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Good Practices and Principles in Health Technology Assessment in Latin America

In 2017, *Value in Health Regional Issues* published a collection of articles describing health technology assessment (HTA) processes in Latin America. Because *Federación Latinoamericana de la Industria Farmacéutica* [FIFARMA]; http://www.fifarma.org/) had already published its position paper online [1], the position paper did not appear in this series of articles published in *Value in Health Regional Issues*. Nevertheless, the journal did publish an editorial by Levy [2] that addressed FIFARMA's position and views on HTA in the Latin America region. Although FIFARMA appreciates Dr Levy's thoughtful comments, we wanted an opportunity to clarify some of the points raised in his editorial.

FIFARMA is the Latin American Federation of Pharmaceutical Industry, a regional organization created in 1962, which represents 13 research and development pharmaceutical companies and 9 local trade associations across Latin America [3]. FIFARMA recognizes that HTA has emerged globally as the preferred discipline through which governments and payers are being recommended in their decisions about whether to pay for a technology (access and coverage) and how much (reimbursement). As a key stakeholder in any HTA-based pricing and reimbursement system, the pharmaceutical industry is responsible for finding an effective manner in which to partner with governments to shape both the design and ongoing application of HTA processes. The goal is to achieve the highest level of openness and transparency, consultation and participation, fairness and credibility, predictability and independence as it relates to value.

Like any entity's position paper, the FIFARMA position paper is intended to promote discussion on emerging topics and to identify the research needed to develop a guideline or to publish as an academic paper. The FIFARMA position paper follows a similar approach of position papers published by other global pharmaceutical associations, including the International Federation of Pharmaceutical Manufacturers and Associations, the Pharmaceutical Research and Manufacturers of America, and the European Federation of Pharmaceutical Industries and Associations [4–6]. A more systematic and thorough review and approach for developing HTA would be out of the scope and interest of the FIFARMA position paper in highlighting current pain points/gaps and proposing best practices to achieve/improve what was previously mentioned.

Levy's criticism on FIFARMA's position paper appears to have considered it as an academic paper or research article. There are at least three points mentioned by Levy in his editorial that need to be clarified to show what FIFARMA truly believes. Those points are ethics matters, quality-adjusted life-years (QALYs) are not so "nice," and HTA-related vendors must be accredited.

Ethics Matters

FIFARMA believes that resource allocation decisions made only from the economic (efficiency) standpoint can be, and often are, conflicting with medical ethics principles including justice, beneficence, nonmaleficence, utility, and autonomy. In a seminal article on resource allocation, Calman [7] points out that "the major conflict is between utility and autonomy, and the concept of justice; it relates to the distinction between the rights of the individual and the needs of the population." It is obvious that no society can pay for all the health care required by its citizens. But resources must be distributed on the basis of what is "morally relevant," and not only from the utilitarian point of view. QALYs are the maximum manifestation of utilitarian thinking, how to maximize outcomes. Patients have to compete with each other for health resources, demonstrating who has more rights than others to access a therapy according to the benefits and the costs they imply with a specific treatment. There are many other values to decide how to use resources and there is no mathematical formula capable of summarizing as a whole the values that must be taken into account to allocate the resources of the health care. HTA agencies must consider that there are legitimate "exceptions" to the cost-effectiveness rules. For a good reference of this ethical debate, the interested reader should consult the article by Fitzgerald et al. [8], in which an ethicist comments on ethical aspects of the debate about cost effectiveness.

QALYs Are Not So "Nice"

FIFARMA's position paper does not advocate for a QALY maximization approach. Because of the influence of National Institute for Health and Care Excellence (NICE) International in the region, the most accepted methodology in the formal HTA bodies that are currently working in Latin America—as stated in FIFARMA's position paper based on a report by the World Health Organization [9]—is based on QALYs. FIFARMA believes that QALYs tend to favor people who are young, healthy, and/or not disabled rather than those who are elderly, ill, or with permanent disability, generic low-cost treatments to innovative ones, and short-term treatments rather than chronic ones. So, the analysis with QALYs is "ethically defective." FIFARMA's position paper states that "HTA should approach new technologies applying not only cost-effectiveness approach, but it should be more inclusive of different methods such as comparative-effectiveness research and multi-criteria decision analysis (MCDA)." FIFARMA has a specific position paper on MCDA [10] due to its relevance. FIFARMA does not think that a NICE-like approach is completely applicable in Latin America. In its position paper, FIFARMA states that "Latin America is

clearly a late adopter of this [the NICE approach]," when even the United Kingdom has been criticized because of the restriction policy (with financial arguments predominantly). FIFARMA believes that a QALY-predominant approach is incomplete (there are many other criteria) and inequitable.

HTA-Related Vendors Must Be Accredited

Accreditation of vendors has been highlighted by Levy as an important point mentioned in the FIFARMA position paper on HTA. Because of budgetary and structural constraints (eg, the lack of people with sufficient training and expertise in Latin America), HTA bodies must often choose to outsource or establish alliances with third parties to develop partial or complete HTAs. Not all of them have the same technical capabilities or expertise and some are not independent, having clear conflicts of interest with one or more actors in the system. FIFARMA believes that, ideally, the HTA system must be fully staffed by well-trained professionals with the appropriate professional skill sets. HTAs that are not conducted by the HTA body itself but are contracted to third parties should be restricted to entities that are accredited or had undergone a selection process. In fact, Colombia's HTA agency Instituto de Evaluación Tecnológica en Salud (IETS) selected 10 institutions as collaborating centers [11], whereas Mexico's federal HTA agency Centro Nacional de Excelencia Tecnológica en Salud (CENETEC) received an accreditation by NICE, which in turn has accredited several institutions in the United Kingdom that provide guidance and advice to the agency [12].

FIFARMA thanks Adrian Levy for his thoughtful editorial and the journal editors for providing us an opportunity to clarify these important points.

Walter Toro, MD, PhD
AbbVie, Chicago, IL, USA

Diego Guarin, MD, MPH, MA
EMD Serono, Rockland, MA, USA
E-mail address: diego.guarin@emdserono.com

(both co-chair Health Care Sustainability Working Group at FIFARMA)

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REFERENCES

[1] Federación Latinoamericana de la Industria Farmacéutica. Position paper on HTA. Available from: https://fifarma.org/web/wp-content/uploads/2017/11/FIFARMA-Position-Paper-on-HTA-April-12th-2016-Final-Version-.pdf. [Accessed April 10, 2018].
[2] Levy A. Editorial comment on health technology assessment: good practices & principles. FIFARMA's position on HTA processes in Latin America: the devil is in the details. Value Health Reg Issues 2017;14:53–6.
[3] Federación Latinoamericana de la Industria Farmacéutica. Available from: http://www.fifarma.org. [Accessed April 9, 2018].
[4] International Federation of Pharmaceutical Manufacturers and Associations. Financing mechanisms for health and medicines. Available from: https://www.ifpma.org/subtopics/health-technology-assessment. [Accessed April 9, 2018].
[5] Pharmaceutical Research and Manufacturers of America. Principles for value assessment frameworks. Published March 30, 2016. Available from: http://www.phrma.org/codes-and-guidelines/principles-for-value-assessment-frameworks. [Accessed April 12, 2018].
[6] European Federation of Pharmaceutical Industries and Associations. The value of industry involvement in HT. August 12, 2011. Available from: https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/111208-joint-healthcare-industry-paperthe-value-of-industry-involvement-in-hta/. [Accessed April 9, 2018].
[7] Calman KC. The ethics of allocation of scarce health care resources: a view from the centre. J Med Ethics 1994;20:71–4.
[8] Fitzgerald DA, Isaacs D, Tobin B. Palivizumab: a debate about funding. J Paediatr Child Health 2012;48:373–7.
[9] World Health Organization. World Health Organization 2007 statistics. Available from: http://www.who.int/health-technologyassessment/HTA_November_meeting_report_Final.pdf. [Accessed April 9, 2018].
[10] Drake JI, de Hart JCT, Monleón C, et al. Utilization of multiple-criteria decision analysis (MCDA) to support healthcare decision-making FIFARMA, 2016. J Mark Access Health Policy 2017;5:1360545.
[11] Instituto de Evaluacion Tecnologica en Salud. IETS se articula en las regiones. May 21, 2013. Available from: http://ietscolombia.blogspot.com/2013/05/iets-se-articula-con-las-regiones.html. [Accessed April 14, 2018].
[12] National Institute for Health and Care Excellence. Accreditation decisions. Available from: https://www.nice.org.uk/about/what-we-do/accreditation/accreditation-decisions. [Accessed April 9, 2018].