Presidenza del Consiglio dei Ministri

COMITATO NAZIONALE
PER LA BIOETICA

MOTION

FOR AN EQUAL ACCESS POLICY TO INNOVATIVE HIGH EFFICIENCY DRUGS FOR SERIOUS PATHOLOGIES: REDUCED PRICES AND COST CONTAINMENT FOR THE NHS AND CITIZENS[1]

23 February 2017

[1] The National Committee for Bioethics has already dealt with the cost of medicines in other opinions: *Secrecy in drug regulatory system procedures* (2010); *Pharmacological trials in developing countries* (2011); *Orphan drugs for persons affected by rare diseases* (2011); *On the communication of the National Health System to patients on the costs of health services* (2012).

The National Bioethics Committee is deeply concerned about the health of hundreds of thousands of patients in Italy suffering from serious diseases such as hepatitis C and some oncological diseases, despite the fact that new medicines are available to treat them or effectively change their natural history. Many patients do not have access to these drugs because the National Health Service (NHS) is unable to provide them because of their high price. This means that hepatitis C drugs are only dispensed to the sickest patients, while those who are in early-stage disease have to wait for their condition to worsen in order to receive treatment. It is a contradiction both of the ethical principles of medicine, which should always be oriented to the prevention and care of all patients, and of the same aim of cost containment for the NHS, since postponing treatment at the advanced stage of the pathology leads to chronic outcomes and foreseeable additional costs for the NHS in the long term. Discriminating between patients with varying degrees of disease is therefore unacceptable, especially as the disproportion of drug prices in many cases does not derive from research and development costs.

In some countries, especially in those in the low to middle income bracket, generic drug manufacturers have acquired patents through the "*voluntary licensing*" offered by the proprietary industries, or even through the facilities for the poorest countries with extraordinary public health problems as envisaged by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and the subsequent Doha Declaration (2001).

The difficult access to essential and innovative drugs, due to their high price, comes from different and conflicting needs: it is the result of the need to promote innovation and research, although the timescales envisaged by current intellectual property protection are objectively too long[2]. Moreover, this difficult accessibility conflicts with the universal right to health, aspects of public health and the sustainability of the public health system.

The Committee is fully aware of the importance for Italy to avoid isolation from the international context, and that Italian policy must coordinate with EMA (European Medicines Agency), WHO (World Health Organization), MPP (Medicines Patent Pool), WTO (World Trade Organization). However, while acknowledging the necessity of avoiding putting a stop to incentives for pharmaceutical innovation, it reiterates the need to limit the excesses of an exaggerated pursuit of profit in a sector, such as health, which should be governed by the public system in a much more incisive, transparent and fair manner. It is essential to find an

[2] It is on this line that, the conditions that led the Constitutional Court to declare the unconstitutionality of *prohibiting* the patentability of *drugs,* (Sent 20, 1978) were overturned. In Italy, as regards the classification system and therefore the marketing of medicines, it should be considered that the system regulating drug prices results from a stratification of norms which have taken place between 1994 and today.

appropriate price for drugs compared to the costs incurred for research (which is, moreover, often publicly financed or acquired by small biotechnological industries) and for marketing.

The Committee, therefore, believes that the ethical principle of equitable and universal care should prevail over the sometimes disproportionate profits of individual pharmaceutical companies.

The recognition of this ethical principle, which among other things enhances the pharmaceutical company as a producer of a "social good", must enforce the right of patients to have free access to necessary medicines, according to the international clinical indications that define appropriateness of use. The Italian National Health Service, as a universalistic system is not able to sustain for long the conflict between the principle of free access to essential and innovative medicines, and the logic of an exponentially growing pharmaceutical market. This is also in the light of the principle that considers the right to health as recognized, unique in the whole panorama of constitutional rights, in terms of the fundamental right of the individual, as well as being in the interest of the community (Article 32, paragraph 1, of the Italian Constitution, which provides for free care to those who can not afford it).

That is why the protection of private economic initiative and therefore industrial property (patents, etc.) must be balanced with the right to health. It is not just a matter of regulating the market as an institution of social utility, but when what is at stake is a fundamental value, such as health, provision must be made to ensure that the logic of profit does not exclude the most marginalized categories from receiving effective treatment[3].

To address the inequalities mentioned above, and to ensure universal access to treatment and drugs, the Committee feels it is its duty to invite the competent institutions of our country to develop sound healthcare choices aimed at the equitable allocation of resources and to make available, as soon as possible, innovative drugs of proven effectiveness to patients suffering from serious diseases, in compliance with clinical criteria.

It will, therefore, be essential to plan for future innovative models, including public-private partnerships, which can ensure equity and sustainability, while respecting the rights associated with the advances in pharmaceutical innovation. As also recently asserted by the Lancet's

[3] Private economic initiative "may not be conducted in conflict with social usefulness or in a manner that could damage safety, liberty and human dignity" (Art. 41). "Private property is recognized and guaranteed by law, which prescribes the conditions for acquisition, enjoyment and limits in order to ensure its social function" (art. 42). Art. 43 of the Constitution provides: "[a] For purposes of general utility the law can originally reserve or transfer, by means of expropriation and compensation, to the State, to public entities or to workers communities or users, specific enterprises or categories of enterprises, related to essential public services or energy sources or to monopoly situations , which provide an overriding general interest."

Commission on Essential Medicines Policies[4], governments must guide decision-making to a framework of global research and development policies as well as agreements which include new funding mechanisms for research to ensure that essential drugs are developed and available at affordable prices.

It is advised to those in charge of the competent Institutions that access to medicines should be non-sector-specific and have wide-ranging horizons so as to include new highly effective drugs as they are produced and combine innovation and distributive equality in providing citizens with appropriate care.

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The text was drafted by Prof. Lorenzo d'Avack, Silvio Garattini, Carlo Petrini.

The external hearings of Prof. Stefano Vella (Director of the Pharmaceutical Department of ISS) and Prof. Mario Melazzini (Director General of AIFA) were a valuable contribution.

The motion was voted in the plenary session on 23 February 2017 by Professor Salvatore Amato, Luisella Battaglia, Stefano Canestrari, Carlo Casonato, Antonio Da Re, Lorenzo d'Avack, Mario de Curtis, Riccardo Di Segni, Carlo Flamigni, Assuntina Morresi, Andrea Nicolussi, Laura Palazzani, Lucetta Scaraffia, Monica Toraldo di Francia, Grazia Zuffa.

Professor Cinzia Caporale abstained, and has sent a personal remark. Prof. Salvatore Amato has also sent a personal note.

The advisory members Maurizio Benato (FNOMCeO), Anna Teresa Palamara (CSS), Carlo Petrini (ISS) have also acceded.

Carlo Caltagirone, Bruno Dallapiccola, Francesco D'Agostino, Paola Frati, Silvio Garattini, Anna Gensabella, Rodolfo Proietti, Massimo Sargiacomo and the advisory member Dr Carla Bernasconi FNOVI) absent from the plenary session, have since acceded.

A Personal remarks

A personal remark submitted by Prof. Cinzia Caporale.

The undersigned, while fully sharing the concerns expressed in the motion, abstained from voting for the reasons described below.

From Roman law to the legal institutes of today's western world, the foundation of nations' wealth has always been the recognition and

[4] V.J. Wirtz, H.V. Hogerzeil, A.L. Gray, M. Bigdeli, C.P. De Joncheere, M.A. Ewen et al., *Essential Drugs for Universal Health Coverage*, in "Lancet", 2017, 389 (10067), pp. 403-476.

protection of property rights. From land ownership, through the ownership of industrial products to intellectual property, material progress - and not only material progress - has always been marked by the evolution of recognition and protection of *property rights*. If today the stock market value of a single ICT company - which has almost no physical production structure - exceeds the entire Italian stock market capitalization and surpasses that of the aggregate of the largest US oil companies, the reason is that in the capitalist world the added value of production, not only of services but also of goods, is largely composed of the knowledge that is incorporated in the services and goods themselves.

It is no coincidence that the most eminent economic historians regard the *turning point* of establishing the United States as the world's leading economic power as being marked by the emergence, during the last quarter of the nineteenth century, of *patent laws* protecting intellectual property – and in particular industrial patents - in a way that no other legal system of any nation at that time no less developed - such as England, France or Germany - did.

Intellectual property protection is the same condition for economic resources - ultimately the work of millions and billions of people – are allocated to marginally more productive uses, or to uses that most suit the needs of the masses. Intellectual property is the foundation of the capitalist market economy which, as one century ago Ludwig von Mises stated, is mass production for the masses. A difference that can be termed radical in relation to the production of pre-capitalist systems, which finalized production to meet the needs of the elite.

The world of medicine does not and can not be an exception. If we want the invention of new drugs and their distribution to the masses to follow the same virtuous "democratic" path of all other capitalist productions, from cars to computer science, it is necessary that the protection of the intellectual property rights of the drugs themselves - patents - follow exactly the same logic. If, for political reasons, drugs are excluded from this logic, inevitably the flow of economic resources would be diverted from the pharmaceutical sector to other areas of production of goods and services, with catastrophic consequences on biomedical progress. Obviously the same topic extends to all biomedical technologies and their marginal remuneration. Paradoxically, that is, we would obtain the opposite results to those desired.

There are certainly very important ethical reasons and also political reasons for citizen consent in democratic systems, which set the accessibility of new drugs and new biomedical technologies to the totality of the population as a key requirement. The question is exactly the same one that arises for the distribution of wealth produced in a sufficiently fair manner as not to create discrimination that is too strong, and, in any case, contrary to the constitutional principles of almost all democracies, between the *have* and the *have-not*.

But the answer to this need can not and should not be either a limitation of the recognition of intellectual property or the functioning of the market - which is equivalent to the most efficient allocation of production factors. The answer must come from redistributive public policies that, while retaining intellectual property, allow access to drugs resulting from the most innovative research - and therefore, these are necessarily, almost always more expensive - for the entire population.

The solution is therefore not a weakening of market mechanisms, but the implementation of public policies that out of the market realize those principles of equality and equity which are one of the foundations of the explicit or implicit constitutional pact upon which modern democracies are founded.

A personal remark submitted by Prof. Salvatore Amato

"It is known that some topics can not be discussed because of 'special interests'. The most sadly known case is the pharmaceutical patents racket." The rightly-controlled style of a National Committee for Bioethics prevents from clearly writing such sentences. Even if it is an opinion of George Orwell. An opinion of 1945 on freedom of the press[5], formulated by one of the writers who understood better than any other the uncertain horizons of our future.

Prize-winning economist, Joseph E. Stiglitz, has made an impassioned plea to take radical measures to avoid the unjustified increase in the price of drugs. I am referring to the article published in the *New York Times* on January 30, 2015: *Do not Trade Away Our Health*. In 2005, two successful *pamphlets* were published in Italy, such as: Marcia Angell, *The Truth About the Drug Companies. How they deceive us and what to do about it (Random House, 2005)* and Thomas S. Szasz*, Pharmacracy: medicine and politics in America (Praeger, 2001).*

Yet our motion, as it touches a crucial aspect of the right to health, has had to "overcome" two crucial obstacles: protecting intellectual property and respecting the market. On these two issues I would like to say a few words, which certainly could not be contained in the short space of a motion.

The protection of intellectual property is a great achievement of our legal civilization. It guarantees the autonomy and freedom of research and is one of the greatest stimuli to technological developments. In my opinion, it is also a fundamental aspect of a democratic society because it allows" everyone to think and think together", rewarding merit, but at the same time promoting a distribution of the benefits of innovation to society as a

[5] Written in the summer of 1945, but published on the Times Literary Supplement of September 15, 1945, the Italian translation can be read in *Romanzi e racconti,*, Mondadori, Milano 2000, pp. 1451-52.

whole. However, as scholars of bioethics, and more simply as citizens who believe in the egalitarian premise of a democratic society, we can not avoid asking ourselves how far the conversion of intellectual property into industrial property, that is, under monopoly conditions affecting research and precluding access to some fundamental goods, may be as automatic and undisputed as it seems from the current patent discipline. Is it not possible to find a different and fairer balance between the reward for intellectual innovations and the needs of society? It is, for example, what was proposed by the European Group on Ethics in Science and New Technology in the document *Ethics of Synthetic Biology* of 17.01.2009 n. 25.

What about the market? I think it should be stated in very clear terms that in this case, the market and respect for the rules of economy on which our social system is based have nothing to do with it. We have only one seller (the patent company) and one buyer (the State or insurance companies in the USA). The sellers are perfectly aware that the price does not depend, as forseen by market rules, on the patient's spending power, but on the will of the State. A virtual price is constructed, (in the sense that it does not correspond even remotely to the cost of development, production and marketing of the drug), taking advantage of both the "blackmail" constituted from the severity of the disease and the possibilities of expenditure of the welfare system.

Take for example the case of anti-hepatitis C drugs, one of the cases which inspired the motion. If the company were actually to operate on the market, selling directly to patients, it would have had to envisage a far lower price. How many people would have ever been able to pay €80,000, €50,000 or even just €30,000? And, by extension, what profits would the company ever gain at such a price? The "virtual" price is due to exploitation of a dominant position and the security of being able to leverage "non-market" spending capacity. Enterprise gains: unimaginable sums. The State saves, in a way, if we consider the cost of a liver transplant. Only citizens lose out, seeing as their right to health is harmed twice. The first time because such a high price imposes unavoidable restrictions on drug distribution (the problem being the subject of the motion). And a second time because they can not directly arrange to purchase the drug, as would happen if we were actually in a situation governed by market rules.