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Contributions towards an "essential" medicine strategy for Latin America

Apuntes para una estrategia de medicamentos "esenciales" para Latinoamérica

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FRAME OF REFERENCE

The starting point of this reflection about the current problems of medicines in Latin America (and, more generally, in the global health market) is the reappearance in the international literature, which is seen as a reference to a term used nearly forty years ago: "essential."[1,2,3,4,5] As presented in *The Selection of Essential Drugs*, one of the fundamental documents in the history of pharmacology and the medicines policies of the World Health Organization (WHO),[6] the term did not refer to a specific technical-scientific definition for medicines. The list itself of the substances presented as models and examples was no more than an "annex." The descriptive definition of what was "essential" pointed towards a bridge between an epidemiological variable (the need for actions for most of the populations) and a public health variable (economically sustainable accessibility). This scenario, which would later receive a more explicit confirmation in the Alma-Ata Declaration,[7] proposed (provocatively, due to its lucidity) an evaluation for medicines in which the technical criteria for efficacy were legitimated by reference to a category that was defying due to its apparent strangeness: the category of human right and of populations' right to a decent life standard and to access to the goods that allow them to prevent and/or control the life threatening risks that pose diseases and/or their causes.

It is evident that such "old" definitions of medicines, as well as their context of use, coincide with the specific challenges of the present day.

Considering the advancement of knowledge and the availability of tools, there is no doubt that the "world" of medicines is completely different to any other. The lists of essential medicines have been adapted – not without contradictions – to the logic of evidence, especially different in areas as critical as oncology, AIDS control, transplants, and some chronic diseases, such as liver conditions. But, on the other hand, it cannot be forgotten that areas as important as mental and degenerative diseases, especially the age-related ones, have not shown any significant improvement.

The most dramatic and impactful changes have occurred however more clearly within the context and categories of reference for the definition of health care. Despite the report about the social determinants of health[8] and of the solemn proclamation about the sustainable goals

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for the development in the coming years,[9] even the most official and qualified literature testifies a progressive structural marginalization of the frame of reference of essential rights, in favor of policies dominated and regulated by strictly economic and financial indicators.

The "recipes" applied in the 1980s by the International Monetary Fund and the World Bank in their "adjustment strategies" forced low income countries to give up their duties and rights regarding health and education. Present global programs, treaties or agreements are binding to the point of even cancelling national constitutions.[10] What occurs in countries such as Italy, Spain, United Kingdom – not to mention the "didactical" criminal adjustment imposed to Greece by a non-authority such as the "EU troika" – shows the severity of the problem: the countries must "agree" with something which is not avoidable, "compliance" with the rules of free trade. Narratives, debates, and scientific publications adopt a language (and impose it, non-violently, as the new normality) where health is *one* of the many variables which are dependent on the algorithms of a (certainly not-evidence based) economic order. Detailing a few scenarios could be useful to make clear that the above points are facts, not the product of pessimistic judgment.

Inverted paradigms

The first indicator (the oldest) of the changes undergone by health care may have been the disappearance (in the "active" sense of the word, well known in Latin America) from the competence of epidemiology of the real populations. The acronym created in the 1990s, GBD (global burden of diseases), has turned into a ubiquitous presence, almost exclusive to epidemiology and public health, and is one of the leading agents of the big data (macro data or massive data) revolution. Diseases and expenses are measured. It is assumed that the historic, cultural, and economic specificity of the populations, whether they are big or small, rich or poor, at war or not, is a "dependent variable" that, where appropriately adjusted, fits into (descriptive, explicative) models that are useful to make decisions, the specific roots of the problems thus "vanishing." From time to time, some "local" narrations are admitted to "discover" that inequalities not only exist, but also they "do not cause any good," and it is recorded with multivariate analyses that the lack of access to medicine is a problem that concerns not only the market or intellectual property. The "hard" message (compulsory even to be allowed to publish) is that populations and health policies are chapters of economy.[10,11]

Human and peoples' rights are still officially declared as "important and essential," but with the implicit, and therefore perfectly binding, assignment of these qualifications to the sphere of recommendations, directives and "ethical" criteria. These "soft" categories are perfectly efficient and cosmetic as preambles, or conclusions for treaties, but are totally silent on the prevention of accountability for even the most severe violations of the rights to life which could be attributed to socioeconomic agents and/or causes and/or determinants.

Such a deep paradigm change does not leave anything unchanged or protected. Access to medicines – a subject so universally tackled in every level, which does not need specific bibliographic reference – does not produce, in this sense, epidemiological studies or regulatory measures that re-establish a hierarchy of values and enforceable rights between the life of people and economic variables.

The good intentions included in the *Millennium Development Goals* (MDG) and the *Sustainable Development Goals* (SDG) that have the formal support of all the members of the United Nations who, in the meantime, have transformed wars into one of the areas less affected by economic crisis. According to this logic, the destiny of the populations and their access to health is a "variable" without urgent deadlines: 2015... 2030... The living beings that in these flexible times are excluded and die without dignity are non-avoidable adverse effects.

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It is important to use them as data – possibly retrospective, neutral, global and not attributable to precise responsibilities – to assess the outcomes of programs and promises, in terms of successes or failures: the problem of accountability is not relevant to those who rule and make decisions.[12,13,14,15,16,17,18]

HORIZONS: THE CHALLENGES FOR MEDICINES POLICIES

First of all, it is necessary to address a fundamental question: Can/must Latin America and the Caribbean be considered a single regional scenario-project, or has history changed its course and the countries now face, separately, the extortions of a global market such as that of medicines (drugs, but also diagnostic and non-pharmacological intervention technologies)? Clearly enough, there is no reasonable answer to this question.

Nonetheless, it is important to know that the possible scenarios – regarding every aspect related to medicines – change in accordance with the answer's "direction": from the autonomy of medicines agencies to the role of "national" laboratories and health care policies in the private and public spheres, and the legal framework of the right to access to medicines, among other things. It is impossible to tackle here all such matters in detail.

The working hypothesis for the proposals put forth is that, in any case, regardless of which dominant scenario emerges as an answer to that question, in a globalized world (both in Latin America and in Europe, regions are irrelevant), the concrete and operative priority must be a project that takes in all seriousness the need to reformulate, in the present and for the future, the frame of reference of what is "essential," which has been the starting point of this article. The conflicts amongst powers, interests, and agents are many and well-known, and they must be faced as a normal component of the contexts of decision-making processes. The greatest risk is to be paralyzed by the apparent/realistic impossibility to change macro-scenarios and their roots.

1. The most critical challenge is to avoid falling in the conceptual trap of thinking of everything in "global" terms: issues at an epidemiological level, sustainable models, measures to control what is allowed and what is not, treaties, and so on. The acceptance of such situation concurs also with repetitive criticism that does put forth new proposals. Regaining the conceptual autonomy to imagine and produce knowledge and consciousness at the professional level, and participatory alphabetization programs at lower levels, is a platform that facilitates (technical, cultural, political) alliances between the different agents that are needed to restore the visibility of the old paradigm, which intends to keep health and its pertaining tools within the field of fundamental and attributable rights.[19]
2. In order to move with "essential" responsibility and ability through the field of medicines, it is indispensable to harness an epidemiology capable of qualifying and quantifying the objectives, paths, results – expected and experienced – of the activities that produce knowledge in accordance with the legal paradigm. The ways in which this epidemiology is described are many and diverse:

    - an epidemiology that restores the visibility of the populations, beyond the "global" imposition of diseases;
    - an epidemiology that identifies and adopts needs in connection with the right to health care, needs for which no response is guaranteed, despite being "technically" available;
    - an epidemiology that explores the causes and outlines the "avoidable" liabilities for the lack of access to health care: inequality, corruption, market policies, among others; and

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- an epidemiology that recognizes, not as objects of investigation, but rather as struggling and resilient subjects, the specific communities with which relationships are established and languages are shared, an epidemiology that does not apply alien guidelines but rather seeks and measures, in cooperation with those communities, attainable responses.[20,21,22,23]

3. Epidemiological research studies that define and visualize healthcare priorities, on the basis of the variability of the contexts that implicate a (conceptual and practical) liberation from the mantra that represent the "suggestions" from the top and from outside, and which intend to make use of "evidences" as strictly as they use intellectual property and patents. In spite of the widely known and increasingly well documented lack of credibility that the "official knowledge" has at every level,[24,25] the health care systems and the training of doctors and nurses are articulated under guidelines that follow a tradition of obedience, which is coupled with the reluctance to acknowledge all those things that are yet to be known: even worse, this tradition is content with following "prescriptions," disregarding the verification of the successes (which often turn out to be failures), because those "guidelines" do not consider the history of a person or a population. The importance of working towards this direction is even clearer when considering the current pressure in favor of "precision" and/or "personalized medicine," which undoubtedly is propaganda and a justification for the "liberal" policies regarding the costs (notwithstanding the irrefutable scientific aspects); this contributes to the marginalization of the majorities' problems.[26,27] If we are to face the global scenarios for which the training in medicine and pharmacology must guarantee dialectical competences, one major challenge is to free ourselves from the rigidity and isolation surrounding the different disciplines included in the "model field" of medicines. Health care professionals (doctors and workers at several levels, such as citizens, economists, jurists, and so on) are trained as independent agents and reciprocally ignore the changes that, throughout the last 20 years, affected the relationships between health and society, law and economy.[19] Experimentation at the training instances and research projects in which different points of view meet and diverge are the fundamental condition to produce perspectives of dialectic resistance and to propose innovative tools. Scientific literature (even those journals traditionally oriented to promoting a critical attitude, such as *Lancet* and *PLoS Medicine*) draws the attention towards what is happening globally and the models for the future that pragmatically exclude the creation of critical networks from the lower levels and in several specific places. The participation of Latin American groups in clinical trials and "global" epidemiological research studies can be useful if they generate autonomous points of view and become learning tools: these are starting points for delving into the implications that differences may have, and a "heretic" and dialectic transferability regarding the models and paradigms that respond to economic indexes (both the general indexes and those pertaining to the medicines and services business). An interpretation of the *Sustainable Development Goals* and the United Nations programs about chronic non-communicable diseases on the basis of academic and community networks in Latin America can and must produce "laboratories" for the development of skills suitable for the real necessities.[28,29,30,31]
4. The macro-theme that is the impact of the medicines "market" on the production, registration, marketing, and the legal and criminal interests in Latin America is well-known. The "world of medicine" is a perfect expression for what takes place in other areas that should be common goods and services in democracy: food, water, environment. The challenge is clearly political.[14,16,32,33] The proposals put forth by this article, that is, the recovery of "essential" practices and traditions, represent a path of alliances among the agents who try to restore and promote trust (not an easy task, but still indispensable) in those solutions that

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assume the concrete assertion of the individual and the collective right to a decent life as the final result and insurmountable indicator of the legitimacy of the agents, treaties and projects that are intended to legitimize themselves with criteria and measures pertaining to commercial and financial legality.

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