IFARMA Conferencia Episcopal de Colombia CIMUN CENTRO DE INFORMACIÓN DE MEDICAMENTOS

Misión Salud

OBSERVATORIO DEL MEDICAMENTO

Bogotá, Colombia, 20 de Enero de 2017

Señor
ALEJANDRO GAVIRIA URIBE
Ministro de Salud y Protección Social de Colombia

Referencia: Consejo Ejecutivo de la OMS 23 Enero – 1 Febrero 2017 y Reporte del Panel de Alto Nivel sobre Acceso a Medicamentos del Secretario General de la ONU.

Respetado Señor Ministro,

La presente tiene por objeto solicitar a usted adelantar las gestiones necesarias para asegurar que el Gobierno de Colombia apoye públicamente el Reporte del Panel de Alto Nivel sobre Acceso a Medicamentos del Secretario General de la ONU y solicite a éste y a la Organización Mundial de Salud (OMS) la implementación de las recomendaciones allí contenidas.

Diferentes oficinas del Gobierno de Colombia ya han reconocido públicamente la importancia del mandato por el que se constituyó el Panel de Alto Nivel citado, con miras a resolver el reto global objeto del mismo. Dan cuenta de ello las comunicaciones enviadas a los presidentes del Panel por la Embajadora María Emma Mejía (21 Julio, 2016) y por usted mismo después de que el Reporte del Panel fuera publicado (8 de Noviembre, 2016).

Como bien lo expresó usted en dicha comunicación, "El reporte del Panel de Alto Nivel está altamente alineado con la Política Farmacéutica Nacional, puesto que se enfoca en la urgente necesidad de garantizar consistencia y coherencia entre los derechos humanos, las reglas de comercio, los derechos de propiedad intelectual y la salud pública". La materialización de las recomendaciones concretas de este reporte es apremiante para empezar a solucionar desde la raíz esta problemática global, que en nuestro caso particular se ve reflejada, por ejemplo, en la imposibilidad de ejercer el derecho-obligación de concesión de licencias obligatorias con miras a favorecer un mejor uso de los recursos públicos del sistema de salud o en los exorbitantes precios que pagamos por medicamentos biotecnológicos carentes de competencia en el mercado. Adjuntamos a la presente el artículo "*Powerful ideas for global Access to medicines*", escrito por la Dra. Suerie Moon y publicado en *The New England Journal of Medicine* el 18 de los corrientes, que ilustra la necesidad de atender las recomendaciones contenidas en el Reporte por parte de los países que enfrentan dificultades para garantizar el acceso a medicamentos por parte de su población.

Por motivos que escapan a nuestro entendimiento, el reporte del Panel, que versa sobre materias enteramente ligadas con el derecho fundamental a la salud, no forma parte

explícita de la agenda del Consejo Ejecutivo de la OMS que se celebrará entre el 23 de Enero y el 1 de Febrero. El secretariado de la OMS ha ignorado peticiones de Estados Miembros y de la sociedad civil para que el reporte se discuta en profundidad en la OMS y se fortalezcan los mandatos de acceso a medicamentos e innovación. Paradójicamente, la Organización Mundial del Comercio sí destinó un espacio de discusión sobre el reporte en su comité sobre propiedad intelectual.

La indignación que ha producido esta situación llevó a que el Dr. Timothy Armstrong, Director del Departamento de Órganos Deliberantes de la OMS, explicara[1] que el Reporte del Panel de Alto Nivel sobre Acceso a Medicamentos puede ser abordado durante la discusión del punto 8.5 Seguimiento del informe del Grupo Consultivo de expertos en investigación y desarrollo: financiación y coordinación (CEWG). Creemos que es contrario a la misión de la OMS el hecho de que su secretariado haya restringido la posibilidad de discutir el reporte en profundidad por los Estados Miembros y consideramos que los problemas causados por la falta de innovación y el acceso a medicamentos y las respectivas recomendaciones allí consignadas son relevantes no sólo frente al punto 8.5 de la agenda, sino también frente a temas como el 7.1 Emergencias sanitarias, el 7.2 Resistencia a los antimicrobianos, el 8.3 La escasez mundial de medicamentos y vacunas, el 8.4 Evaluación y examen de la estrategia mundial y plan de acción sobre salud pública, innovación y propiedad intelectual, 9.1 Plan de acción mundial sobre vacunas, el 10.5 Prevención y control del cáncer en el contexto de un enfoque integrado, y el 11.1 Progresos en la aplicación de la Agenda 2030 para el Desarrollo Sostenible, entre otros.

Con esta comunicación, urgimos al delegado oficial de Colombia ante el Consejo Ejecutivo de la OMS a mantener la coherencia con las comunicaciones oficiales citadas, expresando una posición pública de apoyo a que la implementación de las recomendaciones del reporte del Panel sean priorizadas inmediatamente por la OMS, organismo encargado de velar por la salud en el mundo, y solicitando una discusión en profundidad y de alto nivel sobre los problemas globales de la falta de innovación y los altos precios de medicamentos y vacunas en Ginebra así como en las Naciones Unidas en Nueva York.

Para su información, el mes pasado tuvimos la oportunidad de solicitar el respaldo al reporte del Panel de Alto Nivel durante la Audiencia Temática Regional sobre Acceso a Medicamentos en las Américas que nos concedió la Comisión Interamericana de Derechos Humanos (CIDH) en unión de 25 organizaciones de la sociedad civil del continente y que fue celebrada en el marco del 159º periodo ordinario de sesiones de la CIDH (Ciudad de Panamá, Diciembre 6 de 2016).

Confiamos que la posición privilegiada que tiene Colombia al formar parte del Consejo Ejecutivo de la OMS se traduzca en una actuación clara y decidida en favor de la priorización

[1] http://www.ip-watch.org/2016/11/30/board-may-discuss-un-high-level-panel-report-medicines-access/

del acceso a medicamentos y la innovación en salud por parte de quienes en este momento sufren las consecuencias de modelos de innovación y desarrollo en salud y de fijación de precios de medicamentos que no están centrados en los derechos humanos fundamentales.

Reciba un cordial saludo,

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The NEW ENGLAND JOURNAL of MEDICINE

Powerful Ideas for Global Access to Medicines

Suerie Moon, M.P.A., Ph.D.

One of the few issues uniting U.S. voters in the 2016 election was outrage over the high prices of medicines. From the quadrupling of EpiPen prices to $1,000-per-pill hepatitis C treatments

from six-digit pricing of cancer drugs to the 55-fold price increase on a 62-year-old toxoplasmosis drug, the scandals keep coming. In Europe, where government involvement in price negotiations means that new drugs, diagnostics, and vaccines ("medicines") can cost less than half their U.S. prices, there is nevertheless serious concern that yearly price increases will break health system budgets. Worldwide drug spending grew by about 9% in 2014 and 2015, outpacing both overall health expenditures and economic growth.[1]

But what has recently been headline news in high-income countries has long been a concern everywhere else. Whether low- and middle-income countries (LMICs) are struggling to treat millions of people living with HIV or to immunize refugee children against pneumonia, unaffordable prices mean that many people simply go without. Meanwhile, despite billions of public and private dollars invested in pharmaceutical research and development, urgent needs for new antibiotics and tools for other public health priorities go unmet. Unaffordable medicines and inadequate innovation have become global issues. Like climate change, they require new public policies and international cooperation.

Responding to concerns raised by patients and health advocates worldwide, in 2015 United Nations (UN) Secretary General Ban Ki-Moon convened a High-Level Panel on Access to Medicines led by two former heads of state, Ruth Dreifuss of Switzerland and Festus Mogae of Botswana, together with 13 international experts with wide-ranging perspectives. Even before the report was published in September 2016 (www.unsgaccessmeds.org/final-report), it had attracted an unusual degree of attention — both positive and negative — from governments, the pharmaceutical industry, and civil society. Some of the reaction, epitomized by the U.S. Chamber of Commerce statement "condemn[ing the] U.N. report attacking patents,"[2] reflected a decades-old debate over the appropriate relationship between intellectual property monopolies and medicine prices. Yet the report does not generally go beyond preexisting international agreements on patents. Rather, the true source of consternation may be that it reframes the access-to-medicines challenge not only as involving prices in LMICs, but also as requiring systemic changes to the prevailing research-and-development business model for the sake of all countries. The panel then advances some powerful ideas regarding such changes.

One of those ideas is transparency. Reliable, thorough public in-

formation is not generally available on the safety, efficacy, prices, patent status, sources of investment, and costs of developing lifesaving medicines. Given its profound implications for the public interest, the drug-development system is shrouded in a disproportionate degree of secrecy. The panel recommended that governments mandate disclosure of information on various aspects of pharmaceutical development, including research-and-development costs. Depending on the information source and the methods used, estimates of the cost of developing a new drug vary by a factor of 40 or more — ranging from $92 million to $4.2 billion.[3] Transparency could introduce some measure of reason and evidence into heated pricing debates, which too often deteriorate into hyperbolic claims that any interference with free-market pricing would destroy innovation. A more granular understanding of research and development could also shed light on the efficiency of the processes involved and spark debate about how society ought to appropriately compensate investment, outcomes, and risk and calibrate financial rewards to the degree of therapeutic advance offered.

Transparency is also key to another powerful idea endorsed by the panel: ensuring public return on public investment in medicine development. Drug development is a public–private enterprise, with the public investing in basic research and early-stage discovery through taxpayer funding of academic and public laboratories and then purchasing the medicines that private firms develop through insurance policies or out-of-pocket expenditures. In areas in which the market fails to offer adequate incentives for innovation — such as neglected diseases, emerging infectious diseases, or antimicrobial resistance — public funding and priority setting play an even greater role, subsidizing all stages of product development. For example, the U.S. government's Biomedical Advanced Research and Development Authority has funded private firms to develop medicines for use in potential outbreaks and has obtained approval from the Food and Drug Administration for 24 products since its founding in 2006. Transparency regarding public contributions to the research underlying a medicine could provide a foundation for tempering excessive pricing, either in advance through conditions imposed on public financing or after development through government regulation.

The report also calls for testing and implementing new business models of research and development that would build affordability into the product-development process by delinking research financing from end-product prices. Some such models have already been proven to work in not-for-profit drug-development efforts. For example, with $290 million from public funds and philanthropic contributions, the Drugs for Neglected Diseases Initiative (DNDi) put 26 candidate products into the development pipeline and brought 6 to market in 10 years; because the research costs have already been covered, DNDi's products can be sold for approximately the cost of production.[4] Though there are important differences between drug development for neglected diseases and other therapeutic areas, this example offers proof of principle regarding better ways to manage public and private investments to channel research and development in the public interest.

Finally, the panel called for governments and companies to adhere to established agreements to protect access to medicines under international trade rules. For example, governments have the authority to decide when a private patent right can be set aside in the interest of public health — a right that has been reaffirmed in every relevant UN political declaration since 2001. Though the pharmaceutical industry has criticized the report as an attack on patents, the panel in fact recommended only that preexisting agreements be enforced; it did not recommend additional patent flexibilities beyond what has been agreed on for 15 years. Indeed, some panel members and civil-society organizations expressed disappointment that it did not call for a more dramatic overhaul of intellectual-property treaties.

Among the report's authors is the chief executive officer of GlaxoSmithKline (GSK), Andrew Witty, who has occasionally become a thorn in his industry's side by taking positions ahead of the curve. For example, he has called the $1 billion research-and-development price tag a myth reflecting inefficiencies rather than required costs; he expanded GSK's policy of licensing generic versions of patented medicines in some LMICs beyond HIV to include cancer; and he has endorsed new research-and-development models to combat antimicrobial resistance and pathogens of pandemic potential. His peers may wish to reexamine some of the business models advanced in the report, which could continue rewarding inno-

vation while satisfying growing public demands for affordability and needs-driven innovation.

Given the charged politics of debates over access to medicines, I believe Secretary General Ban was courageous to convene this panel — though the report's fate in the UN system is uncertain, given that there is a new secretary general, a new U.S. president, and a new director general of the World Health Organization in 2017. Nevertheless, the panel's greatest impact may be realized not through intergovernmental talks, but by stimulating public debate over ways of reforming the research-and-development system to better serve the global public interest. The Netherlands' trade and health ministers recently echoed three panel recommendations, calling for transparency of pharmaceutical research-and-development costs, adequate public return on public investment, and testing of new business models.[5]

This report comes at a time when the public appetite for change is growing, the pharmaceutical industry's reputation is in the doldrums, and demand for a more equitable global trade system is building. It puts forth ideas that deserve a fair hearing in countries struggling to provide access to medicines for their people and in the boardrooms of companies with the vision to try new ways of delivering innovation. Business as usual is no longer an option.

Disclosure forms provided by the author are available at NEJM.org.

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1. Outlook for global medicines through 2021: balancing cost and value. QuintilesIMS Institute, December 2016 (http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/outlook_for_global_medicines_through_2021).
2. U.S. chamber condemns UN report attacking patents. U.S. Chamber of Commerce, September 14, 2016 (https://www.uschamber.com/press-release/us-chamber-condemns-un-report-attacking-patents).
3. Morgan S, Grootendorst P, Lexchin J, Cunningham C, Greyson D. The cost of drug development: a systematic review. Health Policy 2011;100:4-17.
4. Maxmen A. Busting the billion-dollar myth: how to slash the cost of drug development. Nature 2016;536:388-90.
5. Ploumen L, Schippers E. Better life through medicine — let's leave no one behind. Lancet 2016 November 4 (Epub ahead of print).

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