Cancer Care Commission
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CANCER CARE COMMISSION – Quality of Cancer Medicines Initiative (as of 5.5.22)

Draft questions aligned with identified themes from Expert Panel July 1, 2021

Each response should include

- An interpretation of the question based on the individual's background
- An overview of the scope of the response
- Specific ways of implementing and measuring the recommended actions
- 3-5 key audiences to address in the recommended action and best ways to reach them
- Consider policy implications

Theme 1: Access to affordable, quality medicines

Q1) How do we improve access to both affordable and quality essential cancer medicines and innovative cancer medicines?

In your response, please consider the following:

- Essential Cancer Medicines, Innovative Cancer Medicines: How are you defining quality and affordability?
- HTAs: Does your country have an HTA organization (e.g., the UK National Institute for Health and Care Excellence (NICE) https://www.nice.org.uk/, The European Patients' Academy on Therapeutic Innovation (EUPATI) has an overview of HTAs as well as a list of those organizations in Europe https://toolbox.eupati.eu/resources/hta-systems-in-europe/)
- How essential and innovative medicines are made available in your country and how affordability and quality are considered in making them available. What are the limitations and opportunities in this process – i.e., what is the impact to patients, healthcare professionals, hospitals, government, policy makers
- The process overall of how a medicine is delivered to a patient [HERE PERHAPS A DIAGRAM? OF OVERALL PROCESS?]
- How to measure the Impact of any modifications to existing processes or new processes– consider current evaluation measures (such as those used in clinical efficacy/safety of a drug), (validation/certification of process and by whom), new authority and roles/responsibilities of that entity, and should the measures be weighted and on what would that be based
- Key 3-5 audiences to which this should be addressed and 3-5 best 'ways' to get this information to those audiences

Following information may be of value in framing your answer:

- **Essential medicines** are defined by the World Health Organization (WHO) as those that satisfy the priority health care needs of a population. They are selected with due regard to disease prevalence and public health relevance, evidence of efficacy and safety and comparative cost-effectiveness. They are intended to be available in functioning health systems at all times, in appropriate dosage

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forms, of assured quality and at prices individuals and health systems can afford. The WHO provides a list of these essential medicines and updates it every two years. It can be found https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.02.

- **Innovative medicines** are defined by the European Medicines Agency as a medicine that contains an active substance or combination of active substances that has not been authorized before. https://www.ema.europa.eu/en/glossary/innovative-medicine. The US Food and Drug Administration (FDA) does not define innovative medicines per se but applies a definition of new molecular entities and new therapeutic biological products for purposes of FDA review. These products usually active substances that FDA had not previously approved, either as a single ingredient drug or as part of a combination product; they frequently provide important new therapies for patients. https://www.fda.gov/drugs/development-approval-process-drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products
- **Health technology assessment (HTA)** defined by WHO is the systematic evaluation of properties, effects, and/or impacts of health care technology. It should include medical, social, ethical, and economic dimensions, and its main purpose is to inform decision-making in the health area. These assessments look at benefits and efficacy, clinical and technical safety, and cost-effectiveness. Informed decision-making comprises issues surrounding coverage and reimbursement, pricing decisions, clinical guidelines and protocols, and lastly, medical device regulation. The main purpose of HTA is to inform a policy decision making in health care, and thus improve the uptake of cost-effective new technologies and prevent the uptake of technologies that are of doubtful value for the health system. https://www.paho.org/en/topics/health-technology-assessment
- **Value and Clinical Benefit of New Therapies:** The ASCO Value Framework assesses the value of new cancer therapies based on clinical benefit, side effects, and improvements in patient symptoms or quality of life in the context of cost. https://www.asco.org/news-initiatives/current-initiatives/cancer-care-initiatives/value-cancer-care. The ESMO Magnitude of Clinical Benefit Scale (MCBS) facilitates improved decision-making regarding the value of anti-cancer therapies, promotes accessibility and reduces iniquity of access to high value cancer treatments. https://www.esmo.org/guidelines/esmo-mcbs

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Theme 2: Reliable, verifiable and sustainable supply chain

Q2) How do we ensure the quality of cancer medicines across the entire drug supply chain?

This should represent a medicine once it has received marketing authorization. Recognize that the supply chain should be from obtaining the raw materials to manufacture the product through the patient taking the medicine.

In your response, please consider the following:

- Please cite examples of issues and/or opportunities if possible
- Please be as specific as possible – you may choose to highlight one or all portions of the drug supply chain
- How to measure the impact of any modifications to existing processes or new processes– consider current evaluation measures (such as those used in clinical efficacy/safety of a drug), (validation/certification of process and by whom), new authority and roles/responsibilities of that entity, and should the measures be weighted and on what would that be based

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Following information, articles, reports may be of value in framing your answer:

- U.S. White House (June 2021) *Building Resilient Supply Chains, Revitalizing American Manufacturing, And Fostering Broad-Based Growth, 100-Day Reviews* (Executive Order 14017)
- Osinde, G., Niyonzima, N., Mulema, V., Orem, J. (15 April 2021) Increasing access to quality anticancer medicines in low- and middle-income countries – the experience of Uganda. *Future Oncology*, https://www.futuremedicine.com/doi/10.2217/fon-2021-0117
- Malhotra, H., Radich, J., Garcia-Gonazlez, P. (2019) Meeting the needs of CML patients in resource-poor countries. *Hematology* p443-442
- U.S. Food and Drug Administration (FDA)
- Safeguarding Pharmaceutical Supply Chains in a Global Economy: Hearings before the House Committee on Energy and Commerce, Subcommittee on Health (October 2019) (testimony of Janet Woodcock, M.D., Director - Center for Drug Evaluation and Research https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019
- FDA Office of Pharmaceutical Quality https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-pharmaceutical-quality

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Theme 3: Guidelines and the rationale use of medicines

Q3) How do we develop and deliver treatment guidelines based on the WHO Essential Medicines List in a way that is most useful to the practitioner?

In your response, please consider the following:

- Please identify if and what guidelines are important to follow and why.
- Please consider digital and/or remote technology to deliver, administer and monitor patients. Please provide examples when possible.
- Are the guidelines currently being used, many of which are adapted from those initially developed for high-income countries, adequate and/or do other guidelines need to be developed
- As to the clinical profile of medicines: If and/or can innovative cancer medicines be considered in treatment guidelines? What is the impact of excluding innovative cancer medicines mean to the overall health of the population and does this establish health inequity?
- Consider administration of therapies – oral, intravenous and the challenges to administration, access and monitoring
- How to measure the impact of any modifications to existing processes or new processes– consider current evaluation measures (such as those used in clinical efficacy/safety of a drug), (validation/certification of process and by whom), new authority and roles/responsibilities of that entity, and should the measures be weighted and on what would that be based

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- **Innovative medicines** are defined by the European Medicines Agency as a medicine that contains an active substance or combination of active substances that has not been authorized before. https://www.ema.europa.eu/en/glossary/innovative-medicine. The US Food and Drug Administration (FDA) does not define innovative medicines per se but applies a definition of new molecular entities and new therapeutic biological products for purposes of FDA review. These products usually active substances that FDA had not previously approved, either as a single ingredient drug or as part of a combination product; they frequently provide important new therapies for patients. https://www.fda.gov/drugs/development-approval-process-drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products
- Labrique, A.B.; Wadhwani, C.; Aerts, A. (2018); Best practices in scaling digital health in low and middle income countries. *Globalization and Health* https://globalizationandhealth.biomedcentral.com/track/pdf/10.1186/s12992-018-0424-z.pdf
- *Unlocking digital healthcare in lower- and middle-income countries, Healthcare Systems & Services Practice,* McKinsey & Company (November 2021) https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/unlocking-digital-healthcare-in-lower-and-middle-income-countries

Please note that guidelines listed below have been adapted for other regions and information/links can be found on these websites

- US National Comprehensive Cancer Network (NCCN) treatment guidelines https://www.nccn.org/guidelines/category_1
- European Society of Medical Oncology clinical practice guidelines https://www.esmo.org/guidelines
- American Society of Clinical Oncology resource-stratified practice guidelines https://www.asco.org/practice-patients/guidelines/resource-stratified

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Theme 4: Measuring and validating quality standards

Q4) How do we measure quality of cancer care and validate quality standards?

In your response, please consider the following:

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- Please identify if and what measures and validation systems or guidelines are used in your country or region. Please also provide examples of successes, failures if appropriate
- Are the measures and validating methodologies or technologies used inclusive? Do they address all the aspects of providing quality cancer medicines or should other standard measures be introduced?
- Consider digital and remote technology, administration of medicines in your responses
- How to measure the impact of any modifications to existing processes or new processes– consider current evaluation measures (such as those used in clinical efficacy/safety of a drug), (validation/certification of process and by whom), new authority and roles/responsibilities of that entity, and should the measures be weighted and on what would that be based
- Key 3-5 audiences to which this should be addressed and 3-5 best 'ways' to get this information to those audiences

Following information, articles, reports may be of value in framing your answer:

- World Health Organization Quality Assurance, Norms and Standards https://www.who.int/our-work/science-division/quality-assurance-norms-and-standards
- US Food and Drug Administration Office of Quality https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-pharmaceutical-quality#:~:text=The%20Office%20of%20Pharmaceutical%20Quality's,quality%20on%20a%20global%20scale
- European Medicines Agency Quality Guidelines https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/quality-guidelines
- American Society of Clinical Oncology Quality Program https://practice.asco.org/quality-improvement/quality-programs, Quality Oncology Practice Initiative https://practice.asco.org/quality-improvement/quality-programs/quality-oncology-practice-initiative, Quality Training Program https://practice.asco.org/quality-improvement/quality-programs/quality-training-program and QOPI Certification program https://practice.asco.org/quality-improvement/quality-programs/qopi-certification-program

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