World Health Organization

European Region

Terms of reference of the WHO Regional Office for Europe

Access to Novel Medicines Platform

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These terms of reference apply to the newly established WHO Regional Office for Europe Access to Novel Medicines Platform, which is intended to provide a framework for collaboration between WHO, Member States, non-State actors and other partner organizations to improve patient access to novel, high-cost medicines in the WHO European Region.

Contents

Context and background

1. Universal health coverage (UHC) means that all individuals and communities receive the health services they need without suffering financial hardship. Access to quality, safe, effective and affordable medicines and health products is vital to achieving UHC. Countries in the WHO European Region have voiced concern over the escalating prices and budgetary impact of novel medicines, which have restricted patient access, increased inequities and, in some cases, resulted in financial hardship. Urgent collective action is required to ensure equitable access for all patients in need, and to safeguard the sustainability of health-care systems and the innovation process.
2. WHO's European Programme of Work, 2020–2025 "United Action for Better Health in Europe"[1] (EPW) emphasizes the need to support universal health coverage by ensuring patient access for all to medicines, vaccines and health products. The Oslo Medicines Initiative of 2020–2022, a collaboration between the WHO Regional Office for Europe, the Norwegian Ministry of Health and Care Services and the Norwegian Medicines Agency,[2] identified the urgent need to define more clearly the roles and social and ethical responsibilities of the public and private sectors with respect to research, development and affordable patient access to effective, novel, high-cost medicines. This initiative paved the way for a multistakeholder collaboration platform through which the private and public sectors can collaborate with the aim of improving access to novel medicines in the WHO European Region.
3. At the 72nd session of the WHO Regional Committee for Europe in Tel Aviv, Israel, in September 2022, the Regional Office, with the agreement of Member States, issued a statement of intent to continue to act as a neutral convenor and facilitator by creating a formal stakeholder collaboration platform – the Access to Novel Medicines Platform (NMP).[3] At this meeting, Member States approved the statement, which sets out six technical areas for potential future collaboration (see paragraph 6). The initial phase for establishing the Platform focused on a series of consultations with all eligible entities (Member States, non-State actors and other partner organizations), through which the technical workplan for collaboration was prioritized, subject to resource mobilization.
4. Improving patient access to novel medicines will depend on concrete actions adopted by all stakeholders. In the WHO European Region, the NMP will serve as a unique multistakeholder collaboration mechanism to facilitate the necessary discussions and to enable stakeholders to agree on actions and potential pilot projects. Existing collaborations are not currently available to all Member States in the Region, or do not involve all the necessary stakeholders.

[1] European Programme of Work, 2020–2025 – "United Action for Better Health in Europe". Copenhagen: WHO Regional Office for Europe; 2021 (https://apps.who.int/iris/handle/10665/339209, accessed 14 April 2023).

[2] The Oslo Medicines Initiative. In: WHO/Europe [website]. Copenhagen: WHO Regional Office for Europe; 2022 (https://www.who.int/europe/initiatives/the-oslo-medicines-initiative, accessed 14 April 2023).

[3] Oslo Medicines Initiative: statement by WHO/Europe. Copenhagen: WHO Regional Office for Europe; 2022 (https://apps.who.int/iris/handle/10665/362320, accessed 14 April 2023).

Aim and objectives of the NMP

5. The aim of the Platform is to identify concrete actions, including pilot proposals, to improve affordable and equitable patient access to effective, novel, high-cost medicines in the WHO European Region. The specific objectives are:
   - to establish a collaboration mechanism to promote dialogue and knowledge exchange between Member States and with non-State actors, other partners and stakeholders to identify concrete actions to improve patient access to effective, novel, high-cost medicines;
   - to agree on actions to improve transparency in order to build trust, promote collaboration, enable horizon scanning and develop indicators to facilitate accountability and corrective actions;
   - to strengthen voluntary collaborations that focus on solidarity to achieve patient access, including evidence generation, demand aggregation, procurement and management of the lifecycle of medicines;
   - to develop principles (including for payment, pricing, health technology assessment and reimbursement) that recognize the need for sustainability of health systems and the industry, and facilitate risk sharing and good governance of markets, including how to address market failures and unmet needs.

Working groups

6. Four working groups – following the themes of transparency, solidarity, sustainability and novel antimicrobials – are proposed to meet the objectives of the Platform (paragraph 5) and to incorporate the technical areas highlighted in the Regional Committee statement:

Working group 1. Transparency

- agreement on what information can be made more **transparent** in accordance with the framework set out in World Health Assembly resolution WHA72.8 of 2019 on improving the transparency of markets for medicines, vaccines, and other health products, including to inform horizon scanning activities;
- identification of **key indicators** that improve and standardize the collection, analysis and utilization of metrics on patients' access to novel, cost-effective medicines;

Working group 2. Solidarity

- a feasibility exercise to explore the scale-up of existing voluntary efforts to **pool demand** and support **joint purchasing** of novel, cost-effective medicines;
- collaboration for the accrual, evaluation and use of **evidence** of clinical and economic value across the lifecycle of novel, cost-effective medicines;

Working group 3. Sustainability

- a review of **affordable pricing principles**;
- determination of the key elements needed for **governance** of the market, including social contracts and the role of corporate social governance.

Working group 4. Novel Antimicrobials

- to identify policy options for sustainable innovation and access to novel antimicrobials,[4] including:
  - a review of incentive coordination mechanisms for enabling sustainable research and development;
  - development of access principles (including for payment, pricing, health technology assessment and reimbursement).

Guiding principles of the NMP, including the working groups

7. The NMP is established by the WHO Regional Office for Europe, and the Secretariat is provided by the Regional Office's Division of Country Health Policies and Systems. The Platform facilitates coordination among eligible entities to agree on solutions and improve patient access to novel high-cost medicines in the Region, in line with World Health Assembly resolution WHA72.8 of 2019. The NMP is not a legal entity. It will operate through participants' voluntary commitment to achieve the shared purpose and to be consulted on the delivery, dissemination and implementation of work groups outlined in these terms of reference (ToR). The activities and operations of the Platform shall be administered by the Regional Office in accordance with WHO's Constitution, the EPW and applicable WHO policies, rules, regulations, procedures and practices, including the WHO Framework of Engagement with Non-State Actors (FENSA).[5]
8. The NMP will only operate within and in accordance with these ToR. Recommendations and proposals by the NMP are non-binding on WHO and other members of the Platformand are only intended to serve as resources to inform policy dialogue, technical action and emerging collaboration in the area of patient access to effective, novel, high-cost medicines. Each member of the Platform is responsible for implementing recommendations and activities subject to and in accordance with its own mandate, internal rules, regulations, procedures and priorities.
9. The work of the NMP will be conducted in an inclusive manner that is objective and impartial, without favour to any particular entity or other party, and that avoids unfounded bias or improper influence of stakeholders. Full and open transparency about who is participating in the NMP, their declarations of interest and the source of any contributions will be exercised and a risk management strategy will be developed and implemented. Accessibility modalities and language translation will be provided on request.
10. The composition of NMP participants will ensure gender diversity to the greatest extent possible.
11. Members of the Platform will be asked to familiarize themselves with the United Nations definitions of sexual exploitation, abuse and harassment, and to commit to zero tolerance for any form of sexual misconduct, as set out in WHO's strategy on preventing and responding to

[4] This proposal will be taken forward to the 73rd session of the WHO Regional Committee for Europe in Astana, Kazakhstan, in October 2023 as part of the development of a new European roadmap on antimicrobial resistance.

[5] In accordance with World Health Assembly resolution WHA69.10 of 2016.

sexual misconduct.[6] They should also familiarize themselves with the Code of conduct to prevent harassment, including sexual harassment, at WHO events.[7]

12. The NMP will operate for an initial period of 2023–2025, after which its further operation will be evaluated.

13. The work of the Platform will be informed by the latest scientific evidence and based on good practices.

14. The sharing and use of confidential and/or proprietary information in connection with the NMP and the working groups will be subject to Platform participants obtaining the prior written consent of the owner(s) of such information. Participants in the NMP will also need to sign a confidentiality undertaking (Annex 1).

Composition of and participation in the NMP, including the working groups

Participants and roles

15. Entities eligible to become participants in the NMP, including the working groups, are the following, with their respective roles:

- Member States in the WHO European Region – including governmental organizations, represented by ministers, senior representatives and officially nominated national and technical focal points for the Platform;
- intergovernmental organizations, including the United Nations and its specialized agencies, the European Commission and the Organisation for Economic Co-operation and Development;
- WHO collaborating centres;
- non-State actors – including nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions,[8] subject to FENSA.

Observers

16. Entities that are interested in participating but fall outside the eligible entities defined in paragraph 15 may be invited by the WHO Secretariat to exchange information and to participate in meetings relevant to implementation of the strategic priorities of the NMP.

Criteria and process for participation in the NMP

17. In order to become a participant in the NMP, each entity must both fall within one of the eligible categories set forth above in paragraph 15, and must fulfil the following application criteria.

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[6] Preventing and responding to sexual misconduct: WHO's three-year strategy 2023–2025. Geneva: World Health Organization; 2023 (https://www.who.int/initiatives/preventing-and-responding-to-sexual-exploitation-abuse-and-harassment, accessed 20 April 2023).

[7] Code of conduct to prevent harassment, including sexual harassment, at WHO events. Geneva: World Health Organization; 2021 (https://www.who.int/publications/m/item/code-of-conduct-to-prevent-harassment-including-sexual-harassment-at-who-events, accessed 20 April 2023).

[8] The categories of non-State actors follow those set out in FENSA.

General criteria

18. Participants should:
    - demonstrate a clear commitment to advancing public health;
    - agree to these ToR and their annex, and any future amendments;
    - commit to provide ongoing contributions and support to the NMP's activities in accordance with these ToR and their annex;
    - nominate focal point(s) for matters relating to the Platform and its activities;
    - demonstrate adherence to and compliance with relevant international technical norms and standards – especially those established by WHO;
    - demonstrate engagement in activities relevant to patient access to medicines.

Specific criteria for non-State actors

19. In addition to the above, non-State actors should:
    - operate at a regional level, or be global organizations that work at a European regional level – either under a registered European entity or with an advocacy focus on European institutions and issues;
    - have a remit and be able to demonstrate recent activity relating to patient access to medicines or representing a clinical professional group;
    - for preference, have a European umbrella organization, if available and possible.

20. Further to the requirements described above, acceptance of non-State actors as participants in the Platform is guided by the following specific requirements that non-State actors should:
    - demonstrate a clear benefit to public health;
    - adhere to WHO's Constitution, rules and procedures including, but not limited to, the overarching principles contained in FENSA;
    - respect the intergovernmental nature of WHO and the decision-making authority of Member States as set out in the WHO's Constitution;
    - support and enhance, without compromising, the scientific and evidence-based approach that underpins WHO's work;
    - not compromise WHO's integrity, independence, credibility and reputation;
    - not engage with the tobacco industry or with non-State actors that work to further the interests of the tobacco industry;
    - not engage with the arms industry.

21. Parties interested in participating in the NMP and its working groups who have not previously been involved with the Oslo Medicines Initiative may submit an expression of interest in writing to the WHO Europe Secretariat. Following receipt of the written expression of interest, WHO will perform a preliminary screening to determine whether the applicant meets the eligibility criteria set out in these ToR for participation in the Platform.

22. All interested NMP participants will be provided with a copy of these ToR (including, but not limited to, the confidentiality undertaking contained in Annex 1), as well as any request for

additional information required to comply with FENSA. Eligible entities will be required to agree to, sign and return to WHO copies of these ToR and of the confidentiality undertaking attached as Annex 1, as a condition precedent to their participation in the Platform.

23. Acceptance of non-State actors will be subject to the conduct of due diligence and risk assessment, in accordance with the provisions of FENSA. Non-State actors will be required to submit adequate information and documentation regarding legal status, membership, mandate, aims and objectives, sources of funding (including list of donors and sponsors) and a summary of activities (nature and scope) as they relate to the criteria to become a participant in the NMP. Non-State actors will be required to sign the tobacco/arms disclosure statement. Following receipt of the supporting materials and documentation, WHO will review the same and determine whether the interested non-State actor meets, in principle, the general criteria and the specific criteria set out in paragraphs 20 and 21 for participation in the Platform and its working groups. WHO may request further clarification from the interested entity, should it be necessary to determine whether any such criteria are met. WHO will determine whether an interested entity will be eligible and formally accepted to join the NMP, and will inform successful applicants of the same in writing.

24. Intergovernmental organizations, including the United Nations and its specialized agencies and the European Commission,governmental organizations (as defined in paragraph 15) and WHO collaborating centres for pharmaceutical policy need only send written correspondence to be considered participant of the Platform and its working groups. Non-State actors, including observers (as defined in paragraphs 15 and 16), will be subject to the full application process as defined in these ToR, including due diligence and risk assessment in accordance with the provisions of FENSA.

Application process for the working groups

25. Following the initial consultation process with all eligible entities and NMP participants outlined above, the WHO Secretariat will call on Platform participants to nominate those who may wish to be actively involved in the working groups outlined in paragraph 6. The WHO Regional Office for Europe will ensure fair representation of eligible entities for each working group.

26. Proposed participants in the working groups will be required to complete a declaration of interest form, and their acceptance is subject to evaluation of completed forms by WHO. Non-State actors will be subject to the full application process as defined in these ToR, including due diligence and risk assessment in accordance with the provisions of FENSA.

Methods of work

27. The WHO Secretariat will support and contribute to the process of achieving the purpose and objectives of the NMP by supporting activities in all areas of collaboration. The work of the NMP will be coordinated by the WHO Secretariat, and oversight and guidance will be provided by the WHO Regional Committee for Europe and the Standing Committee of the Regional Committee. Responsibility for execution of the strategic priorities of the NMP rests with the WHO Secretariat, subject to WHO's rules and procedures and availability of funding. Progress will be reported through consultations with Member States, non-State actors and other partners. All draft NMP documents developed will be shared with and consulted upon by the NMP focal points and there will be regular progress flash reports also circulated. Formal reporting will also occur through the governance subgroup of the Standing Committee of the Regional Committee at their regular meetings.

28. Participants may use face-to-face or online meetings and electronic communication methods for the exchange of information related to the work of the NMP. The need for face-to-face or online

meetings of Platform participants will be determined and coordinated by the WHO Secretariat, which will – at its discretion – convene such meetings and develop the related meeting agenda.

29. In pursuing its objectives, the NMP will respect the responsibilities of the Member States, the Commission and other Union bodies or agencies, and the responsibilities of third countries and international organisations active within the field of public health.In order to ensure that there is comprehensiveness, coherence and complementarity of action, and that actions are coordinated, the WHO Secretariat will seek representation within the Platform and its working groups.

Participation in the working groups

30. Within the NMP, time-limited working groups will be established to deliver its aims and objectives to identify concrete deliverables, including pilot proposals, as outlined in paragraph 6.
31. Participation in the working groups will be voluntary, and each working group will be chaired by a Member State representative, with vice-chairs drawn from non-State actors and other partners. In addition, ad hoc working groups and workshops may be convened by the WHO Regional Office for Europe to address specific issues, as needed. Individual experts may be consulted and/or invited by the Secretariat to provide advice on specific technical issues in accordance with WHO rules and procedures, including FENSA. The scope of work undertaken will be dependent on available resources.
32. The working group proposals, ToR and materials will be developed by the Regional Office in conjunction with the working group participants. The ToR for each working group will outline its objectives, activities and deliverables. Once finalized and agreed by WHO, eligible entities will have the opportunity to disseminate and implement working group materials in their respective contexts, based on need, opportunity and availability of resources, subject to any confidentiality obligations.

Confidentiality

33. A confidentiality undertaking must be signed by each Platform participant, as well as by each observer, as a condition of participation/involvement in the NMP (see Annex 1).
34. Without limiting or prejudicing the terms and conditions of the confidentiality undertaking, each participant in the NMP agrees to:
    - maintain the confidentiality of (and refrain from disclosing to any third parties) any confidential information and materials shared by or on behalf of WHO and/or any Platform participant, except when expressly indicated otherwise in writing by WHO;
    - maintain the confidentiality of (and refrain from disclosing to any third parties) any views or opinions expressed by WHO and/or any Platform participant, as well as of any deliberations and discussions held in the context of the NMP or any of its activities, except when expressly indicated otherwise in writing by WHO.

Financing of the NMP

35. Each member of the NMP shall be responsible for covering all costs and expenses relating to its participation in the Platform’s work and activities – including, but not limited to, travel and subsistence expenses in connection with attendance at meetings.

36. When possible, at its sole discretion and subject to a signed agreement, the WHO Regional Office for Europe may provide financial support to NMP participants for specific Platform activities. This does not prejudice or preclude separate funding arrangements, if any, entered into between WHO and Platform participants.
37. Subject to the availability of sufficient financial resources for this purpose, the day-to-day routine operations of the Secretariat to the NMP will be financed by the Regional Office.
38. The Regional Office may also, at its sole discretion, seek to raise funds or accept financial and/or in-kind contributions from external sources to support NMP activities, in accordance with WHO's rules, regulations, policies, procedures and practices.

Publications and deliverables

39. As a general rule, and at its discretion, the WHO Regional Office for Europe shall be responsible for issuing publications and other materials (including without limitation those of the working groups defined in paragraph 6, as well as communication outputs and meeting/event reports) about NMP activities ("NMP materials"). For the avoidance of doubt, publication and dissemination of such NMP materials will only be made by WHO, or by a Platform participant as decided by WHO on a case-by-case basis. Copyright in any NMP materials prepared or commissioned by WHO shall be vested in WHO. This also applies if the work is issued by WHO as a compilation of works by Platform participants, or is otherwise work prepared with input from one or more Platform participants.
40. Subject to the proprietary rights of WHO, any NMP participant (the "publishing party") may prepare and issue publications on its own subject, with the prior approval of the Regional Office, and provided that WHO has been given the opportunity to comment on the content before publication, which comments shall be given due and good faith consideration by the publishing party.
41. The publishing party shall have the right to claim copyright of any publication as a whole issued by it as part of NMP activities. The copyright of any contribution made to the publication by WHO will be retained by WHO with a non-exclusive, sublicensable, worldwide, royalty-free licence to the publishing party to deal with the contribution for all purposes, in all manners and in all formats, as part of the publication. WHO will be appropriately acknowledged in the publication. The wording of the acknowledgement shall be agreed between the parties.
42. WHO publishes all its publications under the WHO open access policy using the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO (CC BY-NC-SA 3.0 IGO) licence, which permits free reuse of WHO publications for non-commercial purposes. Any publication issued by a Platform participant shall be published under a similar open access licence.
43. No publication or other work resulting from NMP activities shall contain commercial advertising or be taken as an endorsement or used for the promotion of any company, commercial product or service.
44. Any publication about NMP activities issued by a Platform participant other than WHO is to contain appropriate disclaimers as decided by WHO, including that the content does not necessarily reflect the views or stated policy of the participants (including WHO, acting as the Secretariat for the NMP).
45. For the avoidance of doubt, WHO shall be vested with a non-exclusive, worldwide, royalty-free and sublicensable license to use, reproduce, synthesize, adapt, publish and disseminate in whatever format – paper, electronic or otherwise – and in whatever manner WHO may deem appropriate for public health purposes, the work produced by each Platform participant within the context and work of the NMP.

Public communications

46. As a general rule and at its discretion, the WHO Regional Office for Europe shall be responsible for issuing all public communications relating to the NMP's work and activities. In this regard, Platform participants shall not make or issue any public statements/materials or press releases concerning the NMP, its work or any of its activities, or on behalf of WHO, unless specifically requested or authorized to do so in writing by WHO.
47. The contributions to the NMP made by its participants will be acknowledged by WHO in accordance with its applicable rules, regulations and procedures.

Use of the names and emblems

48. The use of the NMP's name, abbreviation and emblem is restricted to WHO and Platform participants, but only with prior express written approval of WHO.
49. NMP participants and observers shall not use the name, abbreviation or emblem of WHO in any manner and for any purpose, without prior written consent of WHO.

Liability

50. Under no circumstances shall WHO assume any liability for acts carried out by Platform participants, regardless of whether such acts were carried out in the name of the NMP. Furthermore, WHO, at its sole discretion, may refrain from implementing any recommendation or proposal of the NMP if, in the view of WHO, such a recommendation or proposal gives rise to undue financial, legal or reputational liability, or is contrary to WHO rules, regulations, administrative practices, programmes and policies.

Termination of participation in the NMP

51. Any participant may terminate its involvement in the NMP by providing three months' written notice to WHO. In addition, WHO, at its sole discretion, may terminate the involvement in the NMP of any participant by providing three months' written notice. Upon the issuance of a termination notice by either party, the WHO Regional Office for Europe and the Platform participant will work collaboratively and in good faith to bring to an orderly conclusion any ongoing activities by the termination date.

Amendments

52. These ToR may be amended by the WHO Regional Office for Europe, and all Platform participants shall be informed of such changes and shall be required to endorse them as a condition of their continuing participation in the NMP.

Annex 1

CONFIDENTIALITY UNDERTAKING

1. The WHO Regional Office for Europe has established a collaborative mechanism for enhanced coordination among relevant eligible entities in implementing the strategic priorities of the European Programme of Work, 2020–2025 – "United Action for Better Health in Europe" by means of the Access to Novel Medicines Platform (hereinafter the "Platform" or "NMP").
2. In connection with the Platform, participants in the NMP may gain access to confidential and/or proprietary information, documents and other materials which are disclosed by WHO and/or other third parties collaborating in the Platform (including, without limitation, participants, supporters and ministries of health), and which are clearly stated or marked by such disclosing parties to be confidential (collectively, "confidential information"). To safeguard the confidentiality of such confidential information, each participant and supporter in the Platform (including, without limitation, the undersigned) is required to sign the undertaking set forth in this document.
3. The undersigned hereby undertakes to treat the confidential information as confidential and proprietary to WHO and/or third parties collaborating in the NMP, and to use the confidential information solely for the purposes of carrying out the activities, meetings and recommendations of the Platform at the regional and/or national levels (collectively, the "purpose"), and for no other purpose. The undersigned also agrees to take all reasonable measures to ensure that confidential information is not used, copied, disclosed or otherwise transmitted, whether in whole or in part, by or on behalf of the undersigned to any third parties; except for third parties who have a need to know the confidential information for the purpose of the Platform's activities and who are bound by obligations of confidentiality and restrictions on use that are substantially similar to those contained in this undertaking.
4. The undersigned shall not be bound by any confidentiality obligations or restrictions on use contained herein if and to the extent that the undersigned is clearly able to demonstrate that the confidential information:
    - was known to the undersigned prior to its disclosure by WHO or any third parties collaborating in the Platform;
    - was in the public domain at the time of disclosure to the undersigned by WHO or any third party collaborating in the Platform;
    - becomes part of the public domain through no fault of the undersigned;
    - becomes available to the undersigned from a third party not in breach of any legal obligations of confidentiality or restrictions on use.
5. The undersigned undertakes not to communicate any of the materials, discussions, outputs, results or recommendations of the NMP or any of its governing bodies or working groups to any third parties, except as authorized in writing by WHO.
6. Upon WHO's request, the undersigned shall promptly return to WHO or third parties collaborating with the NMP, as applicable, any and all copies of their respective confidential information that are then in the undersigned's possession or control.
7. The obligations of the undersigned pursuant to this undertaking shall survive the termination of the undersigned's participation in the Platform.

8. Any dispute relating to the interpretation or application of this undertaking shall, unless amicably settled, be subject to a conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the rules of arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.
9. Nothing contained in or relating to this undertaking shall be deemed or construed as a waiver of any of the privileges and immunities enjoyed by WHO, or as submitting WHO to any national court jurisdiction.

Agreed to and accepted by the undersigned as of the date set forth below.

For and on behalf of

[Insert full name of entity]

Signature: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Name: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Title: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Date: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

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