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Bogotá D.C. 27 de Marzo de 2017

Doctor
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Ministerio de Salud y Protección Social

Referencia: Consulta Informal del Borrador de Resolución contenido en el documento EB140/31 (Prevención y control del cáncer en el contexto de una aproximación integrada)

Respetado Señor Viceministro:

Reciba un respetuoso saludo de parte de la Conferencia Episcopal de Colombia, el Centro de Información de Medicamentos de la Universidad Nacional de Colombia (CIMUN), la Fundación Ifarma, Misión Salud y el Observatorio del Medicamento de la Federación Médica Colombiana (OBSERVAMED), todas ellas reunidas en el Comité de Veeduría y Cooperación en Salud (CVCS).

En relación con el proceso que se está adelantando al interior de la OMS con respecto a la consulta informal del borrador de resolución contenido en el documento EB140/31, titulado "Prevención y control del cáncer en el contexto de una aproximación integrada", específicamente con la fase de consulta a las capitales con fecha límite 31 de marzo de 2017 (se adjunta versión en consulta), nos dirigimos a usted para presentarle nuestras respetuosas apreciaciones, confiando sean tenidas en cuenta al construir el planteamiento del Ministerio de Salud en el marco de este proceso.

En el espacio destinado al citado documento EB140/31 en la pasada 140ª Sesión del Consejo Ejecutivo de la OMS, celebrada entre el 24 y 31 de enero de este año, la delegación de Colombia valoró especialmente la inclusión de este punto en la agenda al considerar esta enfermedad como un tema prioritario y expresó que el proyecto de resolución que se encuentra en construcción es "una oportunidad para garantizar respuestas efectivas a esta problemática global en todos los niveles", agregando que "resulta fundamental que el documento refleje como elemento central el acceso equitativo a todos los servicios, tecnologías y medicamentos requeridos para la efectiva prevención, el diagnóstico y el tratamiento del cáncer".

Desde dicha sesión hasta el día de hoy el documento ha tenido varias modificaciones, llegando a una versión (adjunta) en la que la interrelación existente entre el sistema de propiedad intelectual y el acceso a las tecnologías en salud para prevenir, diagnosticar y tratar el cáncer es escasamente abordada, con el agravante de que los únicos dos párrafos que la atienden están en consulta entre los países. Apoyados en lo expresado por la delegación de Colombia durante la sesión, deseamos llevar su atención a este aspecto específico de la nueva versión del borrador de resolución, que sin duda es determinante para el "acceso equitativo a todos los servicios, tecnologías y medicamentos requeridos" en el abordaje del cáncer.

Concretamente se trata de los párrafos OP1.14 y OP2.5ter. Desde nuestro punto de vista en ambos casos el texto "EN CONSIDERACIÓN PARA LAS CAPITALS" significa un retroceso en la promoción mundial del acceso a medicamentos. La adopción de estas redacciones conllevaría



al absurdo de tener una resolución sobre una enfermedad de alto costo que ignora el impacto del monopolio y del modelo actual de fomento a la innovación y desarrollo de medicamentos sobre los altos precios de los medicamentos. En otras palabras, se trataría de una resolución sobre la segunda causa de muerte a nivel mundial que ignora tanto el mandato que dio origen al Panel de Alto Nivel sobre Acceso a Medicamentos, convocado por la Secretaría General de Naciones Unidas, como las recomendaciones que éste presentó en su reporte final, reporte que honrosamente la delegación de Colombia, a través suyo, destacó en la misma sesión del Consejo Ejecutivo de la OMS. Apoyados en lo anterior y en lo establecido en la Política Farmacéutica Nacional Conpes 155, urgimos de la manera más atenta al Ministerio de Salud a que instruya a la delegación de Colombia para NO apoyar estas redacciones.

En el caso del párrafo OP1.14 puede verse cómo el texto en consulta está dejando por fuera de la resolución la alusión al pleno uso de las salvaguardas de la salud pública contenidas en el Acuerdo de los ADPIC y la Declaración de Doha como herramienta para promover el acceso a regímenes de diagnóstico, tratamiento y prevención robustos y costo-efectivos. Aún más, el texto en consulta no tiene en cuenta la propuesta de Colombia de *“interpretar e implementar (las medidas de protección y observancia de la propiedad intelectual contenidas en los ADPIC) de manera que apoye el derecho de los Estados Miembros a proteger la salud pública y, en particular, a promover el acceso a medicamentos por parte de toda la población”*. Llama especialmente la atención el evidente esfuerzo de los Estados Unidos para reducir cada vez más el lenguaje que promueve el ejercicio del deber-obligación por parte de los Estados de hacer uso de dichas salvaguardas, de las que frecuentemente dependen la salud y la vida de su población. De esta manera se pretende una vez más colocar los intereses comerciales por encima del derecho fundamental a la salud y la vida.

En lo que se refiere al párrafo OP2.5ter, es evidente que se da un paso atrás al cambiar una propuesta original que invita a estudiar la viabilidad de crear un fondo entre países para estimular la I+D en cáncer como alternativa a los incentivos actuales basados en la expectativa de patentar la invención y cobrar por los productos altos precios de monopolio, por una redacción que invita a la elaboración de un documento técnico sobre los mecanismos existentes en la materia. Sin duda un recurso distractor y un desperdicio de recursos en momentos en que el bienestar de la humanidad requiere con urgencia modelos nuevos que desvinculen los costos de la I+D en cáncer de los precios de los productos. Muestra de que Colombia reconoce la necesidad de avanzar cuanto antes en la consolidación de modelos alternativos de I+D en cáncer son la presentación del proyecto “Pruebas de diagnóstico de Cáncer asequibles” en el marco de la selección de proyectos demostrativos para explorar modelos de innovación alternativos al interior de la OMS¹ y el llamado contundente hecho por usted al Consejo Ejecutivo de la OMS en enero pasado en el sentido de *“promover un debate franco, un debate abierto que derive en negociación de un tratado internacional para la coordinación y el financiamiento de la investigación y el desarrollo en salud”*.

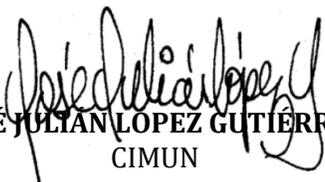
Dado el hecho de que Dra. Heidi Botero, Primera Secretaria de la Misión Permanente de Colombia ante las Naciones Unidas en Ginebra, está ejerciendo las veces de *“chair”* de esta consulta, consideramos indispensable que la Misión Permanente de Colombia allegue de manera explícita sus aportes dentro del plazo dado para la misma.

¹ http://www.who.int/phi/implementation/AMRO_procedure_for_selection_of_demo_projects.pdf?ua=1

El Plan Decenal para el Control del Cáncer 2012 – 2021 reconoce que “la carga creciente del cáncer en el perfil de salud de los colombianos amerita intervenciones oportunas, certeras y coordinadas para lograr el impacto esperado a nivel poblacional e individual sobre su incidencia, discapacidad, calidad de vida y mortalidad”. En coherencia con este hecho, el Gobierno de Colombia se comprometió a alcanzar los Objetivos del Milenio, a cumplir la Declaración Política de la Reunión de Alto Nivel de la Asamblea General de las Naciones Unidas sobre la Prevención y el Control de las Enfermedades No Transmisibles y a promover el acceso en condiciones de competencia para el medicamento imatinib, utilizado para el tratamiento de diferentes tipos de cáncer. Una participación de la delegación de Colombia alineada con estos pasos significa no respaldar las redacciones puestas a consideración de las capitales, lo cual contribuirá a lograr una resolución que efectivamente sirva de apoyo al Gobierno como un instrumento de política pública para el cumplimiento de su obligación de respetar, proteger y cumplir el derecho fundamental a la salud.

Cordialmente,


MONSEÑOR FABIAN MARULANDA
Conferencia Episcopal de Colombia


JOSÉ JULIÁN LOPEZ GUTIERREZ
CIMUN


GERMÁN HOLGUÍN ZAMORANO
Misión Salud


FRANCISCO ROSSI BUENAVENTURA
Fundación Ifarma


OSCAR ANDÍA SALAZAR
OBSERVAMED


JENNIFER M. BUENO ROCHA
Comité de Veeduría y Cooperación en Salud

C.C. Dr. Jaime Eduardo Matute Hernández – Grupo de Cooperación y Relaciones Internacionales

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**OUTCOME OF THE INFORMAL CONSULTATION ON THE DRAFT
RESOLUTION CONTAINED IN DOCUMENT EB140/31
(CANCER PREVENTION AND CONTROL IN THE CONTEXT OF AN
INTEGRATED APPROACH)**

13 MARCH 2017

DOCUMENT AS SHOWN ON SCREEN AT 16:45

DEADLINE FOR COMMENTS : 31 March 2017

Send comments to:

Ms Heidi Botero Hernández

First Secretary

Permanent Mission of Colombia to the UN (Geneva)

heidi.botero@misioncolombia.ch

The Executive Board,

Having considered the report on cancer prevention and control in the context of an integrated approach,¹

RECOMMENDS to the Seventieth World Health Assembly the adoption of the following resolution:

The Seventieth World Health Assembly,

(PP1) Having considered the report on cancer prevention and control in the context of an integrated approach;

(PP2) Recognizing that cancer is a leading cause of [morbidity] globally and a growing public health concern, with a projected increase in new cancer cases from 14.1 million in 2012 to 21.6 million annually by 2030;

(PP3) Acknowledging that [in 2012, cancer was the second leading cause of death in the world with] 8.2 million cancer-related deaths, the majority of which occurred in low- and middle-income countries;

AND SWITCH ORDER OF PP2 AND PP3

(PP4) Aware that certain population groups experience inequalities in risk factor exposure and in access to screening, early diagnosis and timely and appropriate treatment, and experience poorer outcomes from cancer; and recognizing that different cancer control strategies are required for specific groups of cancer patients, such as children and adolescents;

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(PP5) Noting the potential for the prevention of around half of all cancers through risk reduction;

(PP6) Aware that early diagnosis and prompt and appropriate treatment, including pain relief and palliative care, can reduce mortality and improve the outcomes and quality of life of cancer patients;

(PP6bis) Recognizing with appreciation the introduction of new pharmaceutical products based on investment in innovation for cancer treatment in recent years, and noting with great concern the increasing cost to the health systems and the patients;

~~(PP7) Acknowledging the limitations in access to medicines, appropriate technology and human resources for cancer care and the need to address access barriers for patients;~~

PP7alt Emphasizing the importance that the national health system and international cooperation address all barriers in access to safe, quality and affordable medicines, medical products, and appropriate technology, including human resources, for cancer prevention, detection and treatment, including cancer surgery, as well as the need to address access barriers for patients;
(FOR CONSIDERATION BY CAPITALS)

PP7bis [SEPARATE PARAGRAPH ON DISPARITIES WITHIN NATIONAL CONTEXT]

(PP8) Recalling resolution WHA58.22 (2005) on cancer prevention and control;

(PP9) Recalling also United Nations General Assembly resolution 66/2 (2011) on the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, which includes a road map of national commitments from Heads of State and Government to address cancer and other noncommunicable diseases;

(PP10) Recalling further resolution WHA66.10 (2013) endorsing the global action plan for the prevention and control of noncommunicable diseases 2013–2020, which provides guidance on how Member States can realize the commitments they made in the 2011 Political Declaration, including those related to addressing cancer;

(PP11) Recalling in addition United Nations General Assembly resolution 68/300 (2014) on the Outcome document of the high-level meeting of the General Assembly on the comprehensive review and assessment of the progress achieved in the prevention and control of non-communicable diseases, which sets out the continued and increased commitments that are essential in order to realize the road map of commitments to address cancer and other noncommunicable diseases included in the 2011 Political Declaration, including four time-bound national commitments for 2015 and 2016;

(PP12) Mindful of the existing monitoring tool that WHO is using to track the extent to which its 194 Member States are implementing these four time-bound commitments to address cancer and

other noncommunicable diseases, in accordance with the technical note¹ published by WHO on 1 May 2015 pursuant to decision EB136(13) (2015);

(PP13) Mindful also of the WHO Framework Convention on Tobacco Control, ~~[an international public health treaty that was negotiated under the auspices of WHO and adopted by the Fifty-sixth World Health Assembly (2003) and entered into force in 2005,]~~

with 180 Parties committed to reducing the global burden of tobacco use;

(PP14) Mindful further of the Sustainable Development Goals of the 2030 Agenda for Sustainable Development, specifically Goal 3 (Ensure healthy lives and promote wellbeing for all at all ages) with its target 3.4 to reduce, by 2030, premature mortality from noncommunicable diseases by one third, and target 3.8 on achieving universal health coverage;

(PP15) Appreciating the efforts made by Member States² and international partners in recent years to prevent and control cancer, but mindful of the need for further action,³

(OP1) URGES Member States⁴, taking into account their context, institutional and legal frameworks, as well as national priorities;

(OP1.1) to continue to implement the road map of national commitments for the prevention and control of cancer and other noncommunicable diseases included in United Nations General Assembly resolutions 66/2 (2011) on the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases and 68/300 (2014) on the Outcome document of the high-level meeting of the General Assembly on the comprehensive review and assessment of the progress achieved in the prevention and control of non-communicable diseases;

(OP1.1. bis) to also implement the four time-bound national commitments for 2015 and 2016 set out in the Outcome document, in preparation for a third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018, taking into account the technical note published by WHO on 1 May 2015, which sets out the progress indicators that the Director-General will use to report to the United Nations General Assembly in 2017 on the progress achieved in the implementation of national commitments, including those related to addressing cancer, taking into account cancer-specific risk factors;

(OP1.2) to integrate and scale up national cancer prevention and control as part of national responses to noncommunicable diseases, in line with the 2030 Agenda for Sustainable Development;

² And, where applicable, regional economic integration organizations

³ Available at <http://www.who.int/nmh/events/2015/technical-note-en.pdf?ua=1> (accessed 7 December 2016)

⁴ And, where applicable, regional economic integration organizations.

(OP1.3) to develop , as appropriate, and implement national cancer control plans, inclusive of all age groups, with adequate resources, monitoring and accountability that seek synergies and cost-efficiencies with other health interventions;

(OP1.4) to collect high-quality population-based incidence and mortality data on cancer, by cancer type, including measurements of inequalities, through population-based cancer registries, household surveys and other health information systems to guide policies and plans;

(OP1.5) to accelerate the implementation by States parties of the WHO Framework Convention on Tobacco Control; and , for those Member States that have not yet done so, to consider acceding to the Convention at the earliest opportunity, given that the substantial reduction of tobacco use is an important contribution to the prevention and control of cancer, and act to prevent the tobacco industry's interference in public health policy for the success of reducing the risk factors of noncommunicable diseases;

(OP1.6) to promote the primary prevention of cancers; (FOR CONSIDERATION BY CAPITALS)

PARKED [including, to the highest possible coverage of vaccination [including] [against HEP-B and HPV], as appropriate, (ADD FOOTNOTE TO EXISTING DOCUMENTS AND VACCINATIONS)

in accordance with national priorities and epidemiological profiles in line with the immunization targets of the Global Vaccine Action Plan 2011–2020]; (DEL)

(OP1.7) To develop, implement and monitor programmes, based on the national epidemiological profiles, for the early diagnosis of common cancers, ~~[including cervical, breast, oral, and colorectal cancers,]~~ and for screening of cancers, according to assessed feasibility and cost-effectiveness of screening, and with adequate capacity to avoid delays in diagnosis and treatment;

(OP1.8) to develop and implement evidence-based protocols for cancer management, including palliative care;

(OP1.8 bis) to collaborate by strengthening, where appropriate, regional and subregional partnerships and networks to create centres of excellence for the management of certain cancers;

(OP1.9) to promote recommendations that support clinical decision-making and referral based on the effective, safe and cost-effective use of cancer diagnostic and therapeutic services, such as [cancer] surgery, radiation and chemotherapy, and facilitate cross-sectoral cooperation between health professionals, as well as the training of personnel at all levels of health systems;

(OP1.10) to mobilize sustainable domestic human and financial resources and consider voluntary and innovative financing approaches to support cancer control in order to promote equitable and affordable access to cancer care;

(OP1.11) to promote cancer research to improve the evidence base for cancer prevention and control, including on health outcomes, quality of life and cost-effectiveness;

(OP1.12) to provide pain relief and palliative care in line with resolution WHA67.19 (2014) on the strengthening of palliative care as a component of comprehensive care throughout the life course;

(OP1.12bis) to anticipate and promote cancer survivor follow up, late effect management and tertiary prevention, with the active involvement of survivors and their relatives;

(OP1.12ter) to promote early detection of patients' needs and access to rehabilitation, including in relation to work, psychosocial and palliative care services;

(OP1.12quar) to promote and facilitate psychosocial counseling and after-care for cancer patients and their families, also in the light of the increasingly chronic nature of cancer;

(OP1.13) to work towards the attainment of target 3.4 of the Sustainable Development Goals, reiterating the commitment to reduce, by 2030, premature mortality from cancer and other noncommunicable diseases by one third;

PROPOSALS FROM THE CHAIR INSERTED ON 13 MAR 2017 AT 15:10

(OP1.14) to promote the affordability and availability of quality, safe and effective medicines (in particular, but not limited to, those on the WHO Model List of Essential Medicines), vaccines and diagnostics for cancer; (FOR CONSIDERATION BY CAPITALS)

(OP1.14bis) [Promote access to comprehensive and cost-effective prevention, treatment and care for the integrated management of non-communicable diseases, including, inter alia, increased access to affordable, safe, effective and quality medicines and diagnostics and other technologies, including [through the use, to the fullest extent, of the provisions contained in TRIPS agreement, which provide flexibilities for the protection of public health;]

OR

[, through the full use of trade-related aspects of intellectual property rights (TRIPS) flexibilities] (= OP45(p) of A/RES/66/2)

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(OP1.14) to promote the affordability and availability of quality, safe and effective medicines (in particular, but not limited to, those on the WHO Model List of Essential Medicines), vaccines and diagnostics for cancer, recognizing the critical importance of affordable medicines, including generics, in scaling up access to affordable cancer treatment, [through, for example, [public health sensitive intellectual property policies] (Brazil) appropriate financing arrangements, more effective supply systems, and measures to address

high prices,] (EU)
[END HERE] (USA)

MOVE TO PP

[and further recognize that protection and enforcement measures for intellectual property rights should be compliant with the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and should be interpreted and implemented in a manner supportive of the right of Member States to protect public health and, in particular, to promote access to medicines for all;] (Colombia)

(MOVE TO PP6ter) (USA, Japan) (RETAIN LOCATION) (Brazil, Colombia, India, Thailand)

OR

(PP6ter.alt) [noting that the goals of Member State is to increase access to affordable, safe and effective, and quality assured medicines, including, as appropriate, to the full use of the provisions [which provide flexibility] in the agreement on TRIPS noting that intellectual property rights are an important incentive of new health care products;] (USA)

OR

(=OP11 from WHA67.22) [to consider, as appropriate, adopting national legislation in order to make full use of the provisions, contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to that agreement, in order to promote access to essential medicines, in line with the Global Strategy and Plan of Action on Public, Health, Innovation and Intellectual Property;] (Chair)

OR

(= A/RES/66/2 P45(g)) [promote access to comprehensive and cost-effective prevention, treatment and care for the integrated management of NCDs, including, inter alia, increased access to affordable, safe, effective and quality medicines and diagnostics and other technologies, including through the full use of trade-related aspects of intellectual property rights (TRIPS) provisions which provide flexibility] (USA)

(OP2) REQUESTS the Director-General:

(OP2.1) to develop or adapt stepwise and resource-stratified guidance and tool kits to establish and implement comprehensive cancer prevention and control programmes, leveraging the work of other organizations;

(OP2.2) to collect, synthesize and disseminate evidence on the most cost-effective interventions for all age groups, and to support Member States in their implementation and make an investment case for cancer prevention and control;

(OP2.3) to strengthen the capacity of the Secretariat to support the implementation of cost-effective interventions and country-adapted models of care and to work with international partners, including the International Atomic Energy Agency, to harmonize the technical assistance provided to countries for cancer prevention and control;

(OP2.3bis) to work with Member States⁵, and collaborate with NGOs, private sector, academic institutions and philanthropic foundations as defined in FENSA to develop partnerships to scale up cancer prevention and control, and to improve the quality of life of cancer patients, in line with Sustainable Development Goals 3 and 17;

(OP2.4bis) to strengthen the collaboration with NGOs, private sector, academic institutions and philanthropic foundations as defined in FENSA, with a view to foster the development of effective and affordable new cancer medicines;

(OP2.4ter) to provide technical assistance, upon request, to regional and subregional partnerships and networks, including, where appropriate, towards the establishment of centres of excellence to strengthen cancer management;

(OP2.5) to develop, before the end of 2019, the first periodic public health and policy-oriented world report on cancer, in the context of an integrated approach, based on the latest available evidence and international experience, and covering the elements of this resolution, with the participation of all relevant parts of the Secretariat, including IARC, and in collaboration with all other relevant stakeholders, including cancer survivors;

(OP2.5bis) to enhance the coordination between IARC and other parts of WHO on assessments of hazard and risk, and on the communication of those assessments;

(OP2.5ter) [to conduct a [preliminary] (Brazil) feasibility study of creating a multi-country push and pull fund for cancer R&D, as an alternative to incentives-based intellectual property rights and/or regulatory monopolies and to progressively delink cancer R&D costs from product prices;] (India)

OR

(OP2.5ter.Alt) to prepare a technical report towards the end of 2018 on existing mechanisms and options for R&D for cancer medicines, including the delinkage between R&D costs and product prices, that would enhance affordability and accessibility of these products; (FOR CONSIDERATION BY CAPIT ALS)

(OP2.6) to [periodically] report on progress made in implementing this resolution to the Health Assembly [in 2021], through the Executive Board, [as part of the report on progress made in the implementation of the global action plan for the prevention and control of noncommunicable diseases 2013–2020.]

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⁵ and, where applicable, regional economic integration organizations