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HOW TO FACE THE RISING COSTS OF HEALTHCARE?

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Abstract In view of the uncontrolled increase in the costs of therapeutic innovations, the health systems face serious difficulties in maintaining the sustainability of their funding sources. In Argentina, one alternative is the implementation of a reinsurance for "low incidence and high cost" diseases classified as "catastrophic". So far, the healthcare systems managed by trade unions and compulsory social insurance have only implemented this reinsurance for specifically-defined diseases and treatments. The cost estimate of a universal reinsurance premium for all forms of coverage requires very complex calculations, whose structure is exemplified. Another approach is the analysis of the scientific consistency of therapeutic innovations, as performed by health technology assessment agencies, whose examples in Europe and Latin America are mentioned. However, the prospects are difficult for all countries, in view of the demands for legalization expected to be presented by beneficiaries of protection systems and the arguments interposed by those responsible for providing the claimed benefits.

Key words: high-cost health care, catastrophic illness, managed care programs, healthcare financing

Resumen ***¿Cómo afrontar los costos crecientes de la atención médica?*** Frente al incontenible incremento en los costos de las innovaciones terapéuticas, los sistemas de salud enfrentan graves dificultades para mantener la sustentabilidad de sus fuentes de financiamiento. Una de las modalidades posibles en Argentina es la implementación de un reaseguro para enfermedades de "baja incidencia y alto costo", calificadas como "catastróficas". Hasta el momento ese reaseguro solo ha sido implementado para enfermedades y tratamientos taxativamente definidos en las obras sociales sindicales o seguros sociales obligatorios. Los costos de la prima de un reaseguro universal para todas las formas de cobertura requieren estimaciones muy complejas, cuya estructura es ejemplificada. Otra modalidad de análisis consiste en evaluar la consistencia científica de las innovaciones terapéuticas. A tal fin existen agencias de evaluación de tecnologías sanitarias, cuyos ejemplos en Europa y América Latina son mencionados. Pero la perspectiva futura es difícil para todos los países, que se encuentran ante la judicialización que pueden presentar los beneficiarios de sistemas de protección y los argumentos interpuestos por los responsables de brindar los beneficios reclamados.

Palabras clave: medicamentos de alto costo, enfermedades catastróficas, cobertura de gastos catastróficos, planes de salud, financiamiento de salud

Since the 1950's, the pharmaceutical industry of the Western Hemisphere has developed an innovation process whose exponential growth continues to this day. The diverse health systems were organized on the basis of two generic models: a) national health services, in which the resources are financed by the state through general taxes, and b) social security services, where the resources can be either state or private and are financed by aliquots of the salaries[1]. Since the end of the 20th century, the different models are being compelled to adapt to two global phenomena occurring in high- and middle-income countries: a) the epidemiological transition, where the burden of disease is shifting from prevalent infectious diseases to chronic conditions inherent to better socioeconomic levels; and b) the demographic transition, due to the fact that the average life expectancy is extended and the number of those over 65 years grows accordingly in the population pyramid, accompanying the progressive urbanization of the population.

Already in the 1970's, economic studies of the pharmaceutical industry in international expansion showed that investments in research and development were amortized in the first two years of commercialization by means of oversized prices until the new product was imposed in the market, licenses were granted to other companies, or the product was simply replaced by a new improved version. Under these conditions, innovations would be limited to prices reasonably associated with production costs. The formulation of successive drugs – either by the addition

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of radicals to the original molecule or by the discovery of new products with truly innovative action – fueled the economic evolution of the companies, in order to sustain a high rate of return[2]. A similar behavior has been observed in all the countries regarding the introduction of new diagnostic technologies.

One of the industrial sectors that anticipated the globalization since the 1980's was the pharmaceutical industry. Transnational companies showed a particular dynamism in buying assets from national industries and organizing multinational research, production, fractional and distribution networks. Faced with these early globalized markets, there are no international organizations with sufficient regulatory capacity to establish marketing conditions (they set prices according to the characteristics of each country's market), limitations in coverage, analysis of therapeutic efficacy, and incorporation of innovations to clinical practice guides. In fact, the World Health Organization can make recommendations and standardize, but it lacks oversight power, so that countries that do not have their own regulatory bodies must adhere to the decisions adopted by equivalent organizations in the United States, the United Kingdom or the European Community. Since the 90's, the pharmaceutical companies have exerted increasing influence on research financing, planning of therapeutic trials, organization of scientific events, and support of opinion leaders in diverse specialties, including publications. In some cases, certain technical consensuses may displace the thresholds of normality, inducing a greater consumption of the associated chronic medications.

Pharmacological innovations of unsustainable costs have been expressed especially in the fields of oncology and genetic diseases. Some examples can illustrate this process. Ivacaftor, a drug used to treat cystic fibrosis in patients with a particular mutation, has a cost of US$ 340 000/year. Nusinersen, an oligonucleotide approved for intrathecal administration to patients with spinal muscular atrophy, has costs in the order of US$ 840 000/year. In 2017, the cost of the treatment of children with leukemia based on personalized cell identification is US$ 475 000. Peter Bach, an expert in the theoretical estimation of cost of oncological drugs, developed *DrugAbacus*, a tool to calculate the value of these therapies based on their relative importance, tolerance, mechanism of action, dose frequency, and cost per one-year survival. This tool was used to compare expenditures on 52 cancer drugs in US Medicare vs. the National Health Service of the United Kingdom (NHS). It was found that prices in USA are oversized by 80%, while in the NHS they are 50% undersized. Faced with a theoretical annual expenditure of US$ 27 billion, as estimated by the *DrugAbacus*, Medicare spent US$ 32 billion, while the NHS spent US$ 14.5 billion. To face the growing costs of innovations, the National Institute for Health and Care Excellence (NICE) created a special fund of US$ 1.8 billion (1800 million), which allowed the NHS to improve access to innovative treatments, avoiding those that were not cost-effective. Some large pharmaceutical companies implemented certain guarantees. For example, Novartis reimbursed the cost of tisagenlecleucel to patients who had not improved within 30 days after completing treatment of certain leukemias (US$ 475 000). Roche provided trastuzumab to Kenya in 2016 to treat a small group of patients with breast cancer, sharing the price in half with the Ministry of Health (US$ 195 000)[3].

How do countries face these exorbitant expenses –called "catastrophic"– that exceed all types of forecasts? In Argentina, the so-called Social Works (*Obras Sociales* - OSs[#]) contribute to a Solidary Redistribution Fund (FSR*), which allows the reimbursement of expenses for "low-incidence and high-cost" diseases. The disorders included are specifically established through reviews every two years (although innovations are permanent), and include genetic diseases requiring high-cost treatments, organ transplants, prosthesis implant, comprehensive rehabilitation of disabled people, and social assistance for certain natural disasters. The administration of the program was seriously objected during certain periods. In addition, provincial OS's, and those for retired people, university staff, army and security forces, legislative and judicial powers, as well as prepaid medicine, are excluded, either because they are not regulated by the Superintendence of Health Services or because they do not contribute to the FSR. Based on these limitations, a global catastrophic disease insurance has been proposed, in order to reach a broader coverage and review the included diseases[4]. It should be noted that in the USA the item "catastrophic illnesses" is part of the optional sections to set the amount of the premium when hiring health insurance from health maintenance organizations.

In Argentina, there is no agency concentrating information on health expenditure, and even the Health Secretary does not collect such data systematically. Thus, laborious estimates must be made based on multiple fragmented sources. In order to have some dimension on *per capita* insurance expenditures necessary to cover high-cost drugs (MAC*), it is advisable to consult a study that contemplates the prices in force by July 2016, taking into account the distribution of frequencies of use[5]. In order to focus the analysis, global expenses will be considered in the first place, including rehabilitation and transplant benefits (Table 1), and then MAC, which are the subject of this article, aiming to approximate the full cost of an insurance premium for "catastrophic illnesses". If there is a political decision of a universal reinsurance for "catastrophic diseases" in all existing coverage modalities, they should be apportioned according to the magnitude of the

[#]Acronyms in Spanish

populations to be covered, since a reinsurance of this nature would only be actuarially viable if the entire country population were included. As it is a form of distribution of the risks of eventual losses, insurance and reinsurance are prospectively more sustainable when the scale of insured users is higher.

In Table 2, the main MAC groups are presented disaggregated and expenses are discriminated according to type of coverage. To better define the components of these estimates, the main drugs considered in the analysis are listed in Table 3. It is impossible to include the entire therapeutic arsenal, since the introduction of new drugs is very dynamic. In addition, there are no official consumption records, and the estimates must be based retrospectively on the accumulated expenses of the various insurance modalities which, in turn, are extremely fragmented. The data presented has the value of an approximation of reasonable consistency aimed to illustrate political decisions tending to integrate the dispersion of health system resources, but does not cover all protected treatments.

This enumeration did not include all low-incidence and high-cost illnesses protected by the various types of coverage. The following conditions should be added: severe gouty arthritis, systemic juvenile idiopathic arthritis (AIJS*), cryopyrin-associated autoinflammatory syndromes (CAPS*), perennial asthma, alpha 1-antitrypsin deficiency, muscle degeneration, Fabry, Gaucher and Pompe diseases, paroxysmal nocturnal hemoglobinuria, atypical uremic-hemolytic syndrome, pulmonary hypertension, mucopolysaccharidosis I, II and VI, iron overload and hereditary tyrosinemia type I.

In order to face the new challenges posed to the health system sustainability by therapeutic innovations and to determine the scientific consistency of the research endorsing such innovations, many countries have created health technology assessment bodies (ETS*) of different natures, adapted to local institutional regulations. The most important in Europe and Latin America are: *Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen* (IQWiG) in Germany; Spanish Network of Health Technol-

TABLE 1.– *Annual premium per capita for catastrophic expenditure according to type of coverage, estimated in Argentine pesos, July 2016*

Coverage	SSO	EMP	PAMI	PFIS	SP	Total per capita	Total expenditure (millions)	%
High-cost drug	444	1067	1531	1428	444	671	29 630	63
Discapacity	348	348	466	364	–	366	16 176	34
Trasplants	41	26	53	161	9	32	1404	3
Total	833	1441	2049	1952	453	1070	47 210	100

*SSO: compulsory social insurance (national and provincial OS's); EMP: prepaid medicine companies; PAMI: OS for retired people; PFIS: Federal Program "Incluir Salud"; SP: public sector (without coverage)**
**Acronyms in Spanish*

Source: Van der Kooy et al., 2018.
Exchange rate parity, July 2016: US$ 1 = ARS 14.80 to 15.20

TABLE 2.– *Annual premium per capita for the main therapeutic groups in Argentine pesos*

Therapeutic groups	SSO	EMP	PAMI	PFIS	Subtotal	%
Oncohematology	196.2	535.1	783.0	135.7	306.0	45.6
Rheumatology	64.6	135.5	225.2	118.2	93.2	13.7
Multiple sclerosis	57.8	146.8	48.1	55.2	69.1	10.5
Haemophilia	27.2	22.5	185.7	454.4	53.2	6.5

*SSO: compulsory social insurance (national and provincial OS's); EMP: prepaid medicine companies; PAMI: OS for Retired People; PFIS: Federal Program "Incluir Salud"; SP: public sector (without coverage)**
**Acronyms in Spanish*

Source: Van der Kooy et al, 2018 (Ref. 5)
Exchange rate parity, July 2016: US$ 1 = ARS 14.80 to 15.20
Kairos prices, *https://ar.kairosweb.com/* (minus 30%, by discount to institutional buyers)

TABLE 3.– *Drugs considered in major therapeutic groups*

Oncohaematology	Rheumatology	Multiple esclerosis	Haemophilia
Rituximab	Etanercept	Interferon beta 1a	Octocog alpha (Factor VIII)
Lenalidomide	Adalimumab	Fingolimod	Factor VIII monoclonal ultra-high-purity
Bevacizumab	Abatacept	Glatiramer, acetate	Eptacog alfa (activated)
Trastuzumab	Certolizumab pegol	Teriflunomide	Factor VIII recombinant
Abiraterone, acetate	Infliximab	Interferon beta 1b	Factor VIII high-purity
Imatinib	Tocilizumab		Factor VIII monoclonal
Cetuximab	Golimumab		Antiinihibitor Factors VIII and IX
Bortezomib	Rituximab		Factor IX
Pertuzumab			Factor von Willebrand
Everolimus			Factor IX recombinant
Capecitabine			
Enzalutamide			
Leuprolide, acetate			
Clofarabine			
Nilotinib			
Rest of the drugs = 24			

Source: Van der Kooy et al., 2018 (Ref 5)

ogy Assessment Agencies* (Autonomous Communities) in Spain; *Haute Autorité de Santé* (HAS) in France; NICE (already mentioned) in England; *Statens Beredning för Medicinsk Utvärdering* (SBMU) in Sweden. All are part of the International Network Agencies of Health Technology Assessment (INAHTA). In Latin America, mention may be made of: *Comissão Nacional de Incorporação de Tecnologías no SUS* (CITec) in Brazil; Institute of Technological Evaluation in Health (IETS*) in Colombia; National Center of Technological Excellence in Health (CeNETec*) in Mexico[6].

In Argentina, the Government sent to Congress a project in 2016 to create the National Agency for the Evaluation of Health Technologies (AgNET*), which had a long parliamentary debate, since it was opposed by another project on a Federal Agency for the Evaluation of Health Technologies (AFETS*), and the technical issue became politicized. For that reason, the original project was reformulated in 2018 and sent back to the Senate. In our country, the issue is facing not only a prolonged process before being enforced, but also a high risk of resigning scientific objectivity to grant parliamentary feasibility. But beyond the institutional inefficiencies and fragmentations attributable to our health systems, the ETS is not a minor issue even for the most effective and prestigious global health organizations. As expressed in 2012 by Sir Michael Rawlins, former NICE chairman: "no country in the world has sufficient resources to be able to provide all its citizens with all the services with the highest possible quality standards; anyone who believes otherwise lives in Wonderland"[6].

The ETS approach is not only of interest in the field of scientific innovation, but also has broad implications in the legal field, where the rights of individuals to attain the most advanced therapeutic resources are at stake, questioned by the different health financing organisms. Faced with the option of a probable improvement in the prognosis of an illness or the risk of financial sustainability of the insurer, judges always rule in favor of the affected individual, even if the probabilities are remote. These conflicts are not only declared in courtrooms, but also in mass media. A prestigious expert in breast cancer said in a report that "immunotherapy is a treatment modality and personalized therapy is adapted to the needs of each person with his tumor"[7]. Which judge would dare to oppose a patient's request, in the face of foundations supported by these affirmations?

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Cuidará [el médico] que la influencia de la enfermedad en la psique del enfermo no ocasione depresión o angustia, y si éstas aparecen a pesar de todo, le prestará atención debida pues no es al corazón que estamos tratando, sino a todo el individuo. Será su preocupación la de no someter al enfermo a exámenes innecesarios, sobre todo que no se lo estudie "a muerte" como decía Whipple con agudeza. Tendrá suficiente personalidad para resistir las presiones del ambiente o las que produzca su propia angustia para que al enfermo no se lo hospitalice sin necesidad. Tratará que el gasto que requiera el proceso de enfermedad sea el menor posible, y esto no solamente en los enfermos que no tengan "cobertura" económica, sino aun en aquellos a los que entidades estatales o seguros les pagan los gastos de internación, pues dilapidar o gastar innecesariamente ocasiona el aumento de las primas de los seguros o la insolvencia de los mecanismos de previsión. Y en todo esto, tanto la parte exclusivamente médica como el aspecto psíquico, social y económico, es tarea del médico que debe estar, cualquiera sea su jerarquía, al servicio del enfermo. Sir Robert Hutchinson sintetizaba con precisión y elocuencia las cualidades que debería tener el médico en su época y que me animo a decir en todas las épocas: "Líbrenos Dios de interferir en el proceso de curación espontáneo, de entusiasmarse con lo nuevo y despreciar lo viejo, de anteponer erudición antes que sabiduría, ciencia con exclusión del arte, "viveza" antes que sentido común, de tratar los enfermos como casos clínicos, y de hacer el tratamiento de la enfermedad más penoso y fatigoso que la misma enfermedad".

Alfredo Lanari (1910-1985)

Reflexiones sobre la investigación y el futuro de la Medicina (1974). Conferencia pronunciada en el VI° Congreso Internacional de Cardiología el 2 de setiembre de 1974, Buenos Aires, con el título Conferencia Houssay. En: Vocación y convicción. Fundación Alfredo Lanari; Buenos Aires, 1995, p 156-7