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## **Addressing the global shortage of, and access to, medicines and vaccines**

### **Report by the Secretariat**

1. The Executive Board at its 140th session noted an earlier version of this report.<sup>1</sup> The title of the report has been updated as agreed by the Board to reflect the importance of access to medicines as a broader public health issue.<sup>2</sup> The report has been revised (particularly paragraphs 2–15) to provide an account of the latest developments relating to implementation of resolution WHA67.22 (2014) on access to essential medicines. It includes information on progress by Member States and the work of the Secretariat to support countries in ensuring access to affordable, high-quality, essential medicines.

#### **ACCESS TO MEDICINES**

2. In 2014, the Health Assembly in resolution WHA67.22 requested the Director-General *inter alia*: to urge Member States to recognize the importance of effective national medicines policies, and their implementation under good governance; to facilitate collaboration among Member States on how to implement medicines policies most effectively; to support Member States in the selection of essential medicines and in ensuring a supply of affordable and effective essential medicines; to support Member States in monitoring essential medicines shortages; to urge Member States to expedite progress towards the achievement of the Millennium Development Goals; and to provide, on request, in collaboration with other international organizations, technical support on issues relating to intellectual property and access. In 2016, the Sixty-ninth World Health Assembly noted a progress report on implementation of that resolution.<sup>3</sup>

3. The continuing importance of ensuring access to essential medicines has been recognized in target 3.8 of the Sustainable Development Goals, which aims to achieve universal health coverage, including access to safe, effective, quality and affordable essential medicines for all. Access to medicines has also been recognized as a crucial element of the solutions to numerous important public health problems and features in several Health Assembly resolutions, such as resolution WHA60.16 (2007) on progress in the rational use of medicines, resolution WHA69.20 (2016) on promoting innovation and access to quality, safe, efficacious and affordable medicines for children, resolution WHA67.23 (2014) on health intervention and technology assessment in support of universal health coverage, and resolution WHA69.25 on addressing the global shortage of medicines and vaccines.

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<sup>1</sup> See document EB140/19 and the summary records of the Executive Board at its 140th session, ninth meeting.

<sup>2</sup> See the summary records of the Executive Board at its 140th session, eighteenth meeting, section 2.

<sup>3</sup> See document A69/43, G and the summary records of the Sixty-ninth World Health Assembly, Committee B, seventh meeting, section 3 (document WHA69/2016/REC/3).

Access to medicines is central to strategies and action plans for programmes implemented across the Secretariat, such as those on antimicrobial resistance, noncommunicable diseases, maternal and child health, HIV, tuberculosis and malaria. Access to medicines under international control has been identified as a priority by the United Nations General Assembly which adopted in resolution S-30/1 (2016) the outcome document of its special session on tackling the world drug problem.<sup>1</sup> Member States and the Director-General have been requested to improve access to controlled medicines through several Health Assembly resolutions, such as those on palliative care and the management of pain, emergency surgery and anaesthesia, and mental health disorders such as epilepsy.<sup>2</sup>

4. In 2016, the United Nations Secretary-General convened the High-Level Panel on Access to Medicines “to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies”. WHO participated in discussions through its membership in the Expert Advisory Group, and made a substantive submission to the Panel.<sup>3</sup> The report of the High-Level Panel<sup>4</sup> echoes conclusions of previous reports prepared under the auspices of WHO, which drew attention to disparities in research and development and lack of access to essential medicines (in particular the reports of the Commission on Intellectual Property Rights, Innovation and Public Health<sup>5</sup> and the Consultative Expert Working Group on Research and Development<sup>6</sup>). It also picks up elements of WHO’s global strategy and plan of action on public health, innovation and intellectual property. A major theme of the High-Level Panel’s report is the call for more policy coherence – in line with the global strategy and plan of action, which requested WHO to work more closely with other relevant international agencies, namely UNCTAD, WIPO and WTO.

5. Access to quality, safe and effective medicines requires a comprehensive health systems approach that addresses all of the stages throughout the medicines value chain from needs based research, development and innovation; manufacturing processes and systems that ensure quality products as well as managing the problem of substandard and falsified medicines; public health-oriented intellectual property and trade policies; selection, pricing and reimbursement policies; integrity and efficiency of procurement and supply; and appropriate prescribing and use. Throughout this chain there is a need to oversee the quality, safety and efficacy of medicines. Pharmaceutical systems need to meet the needs of specific populations such as children and people requiring palliative care and need to be responsive in the face of emerging threats. In addition, routine and transparent monitoring of quality, access and use is essential to support decision-making and accountability as well as allowing adaptation of national policies to respond to evolving community needs. Progress has been made by the Secretariat in several of these areas, as described below.

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<sup>1</sup> Available at: <http://www.unodc.org/documents/postungass2016//outcome/V1603301-E.pdf> (accessed 15 March 2017).

<sup>2</sup> Respectively, resolutions WHA67.19 (2014), WHA68.15 (2015) and WHA68.20 (2015).

<sup>3</sup> See: [http://www.who.int/phi/implementation/ip\\_trade/high-level-panel-access-med/en/](http://www.who.int/phi/implementation/ip_trade/high-level-panel-access-med/en/) (accessed 14 March 2017).

<sup>4</sup> Available at: <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf> (accessed 21 March 2017).

<sup>5</sup> See: <http://www.who.int/intellectualproperty/report/en/> (accessed 3 March 2017).

<sup>6</sup> WHO. Research and development to meet health needs in developing countries: strengthening global financing and coordination. Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination. Geneva: World Health Organization; 2012 (<http://apps.who.int/iris/bitstream/10665/254706/1/9789241503457-eng.pdf?ua=1>, accessed 16 March 2017).

(a) **Needs-based research, development and innovation.** The Global Observatory on Health R&D went live in January 2017 and provides information on research and development for products for neglected diseases.<sup>1</sup> The Global Antibiotic Research and Development Partnership, a joint activity of WHO and the Drugs for Neglected Diseases initiative, has been established for developing and delivering new or improved antibiotic treatments, while endeavouring to ensure sustainable access. WHO has published a priority pathogens list to highlight neglected areas of research and development. Moreover, under the strategy and plan of the R&D Blueprint, WHO is maintaining a list of priority emerging infectious diseases that have epidemic potential. This list is updated annually. In the future, it is expected that WHO's new Expert Committee on Health Research and Development<sup>2</sup> will provide oversight to the above prioritization exercises.

(b) **National regulatory capacity and local production.** In line with resolution WHA61.21 (2008) on the global strategy and plan of action on public health, innovation and intellectual property, preparatory work was carried out to look at the interplay of health and industrial policies and to explore the trends and context of mechanisms that ensure quality-assured local production. A regulatory benchmarking tool has been developed and used in several countries, it serves as an important method for identifying gaps in regulatory capacity that need to be filled in order to ensure quality-assured medicines. To support access to products in emergency situations, new regulatory pathways are now being evaluated.

(c) **Quality, safety and efficacy.** To ensure access to quality-assured pharmaceuticals, WHO not only sets norms and standards by developing appropriate guidelines and reference standards, but also supports Member States and their national regulatory authorities on issues related to safety and quality of medicines. The Secretariat continues to provide support to countries in building national regulatory capacity for regulation and pharmacovigilance of health products through harmonization and networking initiatives, regional or country-specific training programmes and information sharing. These activities have been endorsed and supported by Member States through numerous Health Assembly resolutions including WHA67.20 (2014) on regulatory system strengthening for medical products. Prequalification of medicines, vaccines, diagnostics and vector control products by WHO is an important component of these activities and mandate.

(d) **Substandard and falsified medicines.** The Member State Mechanism on Substandard/Spurious/Falsely-labelled/Falsified/Counterfeit Medical Products has requested research to examine the links more closely between accessibility and affordability and their impact on the emergence of substandard and falsified medical products.<sup>3</sup> That research has recently commenced with a view to reporting back to the Mechanism at the end of 2017. Examination of reports received by the WHO Global Surveillance and Monitoring System for substandard and falsified medical products clearly indicates that shortages and stock outs of medicines and vaccines contribute to the appearance of substandard and falsified medical products in the supply chains.

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<sup>1</sup> Available at <http://www.who.int/research-observatory/en/> (accessed 22 March 2017).

<sup>2</sup> See document EB140/22 and the summary records of the Executive Board at its 140th session, eleventh meeting.

<sup>3</sup> See document A/MSM/5/2 ([http://apps.who.int/gb/ssffc/pdf\\_files/MSM5/A\\_MSM5\\_2-en.pdf](http://apps.who.int/gb/ssffc/pdf_files/MSM5/A_MSM5_2-en.pdf), accessed 14 March 2017).

(e) **Public health-oriented intellectual property and trade policies.** WHO, WIPO and WTO have intensified their collaboration in order to foster a better understanding of the linkage between public health and intellectual property policies and to enhance a mutually supportive implementation of those policies. Based on the three organizations' joint study on promoting access to medical technologies and innovation<sup>1</sup> the aim of collaboration is that: each agency can fulfil its own mandate more effectively; respective initiatives support each other; efforts are not duplicated; and resources are used efficiently. Collaboration covers various areas, including training activities, joint symposia and joint publications.<sup>2</sup> WHO has also intensified its collaboration with UNCTAD on local production and continues to work closely with United Nations programmes and international agencies, including UNAIDS, UNDP and UNITAID. In December 2016 WHO called for an "all-agency meeting" with UNAIDS, UNCTAD, UNDP, UNITAID, WTO, WIPO and the High Commissioner for Human Rights to discuss the different activities and plan for the future, including how to best follow up on the High-Level Panel's report. The Secretariat provided guidance and advice to Member States on the interrelationship of public health, intellectual property and trade policies, including how to make use of the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights as recognized by the Doha Declaration on the TRIPS Agreement and Public Health in line with the mandate of WHO conferred by the global strategy and plan of action on public health, innovation and intellectual property. Detailed reports on these activities over the past 16 years can be found on the WHO website.<sup>3</sup> WHO has also engaged in various training activities and published updated patent information on the new treatments for hepatitis C and those for cancer and diabetes.<sup>4</sup>

(f) **Selection of medicines.** Additional medicines for cancer and new medicines for hepatitis C and tuberculosis were included in the 19th WHO Model List of Essential Medicines and the 5th WHO Model List of Essential Medicines for Children. Antibiotics for infectious diseases, sexually transmitted infections and paediatric indications were reviewed by the Expert Committee on the Selection and Use of Essential Medicines at its 21st meeting (Geneva, 27–31 March 2017), which also evaluated medicines for noncommunicable diseases including cancer, palliative care and diabetes. WHO is preparing treatment guidelines for the management of pain in cancer patients. In 2015, some 140 countries had established national lists of essential medicines.

(g) **Pricing, reimbursement and affordability.** The WHO guideline on country pharmaceutical pricing policies was issued in 2015 to support Member States in managing pharmaceutical prices.<sup>5</sup> In 2016, WHO published the first global report on access to treatment

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<sup>1</sup> WHO, WIPO, WTO. Promoting access to medical technologies and innovation: intersections between public health, intellectual property and trade. Geneva: World Health Organization, World Intellectual Property Organization, World Trade Organization; 2012 ([http://www.who.int/phi/promoting\\_access\\_medical\\_innovation/en/](http://www.who.int/phi/promoting_access_medical_innovation/en/), accessed 15 March 2017).

<sup>2</sup> For details see: [http://www.who.int/phi/implementation/trilateral\\_cooperation/en/](http://www.who.int/phi/implementation/trilateral_cooperation/en/) (accessed 14 March 2017).

<sup>3</sup> Overview on technical cooperation programmes relating to the implementation of the TRIPS agreement. available at: [http://www.who.int/phi/wto\\_communications/en/](http://www.who.int/phi/wto_communications/en/) (accessed 7 March 2017).

<sup>4</sup> The role of intellectual property in local production in developing countries: opportunities and challenges. Geneva: World Health Organization; 2016 ([http://www.who.int/phi/publications/int\\_prop\\_local\\_prod\\_opportunities\\_challenges/en/](http://www.who.int/phi/publications/int_prop_local_prod_opportunities_challenges/en/), accessed 14 March 2017).

<sup>5</sup> WHO. WHO guideline on country pharmaceutical pricing policies. Geneva: World Health Organization; 2016 ([http://apps.who.int/iris/bitstream/10665/153920/1/9789241549035\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/153920/1/9789241549035_eng.pdf?ua=1), accessed 14 March 2017).

for hepatitis C,<sup>1</sup> which provides detailed information on the patent and regulatory status of the new hepatitis C treatments and pricing information for all new treatments, and describes ways to access these treatments at affordable prices. Expert consultations took place in November 2015 on health technology assessment and in November 2016 for the review of the 10 key policy areas to ensure access to affordable medicines. The consultations prepared the way for the Fair Pricing Forum due to be held in Amsterdam (the Netherlands, 11 May 2017), which will explore options to ensure a sustainable supply of affordable, quality medicines, including assessment of the production costs of essential medicines.

(h) **Efficient procurement and supply-chain management.** Support has been provided to Member States for the establishment of policies and good practices, as well as capacity-building for improving governance, efficiency and quality of procurement and supply-chain management, both in ordinary and emergency situations. The work includes normative guidance and support to countries to improve coordination and quality of donations and the development of pre-packaged medical kits (for example, the Interagency Emergency Health Kit and the piloting and expanding use of noncommunicable diseases kits).

(i) **Appropriate prescribing and rational use.** Guidelines on the use of antimalarials, contraceptives, medicines for the treatment of maternal infections and other medicines have been published.<sup>2</sup> The Secretariat is leading work on surveillance of the consumption and use of antimicrobial medicines. An expert consultation (Geneva, 29 March–1 April 2016) contributed to the development of a WHO methodology for surveillance of antimicrobial consumption.<sup>3</sup> Training and survey implementation began in 2016. The Secretariat developed a protocol for WHO's hospital point prevalence survey on antimicrobial use on the basis of that issued by the European Centre for Disease Prevention and Control. Implementation of surveys of use of antimicrobials in hospitals is planned for later in 2017.

(j) **Access to controlled medicines.** WHO has played a leading role in the promotion of balanced public policies, including a published guidance document.<sup>4</sup> It has also responded to the challenges in forecasting and quantification of controlled medicines by issuing a joint WHO/International Narcotics Control Board guide on estimating requirements for substances under international control.<sup>5</sup> WHO works in close collaboration with the United Nations Office on Drugs and Crime and the International Narcotics Control Board to promote access to controlled medicines, providing training and support to countries. WHO is part of the Joint Global Programme (in cooperation with the United Nations Office on Drugs and Crime and Union for International Cancer Control) on access to controlled medicines for medical purposes,

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<sup>1</sup> Global report on access to hepatitis C treatment – focus on overcoming barriers. Geneva: World Health Organization; 2016 (<http://www.who.int/hepatitis/publications/hep-c-access-report/en/>, accessed 14 March 2017).

<sup>2</sup> Available through the information portal: <http://apps.who.int/medicinedocs/en/> (accessed 16 March 2017).

<sup>3</sup> Available at: [http://www.who.int/medicines/areas/rational\\_use/WHO\\_AMCsurveillance\\_1.0.pdf?ua=1](http://www.who.int/medicines/areas/rational_use/WHO_AMCsurveillance_1.0.pdf?ua=1) (accessed 14 March 2017).

<sup>4</sup> Ensuring balance in national policies on controlled substances: guidance for availability and accessibility of controlled medicines. Geneva: World Health Organization; 2011 ([http://apps.who.int/iris/bitstream/10665/44519/1/9789241564175\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44519/1/9789241564175_eng.pdf), accessed 3 March 2017).

<sup>5</sup> Available at: [http://www.who.int/medicines/areas/quality\\_safety/guide\\_estimating\\_requirements/en/](http://www.who.int/medicines/areas/quality_safety/guide_estimating_requirements/en/) (accessed 3 March 2017)

in particular for the management of pain.<sup>1</sup> The Secretariat provides support to countries for identifying potential regulatory or procurement barriers that limit access to controlled substances and for identifying potential interventions to improve access.

(k) **Transparency.** WHO's Global Price Reporting Mechanism provides pricing and procurement data for HIV, tuberculosis and malaria treatments and has recently been expanded to include the new hepatitis C treatments.<sup>2</sup> The Secretariat has set up a comprehensive web platform that provides data on vaccine product, price and procurement with the goal of increasing price transparency and informing decisions on vaccine introduction and implementation.<sup>3</sup> Within the framework of a new initiative on fair pricing, WHO is assessing the production costs of essential medicines. The results of such analysis will allow procurement agencies to evaluate better their performance and will contribute to the overall objective of transparency.

(l) **Monitoring.** WHO has developed a data collection tool for gathering information on the prices and availability of medicines using a smartphone application. In early 2016, pilot tests in 19 low- and middle-income countries proved the application to be a simple and cost-effective way to collect national data on access to medicines. The use of the tool is now being extended to more countries and being used for programme-specific purposes such as gathering price and availability data on medicines for noncommunicable diseases.

6. Despite the diverse initiatives towards improving access to medicines described above, more effort is required to improve access to quality medicines, including measures in national policies and plans, through regional activities and by committing resources, as recommended in resolution WHA60.16 (2007) on progress in the rational use of medicines.

## SHORTAGES

7. In resolution WHA69.25 (2016) on addressing the global shortage of medicines and vaccines, the Health Assembly requested the Director-General "to develop technical definitions, as needed, for medicines and vaccines shortages and stock outs, taking due account of access and affordability in consultation with Member State experts in keeping with WHO-established processes, and to submit a report on the definitions to the Seventieth World Health Assembly, through the Executive Board".

8. WHO commissioned a systematic review of the available definitions used in the management of shortages and stock outs of medicines and vaccines. The preliminary results revealed, among other things, that functional definitions vary broadly depending on the context in which they are used,

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<sup>1</sup> See <https://www.unodc.org/unodc/en/drug-prevention-and-treatment/access-to-controlled-medicines/accessibility-medicines-availability-glok67.html> (accessed 14 March 2017).

<sup>2</sup> <http://www.who.int/hiv/amds/gprm/en/> (accessed 14 March 2017).

<sup>3</sup> See: [http://www.who.int/immunization/programmes\\_systems/procurement/v3p/platform/module1/en/](http://www.who.int/immunization/programmes_systems/procurement/v3p/platform/module1/en/) (accessed 14 March 2017).

underscoring the need to harmonize and develop well-understood definitions.<sup>1</sup> The review also showed that terms are used interchangeably to refer to different aspects of shortages.

9. Together, the preliminary results of the systematic review and consultations with Member States and experts in supply-chain and programme management for medicines and vaccines allow the following conclusions to be drawn.

(a) On the supply side, existing definitions and indicators are found mainly in reporting mechanisms established by national medicines regulatory authorities – which therefore vary from country to country – and which require timely advance notice of potential shortages by market authorization holders. The advance notification mechanisms use these definitions as part of a system to detect shortages at the manufacturing level and to plan approaches to mitigating the potential negative impact of a shortage or stock out on the public health system, such as the rapid deployment of other supply sources or the temporary use of other clinically appropriate medicines. These systems and the related definitions were developed with a view to providing public health solutions at the national level.

(b) On the demand side, existing definitions are used mainly in reference to problems related to procurement, planning and supply-chain management. These definitions most frequently describe and define various types of disruptions at various levels in medicines and vaccines supply systems, ranging from the absence of a physical inventory to failures to meet the needs of individual patients. In the case of a stock out, the demand-side definitions are generally also linked to the duration of the stock out; however, the time-bound aspects of the demand-side definitions are measured only in terms of hours and days and not in terms of consequences to the patient of delayed treatment.

(c) The existing definitions used in relation to both the supply and the demand sides include references to reporting mechanisms and to the availability of data related to shortages and stock outs. In the case of supply-side shortages and stock outs, summary information on specific products is generally made available to the public by the responsible agencies, usually a national medicines regulatory authority. In the case of demand-side shortages, data come from multiple sources and are not systematically validated or provided to a central entity. Also on the demand side, information is limited regarding the management of data from the various reporting mechanisms, and there is an absence of systems to manage the quality, reliability and appropriate use of these data across multiple potential data sources. Immunization programmes frequently have separate monitoring and reporting mechanisms.

10. Based on the preliminary results of the systematic review and the consultations, the Secretariat has developed a draft technical definition of shortages and stock outs of medicines and vaccines. In addition, it is designing a framework for the purpose of articulating more detailed considerations, such as variables for implementation and indicators for measurement. The overarching draft technical definition is divided into supply-side and demand-side definitions, in accordance with the outcome of the systematic review and informal expert consultations.

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<sup>1</sup> See WHO. Meeting report: technical definitions of shortages and stockouts of medicines and vaccines. Geneva: World Health Organization; 2017 ([http://www.who.int/medicines/areas/access/Meeting\\_report\\_October\\_Shortages.pdf?ua=1](http://www.who.int/medicines/areas/access/Meeting_report_October_Shortages.pdf?ua=1), accessed 16 March 2017).

11. The draft definition, which refers to shortages on the supply side and shortages and stock outs on the demand side, reads as follows:

- On the supply side: a “shortage” occurs when the supply of medicines, health products or vaccines identified as essential by the health system is considered to be insufficient to meet public health and patient needs. This definition refers only to products that have already been approved and marketed, in order to avoid conflicts with research and development agendas.
- On the demand side: a “shortage” will occur when demand exceeds supply at any point in the supply chain and may ultimately create a “stock out” at the point of appropriate service delivery to the patient if the cause of the shortage cannot be resolved in a timely manner relative to the clinical needs of the patient.

12. All definitions must have a clear purpose, and guidance on the appropriate context is needed in order for them to be useful and to avoid unintended consequences. Examples of unintended consequences include instances of reporting of shortages at the wholesale level contributing to hoarding and price increases. In addition, the reporting of shortages at lower levels of the supply chain is considered to be a sensitive area, as health care workers could face reprisals for shortages or stock outs and may therefore avoid reporting them. A report of a facility stock out is a useful indicator of the overall status of a facility or system, but is not diagnostic in nature, underscoring the need for guidance on the use of such reports. National medicines regulatory authorities that monitor shortages and stock outs among their market authorization holders have specific requirements and use reported data to react with multiple mitigation responses; however, the capacity to implement a reporting and response system depends on resources. Furthermore, the impact of shortages in one region of the world may be limited to that particular region, or may have global consequences, depending on the manufacturing base of the medicine or vaccine. Final definitions will be accompanied by guidance on how to use the definitions in various contexts, including on how best to use the definitions in appropriate strategies in order to mitigate or avoid a shortage or stock out.

13. The Secretariat will conduct a broader Member State consultation in 2017 in order to expand the involvement of stakeholders, including those from countries with small markets and in remote locations, in the development of these definitions and the understanding of the causes of shortages and the relation with issues of access and affordability. Appropriate guidance will be developed and strategic efforts will be continued to develop a notification system for medicines and vaccines at risk of shortage.

14. Pursuant to the other provisions of resolution WHA69.25, the Secretariat has embarked on collaborative work on health data management, notably as part of the Health Data Collaborative, to promote the availability of reliable data on shortages and stock outs and data for improved planning and management. In addition, WHO’s programme on the prequalification of medicines and vaccines aims to include medicines at risk of shortage and stock outs in order to provide efficient regulatory pathways and contribute to improved market stability. In this regard, the programme’s fee structures have been revised to ensure its sustainability. WHO is also supporting collaboration at high levels across supply-chain programmes and will serve as the secretariat for the Interagency Supply Chain Group in 2017.

## **ACTION BY THE HEALTH ASSEMBLY**

15. The Health Assembly is invited to note the report.

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