethical basis for the funding of three groups of drugs, namely retroviral drugs for HIV+ patients, oncologic drugs and biological drugs in patients with rheumatoid arthritis.

The criteria already used by some state hospitals([1]) in the acquisition of some of these drugs were not explained in detail, just the indication of the pharmacological groups involved, whose cost evolution is known (see Annex I[*]) and which represents a high share of the cost of specialised hospital health care.

The request for an Opinion stated clearly that the measures in question fall into the need for sustainability of the National Health Service (NHS) and points out that ensuring access to health care for all citizens is essential.

The CNECV paid particular attention to reflection on this theme in its seminar 'Ethical Grounds in Health Priorities,' held on 29 November 2011 at the Calouste Gulbenkian Foundation, Lisbon (CNECV, 2012).

In this regard, one has to bear in mind that 'the budgetary restriction is clearly established at the level of public expenditure on medicines, by means of the Memorandum of Understanding signed with the European Commission's Tripartite Commission — the European Central Bank — the International Monetary Fund. Given this clear restriction, it is important to know the extent of this requirement. The answer is equally clear – it is a very demanding requirement. It means decreasing by about 1/3 the public spending on medicines compared with October 2010. It is worth looking at the numbers involved with some caution.' (Pita Barros, 2011).

In any case, because there is an ethical dimension in health care rationing that it is important to explain, this rationing – when it occurs – should be made transparent to citizens and health professionals, valuing the resources available as an invaluable social good at the service of solidarity and universality.

Although most of the debate over spending and priorities in health is focused on possible additional costs, there is also the need to, in the context of the NHS, reassess and intervene transparently on replacement, disinvestment, or suspension of the services or interventions currently already funded by the NHS. Notwithstanding the fact that the disinvestment on health costs may occur at any time or in any context, it is more urgent in the context of reduction or scarcity of resources.

([1]) Centro Hospitalar de S. João, EPE; Centro Hospitalar de Póvoa de Varzim/Vila do Conde, EPE; Centro Hospitalar de Entre o Douro e Vouga, EPE; Centro Hospitalar de Trás-os-Montes e Alto Douro, EPE; Centro Hospitalar de Vila Nova de Gaia/Espinho, EPE; Centro Hospitalar do Alto Ave, EPE; Centro Hospitalar do Médio Ave, EPE; Centro Hospitalar do Porto, EPE; Centro Hospitalar do Tâmega e Sousa, EPE; Hospital de Braga; Hospital Santa Maria Maior, EPE; Unidade Local de Saúde do Nordeste, EPE; Unidade Local de Saúde de Matosinhos, EPE; Unidade Local de Saúde do Alto Minho, EPE.

The explanation of priorities in the planning and implementation of health care constitutes a legitimate and necessary procedure in any contemporary health policy (Williams, 2012).

The issue is not on cost containment in itself, always inevitable no matter how large the resources, but on the rational responsibility of choosing priorities and on the effectiveness of the fight against inefficiency and waste in the health area. The point is to move from the current implicit rationing – which, for decades, many have argued as ethically and politically unacceptable (Sulmasy, 1992) and at the mercy of multiple contingencies, sometimes unilateral, from doctors or other hospital decision-makers – to an explicit and transparent choice and rationing, in dialogue with the citizens who must be informed (because nothing replaces democratic participation), so that the patients' trust in the health professionals and the NHS remains untouched and the responsibility of decision-makers is maximized.

For the preparation of the document, the following points were identified as fundamental:

a) Models of justice: the adopted measures (rationalisation of the supply of health technologies, aggregation of the drug acquisition process, selection and dispensing of a limited number of therapeutic agents with the same purpose) seem to constitute a paradigm shift in relation to an egalitarian vision of the principle of justice ('the greatest good for the greatest number'); it is necessary to introduce other assumptions to the previous model that are based on models with consequentialist and utilitarian character. According to Maria do Céu Patrão Neves and Walter Osswald (2007), the various models of justice in the distribution of resources should be considered together in the search for a satisfactory response to various concerns.

b) The technical independence of the prescribers: doctors have the duty to participate, due to the weight of their activity as prescribers, in cost containment ([2]). Integrity, transparency, publicity, consistency and thoroughness are issues that should be the basis of the protocols that justify the cost-effectiveness analyses that sustain the political decisions and that will be the object of analysis in this opinion.

c) The right to the best care: the central role of a National Health Service, with the constitutional characteristics of the Portuguese case, in ensuring universal access and in regulating equity in the distribution of resources, cannot fail to be taken into account. The right of access of all citizens to health care, even though rational and transparent, does not solve by itself, the problem of potential injustices generated by the necessity of rationing. Any cost reduction measure should always ensure the maximisation of efficiency and safety.

([2]) Deontological Code of the Medical Association - Regulation no. 14/2009, *Diário da República*, 2nd series - No. 8 - 13 January 2009 - Article 111 (Accountability).

B. Theoretical Framework

The evolution of prices of medicines, medical interventions and auxiliary diagnostic methods has placed significant challenges, both in terms of potential health gains, and in terms of increasing escalation of costs. Thus, it becomes crucial to involve health professionals and researchers in guidelines for determining priorities (Gibson *et al.*, 2004). This issue, which today in Portugal and in some European countries was aggravated by the crisis, is of great importance. The dimension of this problem, the debate about the costs of medicines and restrictions on prescription, has intensified recently within the health professions and in public debate, making the need to propose a decision model based on the principle of justice even more urgent which, ultimately, will allow to safeguard the dignity of who is treated and who treats.

The problems of the health professional/patient relationship as well as that of the researcher/research subjects were, without doubt, the dominant reflections in the context of medical Ethics. Such problems result primarily from the increase in power and concomitant responsibility inherent to new knowledge and new technologies in the area of the life sciences and in particular in the field of Medicine. The interaction between healthcare provider and patient and between researcher and research subject is a vast field of ethical reflection, not always enlightened by the countless unproductive dissent and media outcry. On the other hand, in recent years, especially with the emergence and recognition of the global financial crisis with still unpredictable consequences, an important reflection on the health of populations and the fair distribution of resources has been promoted.

Currently, these issues, which arise when the sustainability of resources for health begins to be seriously threatened, should encourage an approach which takes into account the fundamental principle of justice in two fundamental aspects: **a)** the correction of inequalities in health between different social groups and the means to reduce expenditure; **b)** the distribution of resources in care throughout the life cycle in the context of a rapidly aging population.

The principle of justice requires the pursuit of equity in health promotion policies and should, in our opinion, serve as a guideline for the definition of these policies. However, before starting this debate on the conditions of health promotion in this specific context, we must necessarily accept that the definition of health proposed by the World Health Organization – health as 'physical, mental and social well-being, and not merely the absence of disease or infirmity' (WHO, 1948) – may not be the most appropriate for our reflection (Feytor Pinto, 2011). The concept of WHO expands, wrongly in our view, the notion of health to include almost all the well-being, preventing the establishment of boundaries and, consequently,

blocking or hindering the possibility of setting limits when these are imperative. In fact, in an environment of economic difficulties, a possible understanding of more egalitarian characteristics on the objective of equity in health is that we should seek that all people are healthy. Thus, pursuing equality means a 'levelling up' — to try to turn all those that are not healthy into healthy people.

These maximisation strategies should, however, be implemented according to criteria of justice or equity. For example, when a specific drug is selected based on a cost-effectiveness analysis, we may be maximising the health benefits of certain group of patients and simultaneously contribute to an unfair distribution of resources in other groups by exhausting the available resources. Thus, this maximisation strategy, with no resources to give the best to all groups, comes into conflict with the concerns for equity.

A cost-effectiveness analysis based on the principle of justice requires the pursuit of equity in health promotion, and, in our opinion, an ethical guideline in the definition of health policies and the implementation of its priorities is of great importance.

Doggedly pursuing the 'best results' — for example, number of years of life after treatment — can deny the opportunity to bring some benefit to those with worse outcomes, i.e. with a lower perspective of lifetime after treatment. How are we to balance the best results in terms of fairness in the distribution of opportunities? How to balance fairly the issue of 'best results' with equity of opportunities? We have, without doubt, to assume that there is no appropriate way to introduce models that give an answer to issues of this sensitivity and that have at their core the dignity of every human being.

Equal access to medical services is not, by itself, a guarantee of equity. We cannot guarantee equity in health simply by equitable distribution of resources, since the inequalities in this sector have more complex origins. About the inequalities, which will be the best assumption? The socioeconomic differences?

In fact, we live in a society that tolerates a significant degree of inequality. Must we consider as unjust the inequalities in health that result from other social inequalities? Or should we consider them as acceptable or justifiable? In Norman Daniels's arguments, listed below, we can, somehow, find factors that should frame this issue:

a) Fully maximising the population's access to health care implies that it is possible to ensure the best levels of health to everyone. By making all people healthy we manage the complete implementation of the principle of equity.

b) There is no social justice without equity in health.

c) There can be no equity in health without social justice. This is a statement that depends above all on our knowledge about the social determinants of health (Marmot, 2010). Thus, only the intersection of these determinants with the perspective of distributing resources fairly can effectively decrease the level of inequalities.

d) Therefore, to achieve the best level of health of the population, making all people healthy, requires making the concept of justice much more comprehensive.

We live in a non-imaginary world, where there may no longer be a place for the theory of John Rawls (Rawls, 1971). The theory developed in the context of an almost utopian society that advocates harmony between rationality and reasonableness does not allow full implementation in any democratic and imperfect society. We must, therefore, reformulate, at the professional, social and political level, Rawls's utopia of 'the greatest good' for the largest number, by a more ethically committed vision of 'the greatest good possible' for the largest number. Thus, the commitment to increase the level of health of the entire population can, at this stage, result in increased ethically unacceptable inequalities in the distribution of existing resources (Mechanic, 2002). In this way, it only becomes ethically permissible to improve the health of the population if this improvement brings improved health to all population groups.

If social justice is important for the health of the population and for its equitable distribution, the policies for equity in health should be cross-sectorial in the scope of their application. On the other hand, the socially controllable factors that affect the distribution of health should also be a concern at the level of equity in health. In this perspective, to defend that one must treat health as a separate 'sphere' – focusing exclusively on the potential health benefits, without weighing the inherent costs – is not suited to current reality.

Given the complexity of the issues described above, Bioethics should provide guideline proposals for a decisions policy involving different forms of negotiation, whenever equity cannot be understood or practised in a maximalist manner.

There are two different perspectives in the context of this Opinion.

The first, purely regulatory, listed below, can function as a possible methodology for finding consensus on the guiding principles of the different policy options, including those resulting from the development of new pharmacological strategies:

1) Promote the ethical reflection about the costs to the NHS in the distribution of drugs; this reflection should take place at an early stage about the drugs in which there are larger differences and should be supported by economic studies based on scientific evidence.

2) Clarify the situations of inequality in terms of access to medicines by different groups of patients in order to help identify those that constitute unacceptable injustices.

3) Define and evaluate processes that can result in the reduction of inequalities in health.

4) Test the implications of 1-3 in the context of the actual policy choices aimed at reducing inequalities, including those involving the use of new drugs.

The second perspective must consider what Bioethics should do when it is not possible to reach consensus or compromise on the principles that would resolve the differences in the above items. When it is impossible to achieve consensus or compromise with regard to the principles of distributive justice, there is no other alternative but to leave the fair and legitimate resolution of moral disagreement to the governmental bodies.

In this way, Norman Daniels developed an approach called 'accountability for reasonableness' ('*A4R – accountability for reasonableness*') (Daniels *et al.*, 2003) ([3]) that has been used and adapted (e.g. Canada, Norway, Sweden, New Zealand and the United Kingdom) to different contexts to evaluate the distribution of health resources. In this context, more points were added to the previous points that, in our opinion, enrich the approach previously presented:

5) Develop and implement models of accountability, allowing people who disagree or who are affected by the decision, to know the criteria used.

How should we think about the criteria for intergenerational equity? The key to thinking this problem may lie in the fact that we all get older – to treat people differently along the life cycle, as is done systematically, creates inequalities (Williams, 1997). Treating people differently according to their race, social class or sex, creates inequalities which always require detailed justification. However, the structure of society is based on the premise that the contributions that all make throughout their working life will be used in the future, making it possible to enjoy benefits during the retirement phase. It should be noted that this debate cannot be ignored when we deal with the inequalities in health and when we think of a

([3]) This was understood to be the most appropriate formula in the context of this Opinion, whilst considering that accountability entails, not only responsibility, but to be available for proper accountability, to respond.

model for minimising them. Thus, a prudential stance in the distribution of health resources during the different stages of the life cycle should be the guide for a fair treatment of the different age groups. Implicit rationing, according to the dominant culture, may be discriminatory in a particular institution or social context, if based on facts like age, social class or gender (Coast and Donovan, 1996), at the whim of the variability of physicians or hospital decision-makers, perpetuating the exclusion of marginalised groups.

Thus, we include one more point which should be the object of ethical scrutiny:

6) Carefully analyse the issues of distributive justice relating to different age groups, including: **a)** the impact of new drugs on the distribution of resources throughout life; **b)** the evaluation of the permissibility of rationing by age; **c)** the evaluation of care available to treat those who are in the final phase of life and in terminal phase.

The above allows us to clarify the importance of the issue of distributive justice in health and the need to give a thorough, prudent and ambitious response. The first challenge is, without any doubt, training. Many of the issues raised by us should be included in the training contents of different health professionals, enabling them to make fairer decisions and therefore ethically and deontologically more sustainable. Similarly, the global knowledge of citizens should be deepened. The second challenge is political. It is necessary to emphasise and understand how the large inequalities in the distribution of other goods affect health inequalities. It is not ethically legitimate to solve only the problem of distributive justice in health care, disregarding other determinants of health (Marmot, 2010) where this justice, understood as equity, does not exist (education, food, housing, transportation, access to culture …).

C. A decision model for financing the cost of medicines in hospitals

As a basis for the construction of a fair and acceptable decision-making model on the use of medicines we shall use an adapted version of the 'accountability for reasonableness' model (Mitton *et al.*, 2006).

In the current absence of a nationally known tool that includes the ethical dimension of this problem, we suggest a project for the development of a decision/resolution model within the context of the Portuguese

system. The decision model on pharmaceutical products for public financing will be organised by modules. While a model, it works as a pilot; it may undergo changes over time and allow it to be, in the future, developed and adapted to justify wider application and promote its improvement.

C.1. Methodology

C.1.1. Assumptions

This model was designed to be used in a context of budgetary restrictions, which is a reality in the NHS, and is intended to aid the daily decisions about mandatory restrictions in the face of this new reality.

The use of this model should be based on formal economic evaluation methods that allow for a more comprehensive and informed approach to the costs. However, as many of these studies are non-existent in Portugal, and performing them would require time and money that we do not have, in this model the different participants may initially have to, in some cases, resort to the analyses made in other countries trying to adapt them, always with some bias, to the national context.

C.1.2. Model design

The design of the model was based on work carried out in the context of the Canadian health system ('6-STEPPPs') (*Browman et al.*, 2008) and the Australian one *(Gallego et al.*, 2007) and its theoretical framework based on the works of Norman Daniels (2003) through the use of the A4R principles or 'accountability for reasonableness': **'publicity**' (i.e. transparency of the process and the decisions); '**reasons'** (i.e. the logical decision, which could be called the validity of the content); '**appeal'** (i.e. opportunity for decisions to be always under review); and '**imposition'** (i.e. a mechanism to ensure all other conditions). This model adds, just as the Canadian, to this range of four principles that of '**consistency**', ensuring that in decisions taken at different times similar analysis mechanisms are used, and '**efficiency**', ensuring that decisions are timely.

The principles called A4R are designed to give legitimacy to the financing of the implementation of the decisions made in a context of scare resources, so as to give the best to the largest number possible. However, it is important to stress that this model is ethically flawed from the outset, since it is not possible to give the best to everyone, thus making it imperative that the setting of priorities should be analysed fairly, making it possible to allocate resources to the largest number of people.

The section that follows describes a possible decision tool built from a systematic review of different decision-making models (Vuorenkoski *et al.*, 2008; Zdybal, 2011*)*. The model is schematically shown in the table reproduced below.

The proposed model consists of a series of modules that represent, in essence, a proposal for a decision-making process involving three sequential phases with three distinct components: clinical evaluation phase, clinical and administrative evaluation phase and the policy decision phase. These moments should occur sequentially, with very clear information processes in the transition between them. The clinical evaluation phase should involve doctors, other relevant health professionals, researchers from the more relevant scientific area and pharmacy and therapeutic hospital committees, who must work in network and share the respective decisions. Given the country's current situation, this phase should review the rules of the Directorate-General of Health (http://www.dgs.pt/) presented as Standards for Clinical Guidelines and propose a list of drugs indicated for one or more pathologies, always with the premise that this list be reviewed in accordance with the progress at the level of state-of-the-art, whose effectiveness should be based on bioactivity and bioequivalence studies. Pathologies in which standards do not yet exist, these should be produced, and the criteria and theoretical assumptions introduced that inform this Opinion. The clinical and administrative phase must involve the group in the first phase and now, faced with an analysis of the benefit and therapeutic evidence (which stems from the first phase), meet with hospital administrations. These, in view of the benefit/cost analysis, may or may not change the ordering of drugs to be made available in hospitals for a given pathology.

As a matter of principle, it is important that at this stage patients, with that specific pathology, are involved. Within the context of this work, the policy-making phase is ensured by Ministry officials who, after hearing a number of representatives from the working group of the second phase, will make the final decision. There should be minutes of the decision model which should be published and accessible to all through electronic platforms, allowing transparent involvement of society on such decisions *(Gallego et al.*, 2011).

C.2. Table: Phases of the decision-making process and their different attributes

	1. CLINICAL PHASE	2. CLINICAL AND ADMINISTRATIVE PHASE	3. PUBLIC DECISION PHASE
OBJECTIVE	Evaluate the appropriateness and clinical value of existing drugs for a given pathology.	Financial evaluation and weighting of the clinical value of drugs for their introduction for the treatment of a particular pathology. Cost/benefit analysis of the different drugs competing for funding. Not forgetting the highly debilitating or rare diseases.	To ensure fair process in the evaluation of new drugs. Evaluate political factors and integrate decisions based on the results of the previous phase to enable a fair and equitable decision on public financing of drugs in hospitals.
PROFESSIONALS INVOLVED IN THE DECISION	Doctors, researchers in the life sciences and health of the area, and pharmacy and therapeutics committees in the network. All those involved have to make the corresponding declaration of conflict of interest, clearly and with public access.	Hospital administrations, associations of patients or patients with that specific pathology or family members of patients and representative group of the first phase of the process.	
RESPONSIBILITIES	Provide a critical evaluation of the scientific evidence and relative clinical benefit given the current standards. Analyse the impact on the improvement and monitoring of chronically ill patients and evaluate all available alternatives. Prepare an ordered list of choices of x drugs recommended for treating certain pathologies. This list has to be reviewed with the periodicity required whenever there are state-of-the-art developments of the specific pathology.	Evaluate the cost implications of the list drawn up in the first phase. Develop a cost/benefit analysis, and sort the list according to this analysis. Establish compromise / consensus with representatives of the group of phase 1 of the decision process.	Weigh the relative value for patients, the opportunity costs for the population / society and the financing mechanisms. Make the process transparent and public and the process reports available online.
EXPECTED RESULTS	Valuing and prioritizing indications for use of a particular drug for a given pathology.	Recommendations based on the priorities as regards the inclusion of drugs in the Standard for Clinical Guidelines (SCG) in view of appropriate and sustainable financing conditions.	Final decision concerning priorities in dispensing medicines in hospitals. Always with the provision of review in the face of changes in state-of-the-art.

D. Conclusions

1. The National Council of Ethics for the Life Sciences (CNECV) considers that there is an ethical foundation for the National Health Service to promote measures to contain costs with medicines. Such measures should be based on a model such as the above, in order to ensure the most equitable and balanced distribution of existing resources.

2. The CNECV recommends that, in decisions on cost rationalization, it is clear that the fundamental choices are between 'the cheapest of the best' (drugs of proven effectiveness) and not about 'the best of the cheapest'.

3. The CNECV considers it essential that the Ministry of Health and its services proceed with collegiality and transparency in the decision-making process about rationing costs. In this sense, the principle of accountability for reasonableness implies the involvement of the civil society and health professionals in the decision-making process, and all should make the respective declaration of conflict of interest, to which there is public access.

4. In all protocols or clinical guidelines, the CNECV believes it should remind that, since independence and responsibility in the prescription are inseparable from good clinical practice, the right to exception, stating the full reasons therefore, should be included (such as penalising the unfounded exception).

5. The CNECV considers ethically insufficient to want to resolve only the distributive problems in healthcare while disregarding important determinants of health. The policies for health equity should be cross-sectorial in their application, not restricted only to interventions under the Ministry of Health.

6. The CNECV recommends that, as part of their ethics training, training content on this issue must be introduced in the core curriculum required at pre- and post-graduate level in the health courses, allowing professionals to make fairer and more responsible decisions.

7. The CNECV considers it urgent to identify situations of inequality in access to medicines by different groups of patients, in order to try to prevent ethically unacceptable situations. The processes and situations that might result in the reduction of inequalities in health should be defined and evaluated, and the issues of distributive justice relating to different age groups should also be carefully examined, in particular the impact of new drugs and lifelong care with attention to intergenerational equity.

8. The CNECV recommends that models of accountability of expenditure on health should be developed and applied, allowing in a clear manner for everyone to know the criteria used.

9. The CNECV cannot fail to emphasise that there is also certainly a lot to do to contain costs with drugs of dubious effectiveness, which should be re-evaluated regularly in their effectiveness and expenditure by the State.

10. In drugs subsidised by the NHS, the CNECV considers it urgent to re-evaluate current spending in terms of cost-opportunity and cost-effectiveness, with possible substitutions, disinvestments or suspensions. Indeed, the debate cannot be limited to containment of additional costs, but to make better use of existing resources and to fight waste and inefficiency in Health.

11. The CNECV considers it important to emphasize the reduction of service costs in areas such as interventions and diagnostic tests and therapeutics, if poorly justified and/or unnecessary. These should be the object of careful reflection, with the need to establish ethical models to support decisions.

12. In any case, the CNECV considers it essential to not undermine the trust connection and therapeutic alliance between patients and health professionals.

13. The CNECV recommends that decisions in the area of pharmacy should be based on the decision model for financing the cost of the medicines presented in the table included above in this opinion.

Lisbon, 21 September 2012

The President,

Miguel Oliveira da Silva

It was approved in the plenary meeting of 21 September 2012. Besides the Chairman, the following Counsellors were present:

Ana Sofia Carvalho (rapporteur); Rosalvo Almeida (rapporteur); Carolino Monteiro; Francisco Carvalho Guerra; Isabel Santos; José Germano de Sousa; Lucília Nunes; Maria de Sousa; Michel Renaud; Pedro Nunes.

Hearings

Fontes Ribeiro PhD, Professor of Pharmacology at FMUC (Coimbra Medical School) and INFARMED consultant.

António Vaz Carneiro PhD, Director of the Centre for the Study of Evidence-Based Medicine (CEMBE) of FMUL (Lisbon Medical School).

Dr Francisco Ramos, President of the Lisbon IPO (Portuguese Institute of Oncology).

Dr João Oliveira, Clinical Director of the Lisbon IPO.

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∗ INFARMED data: table of the cost of medicines for three groups of drugs, 2009-2012.