### Progress report in implementing WHA 70.12 on Cancer Control



### **Objectives of MS Briefing**

- Present WHO's programme of work in cancer including WHO cancer initiatives through an integrated approach
- Progress in cancer control planning nationally, regionally and globally – tracking progress and impact of programmes
- Proposal for mapping, expected output and strengthening cancer control mandate, in line with the request from Slovak Republic and other EB members (EB 143)
- Next steps including reporting on progress to Governing Bodies

Time	Agenda Item
11:30	Welcome addresses
11:40	<b>Item 1</b> : WHO programme of work in cancer control: Progress in the implementation of initiatives in childhood, cervical and breast cancers
12:05	Item 2: Reporting on progress in cancer control: Mapping current status and data gaps
12:20	Item 3: Methodology for stock-take and setting a strategic direction for 2025 and beyond Review of proposed approach, sharing of best practices and results
12:30	Item 4: Moderated discussion with Member States
12:50	Wrap up and end of session



### **Opening Remarks**

#### Prof Dr Jérôme Salomon

Assistant Director-General,

Division of Universal Health Coverage, Communicable and Noncommunicable Diseases

#### Dr Maria Neira

Assistant Director-General (a.i.),

Division of Universal Health Coverage/Healthier Populations







### Agenda item 1:

## WHO programme of work in cancer control

Progress in the implementation of initiatives in childhood, cervical and breast cancers

Time	Торіс	Speaker
11.40 – 11.50	Current status of strategic priorities in cancer control	Dr Bente Mikkelsen, Director,
11.50 – 11.55	WHO cancer initiatives and inclusion of communities with lived experience	Noncommunicable Diseases Department/HQ
11.55 – 12.00	Cancer control link to health system strengthening with focus on access to medicines	Dr Rogério Pinto de Sa Gaspar, Director, Regulation and Prequalification Department/HQ
12.00 – 12.05	Integrated approach to cancer management with co-morbid conditions	Dr Meg Doherty, Director, Global HIV, Hepatitis and STI Programmes/HQ



### **Current status of cancer control:** *major burden, marked by inequalities*

Diagnosed with cancer per year; 1 in 3 lifetime risk of being diagnosed with cancer in HIC; Lifetime risk in LMIC is 1 in 6

**14** (of 196)

**20** mil

Countries on track to reduce premature mortality from cancer by one-third by 2030



Cancer deaths in men in Europe associated with educational inequalities; 1 in 6 deaths in women in Europe



Cancer & CVD ranks as the two leading causes of premature death in **127 countries** (2019). Cancer may be the leading cause of premature death this century.



### **Generational harm:** premature deaths & impoverishment





### **Tracking Progress in WHA 70.12 Implementation**

Secretariat activity along strategic shifts	Output (2017 – 2023)	SEVENTIETH WORLD HEALTH ASSEMBLY Agenda item 15.6 Cancer prevention and control in t	WHA70.12 31 May 2017 he context of
Overview	Launched 3 integrated cancer initiatives (cervical, childhood and breast cancers)	an integrated approac The Seventieth World Health Assembly,	h
Technical guidance	Produced 10 strategic guidance documents and 2 implementation tools	Having considered the report on cancer prevention and control approach; Acknowledging that, in 2012, cancer was the second leading ca 8.2 million cancer-related deaths, the majority of which occurred countries;	n the context of an integrated ase of death in the world with in low- and middle-income
Country support	Increased country support from 5 (2017) to 75 (ongoing)	Recognizing that cancer is a leading cause of morbidity globall concern, with the annual number of new cancer cases projected to incr to 21.6 million by 2030; Aware that certain population groups experience inequalities i access to screening, early diagnosis and timely and appropriate t experience poorer outcomes for cancer; and recognizing that different	v and a growing public health asse from 14.1 million in 2012 n risk factor exposure and in reatment, and that they also t cancer control strategies are
Leadership & advocacy	Increased partner networks including 10 MoUs, 300 implementing partners; Launched network for people affected by cancer	required for specific groups of cancer patients, such as children and ado Noting that risk reduction has the potential to prevent around half Aware that early diagnosis and prompt and appropriate treatm palliative care, can reduce mortality and improve the outcomes and qual Recognizing with appreciation the introduction of new phan investment in innovation for cancer treatment in recent years, and i increasing cost to be the systems and assisters.	escents; of all cancers; ent, including pain relief and ity of life of cancer patients; anceutical products based on soting with great concern the
Implementation capacity	Increased WHO capacity in RO and CO to >40 new staff & consultants	Emphasizing the importance of addressing barriers in access affordable medicines, medical products and appropriate technology for screening diagnosis and treatment, including surgery, by strengthenin international acoperation, including human resources, with the ultimat patients, including through increasing the capacity of the health systems Recalling resolution WHA58.22 (2005) on cancer prevention and	<ul> <li>safe, quality, effective and cancer prevention, detection, g national health systems and e aim of enhancing access for to provide such access;</li> <li>control;</li> </ul>
	voluntary contribution – manny, non-state actor	- And the second s second second sec second second sec	



WHA70.12

### **Overview of major milestones by MS request**



Pricing of cancer medicines and its impacts



guidance

resource-stratified approach

Announce Global Platform for access to childhood cancer medicines

practice established

Partner and donor network expanded guidance for Global

Position paper on alcohol use integrated RF and management

WHO-IARC workplan established

**Global Initiative for Childhood Cancer** 

>80% children with cancer in
HIC survive

<20-30%

## children with cancer in LMIC survive



OF CHILDREN







### CureAll Country Showcase: GICC Milestones



Funding support distributed to major WHO Budget Centres, Years 1-4



Childhood cancer centres supported in providing care across 6 WHO Regions





Children newly diagnosed with cancer accessing care improved care in **70+ countries** 





### CureAll Country Showcase: GICC Milestones









### **Global Platform for Access to Childhood Cancer Medicines**

Platform vision: a **comprehensive** solution engaging **global partners** to provide an **uninterrupted** supply of **quality** childhood cancer medicines

		Initial Phase		e	irowth Phas	e
	2022	2023	2024	2025	2026	2027
Countries		6	12	30	40	50
Children		5,000	12,000	25,000	35,000	50,000
Budget (USD)	2 mil	11 mil	21 mil	39 mil	50 mil	65 mil

\* 50,000 children per year by 2027 represents approximately:

- 25% of all children with cancer in the world
- 60% to 70% of children with cancer in low- & lower-middle income countries

By 2027, the Global Platform will have provided medications for > 120,000 children







### The Global Strategy

THRESHOLD: < 4 cases per 100 000 women per year

#### **2030 Control Targets**



#### LIFE-COURSE APPROACH:

Three pillars provide a **comprehensive strategy** to ensure lifetime benefits are maximized.

Global strategy to accelerate the elimination of cervical cancer as a public health problem



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### **Cervical Cancer Elimination Initiative**: timeline & progress

Flagship launched by WHO Director-General (2018)



"One woman dies of cervical cancer every two minutes...Each one is a tragedy, and we can prevent it."



#### Partnership, advocacy, and monitoring and evaluation



### **CCEI** Implementation

#### COORDINATION

**Building on existing UN coordination mechanism** – dialogues with UNFPA, UNICEF, GAVI, Unitaid and others

**Partner networks** Developing WHO implementation network with South-South engagement

**Expanding stakeholder dialogue** For example, African Union Commonwealth, Union for Mediterranean, cancer institutes



#### ADVOCACY

**17** November: day of action



**Uzbekistan**: Great Silk Road

WHO Ambassador CCEI led a history-making endeavour to honor Henrietta Lacks



First Spouse Network >10 First Spouses engaging with CCEI



#### CCEI direct support to 20 Member States, leveraging implementation partners for impact.



Knowledge repository & exchange including communities of practice



### **Global Breast Cancer Initiative**



### **Global Breast Cancer Initiative**



### Launch of campaign to engage communities affected by cancer



a long-term commitment to place people affected by cancer properly at the center of the agenda, to co-create better solutions.

#### Primary objective:

 to <u>understand and support</u> impact of cancer in the medium to long-term, in a diversity of settings

#### Secondary objectives:

• to **define and innovate** ways stakeholders support people facing a cancer diagnosis and their families.



## **73%** BUT **30%**

Wanted to speak with their health professional about their emotional health Had any discussion on emotional well being



### Levers in access to oncology medicines



Policy, including National Essential Medicines Lists (nEML) and treatment guidelines, reflect oncology medicines, including biosimilars.



Procurement, pricing and financing strategies are in place to ensure sustainable access.



Regulatory affairs are enabled, including pharmacovigilance, to ensure safe distribution and use of medicines.

- Normal levers along the value chain for access to medicines may not be well developed for oncology medicines if treatment options have been limited to private institutions.
- All of these areas will need to be assured. In some cases, regulators require support, which can be available from WHO Prequalification Programme for many situations.



### Access to medicines: prequalification & regulatory pathway

- The regulatory environment can be complex, particularly for oncology medicines and especially in LMIC markets.
- To stabilize markets, it will be critical to ensure products have market authorization from National Medicines Regulatory Authority.
- If the products have been imported through informal means, or if they are being used "off label", availability and quality are often unstable.
- In some cases, regulators require support, which can be available from WHO Prequalification of Medicines Programme for many situation.



### PQ pilot for biosimilar oncology medicines ongoing

- Trastuzumab (breast cancer): 4 manufacturers
- Rituximab (non-Hodgkin's lymphoma & leukemia): 3 manufacturers

### PQ will expand to include additional oncology medicines

- Identification and prioritization for products included into the WHO Prequalification Programme is based on ongoing recommendations from technical department.
- Work is in progress

### Support is available for the best regulatory pathway

- WHO Collaborative Registration Procedure is an option for products prequalified by WHO
- Other reliance mechanisms may be used, where available, for other products

Cervical cancer and HIV are intricately linked

### Women and girls living with HIV have:

- Higher risk of getting HPV infection
- Lower chances of clearing the infection
- Faster progression from infection to cancer
- Lower regression of pre-cancer lesions
- Higher recurrence following treatment
- Younger age at presentation

### Our goals are to:

- Better understand this relationship & prioritize resources
- Develop guidance relating to cervical cancer & HIV
- Support woman-centred program integration and expansion of coverage



Risk for cervical cancer among women living with HIV is 6x higher (RR = 6.07)

## Population attributable fraction of women with cervical cancer living with HIV, 2018



Source: Stelzle D, Tanaka LF, Lee KK, et al. Estimates of the global burden of cervical cancer associated with HIV. Lancet Glob Health 2020; published online Nov 16.



Over 15 million women on ARVs provide an opportunity for screening and treatment.

### **Two Important WHO Guidelines**

#### Screening and treatment to prevent cervical cancer

- Age of screening initiation
- Interval of cervical cancer screening
- Optimal algorithm for screening and treatment
  - Limited data for multiple test/treatment algorithms in WLHIV
  - Modeling of ~30 scenarios with differing screening tests and treatment options

#### **Consolidated HIV Guidelines**

- Clinical services
- Service delivery
  - Focus on people-centered care
  - Integration and linking services
    - Section on cervical cancer screening for women living with HIV



## Summary Cervical Cancer Screening & Treatment Recommendations

Summary Recommendation for the general population of women

WHO suggests using either of the following strategies for cervical cancer prevention among the general population of women:

- HPV DNA detection in a screen-and-treat approach starting at the age of 30 years with regular screening every 5 to 10 years.
- HPV DNA detection in a screen, triage and treat approach starting at the age of 30 years with regular screening every 5 to 10 years.

Summary Recommendation for women living with HIV

WHO suggests using the following strategy for cervical cancer prevention among women living with HIV:

 HPV DNA detection in a screen, triage and treat approach starting at the age of 25 years with regular screening every 3 to 5 years.



### Awareness of cervical cancer prevention

Low levels of knowledge on cervical cancer, its association with HPV and the ability to prevent it

High acceptability (70% or higher, several with 90%) across studies for self-sampling, VIA, HPV DNA tests or triage-based methods

Clear and strong preference for immediate treatment following a diagnosis of a cervical intraepithelial lesion among all women

Single-visit based approach and multi-visit approach feasible across multiple intervention types – self-sampling, HPV test, VIA, cryotherapy, LEEP and thermocoagulation

• An online survey found that women stated they were likely to have difficulties returning for follow-up

Clear request from the community for better counselling, patient education, availability of choices of treatment and screening tests



### Care for HIV and screening for cervical cancer can be provided together

Integrating services can more efficiently combat these two diseases



### **Policy & Program Implementation**

#### Support ministries of health in adopting guidelines

- Increase country-level impact
- Improve awareness in communities

### **Bi-directional integration of HIV and cervical cancer services**

- Improve service provision in settings with high HIV prevalence
- Facilitate referrals between programs
- Early identification of STIs

#### Further strengthen links with the community

- Advocate for better counselling, patient education, availability of treatment and screening tests
- Involve community of women in all aspects of programme development

### Address knowledge gaps with implementation science



### Agenda item 2:

## Monitoring progress in cancer control

Current reporting on core indicators and data gaps

Time	Торіс	Speaker
12.05 – 12.10	Mandate to report on programme of work in cancer	Dr Bente Mikkelsen, Director, Noncommunicable Diseases Department/HQ
12.10 – 12.15	IARC Global cancer observatory	Dr Freddie Bray, Head, Cancer Surveillance Branch
12.15 – 12.20	Reporting social and economic impact of cancer	Dr Tessa Edejer, Director (a.i.), Health Financing and Governance Department/HQ
12.20 – 12.25	Using data to shape innovation in cancer control	Dr John Reeder, Director, Research for Health Department/HQ



### Reporting to WHA on progress in cancer control: current mandate

**Cancer indicators** 

Monitoring framework

		0			
SIXTY-SIXTH WORLD HEALTH ASSEMBLY Agenda item 13.1 Agenda item 13.2 Follow-up to the Political Declaration High-level Meeting of the General Ass on the Prevention and Control of Non-communicable Diseases	WHA66.10 27 May 2013 of the embly	<complex-block></complex-block>	<ul> <li>(1) Cancer incidence</li> <li>(2) Proportion screened for cervical cancer</li> <li>(3) HPV vaccination availability</li> <li>(4) Hep B vaccination coverage</li> </ul>	(1) (2) CD vol	Yearly Progress Monitor to WHA until 2031 2024 Progress report to UN SG, preparation for 4 <sup>th</sup> HLM on NCDs <i>untary targets</i>
eventieth world health assembly Agenda item 15.6 Cancer prevention and control in the an integrated approach	WHA70.12 31 May 2017 context of	None requested	None	(1) (2)	Narrative reporting in line with WHA 66.12 (yearly) "Periodic" global report on cancer
SEVENTY-THIRD WORLD HEALTH ASSEMBLY Agenda item 11.4	WHA73.2 3 August 2020	In development	<ul><li>(1) HPV vaccination coverage</li><li>(2) Proportion screened for cervical</li></ul>	(1)	Narrative reporting in line with WHA 66.12 (yearly)
Global strategy to accelerate the elimin cervical cancer as a public health proble associated goals and targets for the period	nation of em and its 1 2020–2030	"MS adopt strategy with associated goals and target"	cancer (3) Proportion with cervical disease receiving treatment	(2)	Implementation progress in 2022 and 2025
World Health			Two indicators related to GMF for NCDs	(3)	Final report in 2030

Frequency & End Date

### **Core indicators for WHO Cancer initiative:** data gaps







### Childhood cancer survival >60%

(collected by 30-50 MS)

Annual ↓ breast cancer mortality (2.5%/yr)

 Number of children completing treatment

(2) Inclusion of childhood cancer in benefit packages/policies

(3) Number of public childhood cancer centres

(1) Stage of diagnosis (collected by 70-90 MS)
(2) Time to diagnosis
(3) Treatment completion rate



### **Current guidance & capacity building in NCDs**





- 1<sup>st</sup> phase: Meta-data provided for 20 facilitybased (primary care) indicators
- **2**<sup>*nd*</sup> **phase:** selection and finalization of facilitybased data for cancer centres
- Implementation approach (sample):
  - Integration of indicators into DHIS-2
  - Pilot testing planned; broad engagement of implementation partners



### **NCD Data Portal & visualization platform**



World Health Organization

- **1**<sup>st</sup> **phase**: NCD indicators routinely collected and reported to WHO including RF and disease burden
- 2<sup>nd</sup> phase: data visualization platform to support adoption of "NCD best buys" and to demonstrate the value (impact and costeffectiveness) of implementation

### Sample implementation monitoring: draft approach from GICC

				Cure	All Country Pr	ojects			<b>La</b> 2023	st Updated -04-01 00:36:
HO REGION	cou	INTRY	CORE PROJE	ст	CURRENT STATUS	M	AIN PARTNER		MAIN FUNDING	
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this page to display pleted by June 202	y visualizations o 24). All data shov	of main collaborativ vn was reported by	e country projects ( <i>to b</i> country teams.	e	34	2	3 2	5	25	
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R Pillar		Leverage		TOTAL		19	0	0	U	
E Pillar		Linked Policies/	Sovernance	PROJECTS	A	DVOCACY		LINKED + GOVE	POLICIES	
C Pillar		Linked Tolicicare	Jovernance	14 Countries Repo	orting					
iacta Aarosa Eng	ablare									
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					Culture and Communication Palliative Care				8	
26	13		40		Professional Education Metrics and Performance				5	
		20	19		Nursing Infectious Diseases			4	5	
8	8	3	5		Hematology			3		
C Pillar	U Pillar	R Pillar	E Pillar		Neuro-Oncology			1		
Advocacy	veraged Financin	ng OLinked Policie	s/Governance	CUTO	Pathology Retinoblastoma			1		



### Cancer Surveillance at WHO/IARC



consolidate and expand IARC's role as a global reference for cancer data



ensure locally recorded data are of high quality available for cancer control and research



conduct research that illustrates the transitional nature of cancer and the benefits of interventions









together





### Global Initiative for Cancer Registration (GICR) – data for action

h-Eastern Asia

West Asia

Not applicable

VISION

#### SAVING LIVES THROUGH RELIABLE DATA

#### OUTCOMES

#### Long-Term:

- 50 new high quality cancer registries by 2030
- Evidence base for cancer control planning
- Greater understanding of the cancer burden

#### Medium-Term

- First cancer registry reports in 50 countries
- Regional and national cancer registry networks
- Accelerate the development of new free and open-sourced electronic tools

#### Short-Term:

- 50 country led plans to implement population-based cancer registries
- Training for over 700 professionals
- Development of mentorship programme

#### STRATEGIC GOALS

<ol> <li>Country Leadership</li> <li>Increase qualified staff through training, educational resources, and access to experts</li> <li>Support improvements in the qualify and use of sustainable population- based cancer registry data</li> <li>Enhance the use of reporting tools</li> <li>Contribute to the integration of cancer</li> </ol>	2. Regional Focus  2. Equip six IARC Regional Hubs as local providers to PBCRs  2. Develop regional networks to promote peer-to-peer country interactions  3. Accelerate the scale up new solutions by documenting and sharing proven strategies 3. Inspire innovation with	3. Global	Coordination ge partners to lop strategic tions and ational plans ide support to onal Hubs and tries e awareness of the of PBCRs in nal cancer control egies dinate and ide over sight for	
data in health care planning PRINCIP	FOUNDATION	CORE FU	NCTIONS	
Country led cancer actio     Focused on low- and min     Collaborative, flexible m     Scientific integrity     Results-based managem	n ddle– income countries odel ent and accountability	Training Networks	Directed Support Cancer	

- A global partnership to improve the quality, availability and use of data from population-based cancer registries (PBCR) worldwide
- Six IARC Hubs created with support of 13 IARC-GICR Centres of Expertise
  - GICRNet
     Train the trainer' ++ model to form subject specific networks to deliver regional courses and provide support to registries
  - Move towards greater responsibilities of regional trainers in courses and support
  - Integration of learning materials to develop certification programme in-person;
     E-learning modules; and technical reports

#### Dectronic medical health data linkages

- District Health Information System v2 (DHIS2) cancer module to link data w CanReg5+
- Rifeted in the Caribbean with the OFCS and the IARC Caribbean Hob (11 countries)
- CanReg5+, enhanced to take advantage of modern technology using insights gained from users and the CanReg5 GICR/Net

Johannesburg

#### **GICR** Parmer Countries

- Identity and develop joint work plans to improve the registry in selected countries; clear opportunity with commitment from the country and agreement to monitor progress towards goals
- Up to an additional 30 Partner Countries in next five years

### IARC global data launches 2023

### **Cancer Incidence in Five Continents**



#### Cancer Incidence in Five Continents Vol. XII



Edited by F. Bray, M. Colombet, J. Aitken, A. Bardot S. Eser, J. Galceran, M. Hagenimana, T. Matsuda, L. Mery, M. Piñeros, I. Soerjomataram, E. de Vries, C. Wiggins, Y.J. Won, A. Znaor and J. Ferlay

ARC Scientific Publications No. 169





- Compendium of comparable data on cancer incidence in different subpopulations
- Reference source for studies exploring cancer variations
- Volume XII (2013-17) online end-June 2023



### GLOBOCAN

- Incidence, mortality and prevalence estimates in 185 countries, 36 cancers, by sex and age
- Estimates derived from best available information in each country
- GLOBOCAN 2022 launched end-May 2023 on the Global Cancer Observatory (GCO)









### How do we get robust national estimates of the cancer burden?



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement





Methods of national incidence estimation, GLOBOCAN 2020

PBCR data used directly in 25 SSA countries to estimate national incidence

#### Incidence method Observed national incidence rates were projected to 2020 (2) The most recently observed incidence rates were applied to the 2020 population (23 Rates were estimated from national mortality data by modelling (3) Age- and sex-specific national incidence rates for all cancers combined obtained by averaging overall rates from neighbouring countries hese rates were then partitioned to obtain the national incidence for specific sites using available cancer-specific relative frequency data (4) Rates were estimated as an average of those from selected neighbouring countries (16) o data Not applicable **GLOBAL CANCER** Data source: Globocan 2020 Map production: IARC World Health Organization © WHO 2021. All rights reserved

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World Health

Organization

### How do we get robust national estimates of cancer survival?



1- and 3-year survival differences by region and HDI, colon cancer

Soerjomataram et al. Cancer survival in Africa, Central and South America, and Asia (SURVCAN-3): a population-based benchmarking study in 32 countries. Lancet Oncol 2023;24(1).

PBCR in the African Cancer Registry Network (AFCRN)

Medium

Low

70

Very high

80

90 100

40

● —● min-max

### **GLOBAL CANCER OBSERVATORY**



### The social and economic impact of cancer: lack of prioritization

- In addition to being a leading cause of mortality and morbidity, cancer also negatively affects countries' economies and impose a heavy economic burden to patients and families
- The burden of cancer affects a country's economy because of premature mortality, absence from work and lost productivity.
- Cancer impacts patient and families due to out-of-pocket expenditures, in particular in settings with no or limited universal health coverage, but also due to psychological and subjective financial distress.
  - Worldwide, only 41% of national benefit packages include core childhood cancer services.
  - 50% of health benefit packages in low-income countries include screening, but only 20% cover treatment.



### WHA mandate and response

- Development of a cancer priority setting and costing tool
- Use cases:
  - Support to Member States in costing the national cancer control plan
  - Development of investment cases (e.g. Mozambique, Kenya, Senegal, Palestine, Honduras, five in pipeline)
  - Update of appendix 3 of Global NCD Action Plan → 24% of all assessed interventions are related to cancer prevention and control.



• A majority of these interventions represent *very good value for money* and should be a priority for inclusion in health benefit packages.



### **Gaps and priorities**

- Ensure optimal use of resources by prioritizing cost-effective and affordable interventions to promote universal access to comprehensive cancer care.
  - There is a need to expand the evidence-base on cost-effectiveness of cancer control interventions and consider additional criteria such as equity.
- There is limited evidence on the macro –and microeconomic impact of cancer.
  - Several systematic reviews on the economic burden of cancer are ongoing to better understand the determinants of financial hardship experienced by patients and families.
  - There is a need to estimate the global economic cost of cancer and to make an investment case for cancer prevention and control.
    - Initial analysis has shown that for each US\$1 invested in cancer care, the direct productivity return is US\$2.30
  - We are currently updating EPIC, a tool to estimate the burden of ill-health, to better capture the economic impact of cancer (e.g. loss of employment to caregivers)



### **R&D** processes at WHO





Outcomes: development of health products that address global health needs and accelerated implementation and uptake in countries

### What is the Global Observatory on Health R&D?

- Established through resolution WHA66.22 (2013) "to consolidate, monitor and analyze relevant information on health research and development activities" to identify gaps and opportunities in health R&D and coordinate actions.
- Supports evidence-informed decisions related to R&D gaps, funding and capacity.
- Scope: all health and health-related fields and all types of research
- Target users: Governments, policy-makers, funders, researchers.

A comprehensive source for up-to-date global information and analysis on health R&D, including resources, processes and outputs.





### Analysis example – Research Investments

- Who is funding what and where?
- In Europe 8.37% of research funding spent on cancers,
- In Europe \$USD 282 million spent on research for malaria, HIV and TB

WHO region	High income	Upper middle income	Lower middle income	Low income	Grand Total
Africa		111.44	58.45	63.87	233.76
Americas		28.37	2.02		
Eastern Medite		0.46	5.41	1.08	6.96
Europe	2,377.20	0.61	0.58		2,378.39
South-East Asia		4.82	42.49		47.30
Nestern Pacific		11.60	2.78		94.31
Grand Total	35,047.58	157.30	111.73	64.95	35,381.55







### Analysis example – Research topics funded

#### Grants on NCDs:

- 17 million USD to LMIC
- 19,673 million USD to USA

#### Cancer:

Despite

 In LMIC: < 1million USD in on cancers (in only 6 cancer topics)



Centre for global health strategic plan 2021-2025







#### B. Annual grant amount by type



### A concerted response across the product life-cycle



#### **Prioritizing and Evaluating:**

Developing a prioritized drug portfolio of the most needed formulations and assisting in the design and implementation of efficient, and high-quality clinical trials.



#### Establishing and maintaining relationships to launch effective products and supporting regulatory

submission activities to facilitate paediatric medicine approvals.



Supporting efforts to introduce new, adapted formulations in an equitable, accelerated, safe and coordinated manner.



Accelerating priority paediatric drug formulation development and uptake

### Agenda item 3:

### Methodology for stocktake and setting strategic direction

Review of proposed approach, sharing of best practices

Time	Торіс	Speaker
12.25 – 12.35	Current and planned reports, in response to Member State mandates Performing stock-take to inform strategic priorities in WHO's programme of work for cancer Childhood cancer as a tracer in NCD agenda to inform and contribution to current mandates (e.g., clinical trials, access to medicines, social determinants)	Dr Bente Mikkelsen, Director, Noncommunicable Diseases Department/HQ



### Next steps: stock-take methodology





#### **Objectives:**

- (1) Present current best practices and gaps/inequalities in cancer control
- (2) Gather and present MS with models and tools to improve outcomes through an integrated approach
- (3) Promote incorporation of key indicators for WHO cancer initiatives into routine national NCD reporting

#### **Anticipated Outputs:**

- (1) Stock takes for WHO cancer initiatives presented to EB 154
   (2024) in annual NCD report
   (cervical ca, May 2023; childhood ca Q3 2023; breast ca Q3 2024)
- (2) WHO global status report (in line with WHA 70.12) to be presented to EB 156 (2025)
- (3) Communication events (eg, WHA side events)
- (4) Updated mandate / programme of work for 2024-2025

### Cancer & broader health agenda: Example of childhood cancer

## Mapping current strategies and gaps in cancer.

#### Objectives

- 1) Demonstrate how progress in and implementation of WHO Global Initiative for Childhood Cancer tracer for NCDs & strengthen health systems through an integrated approach
- 2) Track progress, drive innovation
- Leverage recent commitments (eg, Global Platform for Access to Childhood Cancer Medicines to ↑programmatic investments)





### Stakeholder engagement: partners for stock-take/mapping

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### WHO, IARC

Responsible for full process of mapping to dissemination and implementation of recommendations

### **UN** agencies

Close collaboration throughout process including data inputs, review and communication

## Affected communities

Consultation on priority indicators, summaries of best practices and presentation of results

### **Civil society**

Inputs on priority indicators, participation in communities of practice, dissemination of findings

### **Private sector**

Dialogue as advised in WHA 70.12 (2017) and in line with FENSA

### Professional society & academia

Including participation of WHO Collaborating Centres including data collection and dissemination of results

### Philanthropic foundations

Participation in development of investment cases / business plans



### Horizon: Strategic opportunities in cancer

#### Advocacy & leadership

- Anticipate multiple side events during World Health Assembly 2023 to further elevate cancer agenda
- UN High-Level Meeting on UHC including event(s) on childhood cancer (Q3/4 2023): launch of Global Platform and stock-take of GICC
- Global partners forum (Nov 2023) with multisector engagement (provisionally 16-17 Nov), and Civil Society Dialogue

### Capacity building & communities of practice

- WHO expanding Knowledge Action Portal for cancer control as community of practice to gather best practices & accelerate implementation
- Number of countries engaging in WHO cancer initiatives continue to increase, likely to reach 100 countries by 2024
- Additional MoUs, partner engagement strategy: WHO working with UN agencies and >300 implementing partners for coordinated support

#### **Expanding mandate**

- Dialogue on strategic priorities for 2024-2025
   Programme of work ongoing with MS through three-level WHO approach
- Align cancer mandate with relevant
   resolutions including on research & innovation
   (clinical trial), access to medicines, quality of
   care, workforce optimization



### **Next steps & conclusion**

- Methodology on stock-take/mapping
  - Initiate consultative process in Q2/3 2023
  - Stock-take (narrative) cervical cancer in May 2023; childhood cancer in Q3 2023
  - Progress toward global status report in 2024
- Communicate data gaps & priority targets
  - Increase and standardized reporting frequency
  - Expand reporting to include socioeconomic impact of cancer & horizon scanning
- Accelerate integration of cancer with other programmes, leveraging cervical cancer as entry point

#### Thank you for your commitment to cancer control



## Questions ? Moderated discussion

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# Wrap-up & Closing



Mubyeyi, Onsa umwana mezi atandatu ya mbere umuvangiye habe n'amal amashereka yonyine intungamubiri zimuhagije, bizatuma agira ubuzima bi akure n ta mu gihagararo n no n

umwa

## Thank you

Further information on cancer is available at: https://www.who.int/health-topics/cancer.

Should you require additional information please do not hesitate to contact Dr Bente Mikkelsen, Director, Department of NCDs (mikkelsenb@who.int);

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### Annex

### Additional slides





### **Current status of NRAs based onWHO GBT Performance Maturity Levels**



GBT

OHM



No formal approach

Some elements

of regulatory

system exist

98

**Countries** 



Reactive approach

**Evolving national** 

regulatory system

that partially

performs essential

regulatory functions

38

**Countries** 

Can ensure the quality of products if rely

on ML 3/ ML 4 regulatory systems

70%

3 **Stable formal** system approach

Stable, wellfunctioning and integrated regulatory system

Target of WHA

Resolution 67.20



**Continual** improvement emphasized

**Regulatory system** operating at advanced level of performance and continuous improvement

Advanced and well resourced regulatory systems

58

**Countries** 

30%

60



### What is WHO Prequalification?

- WHO prequalification aims to ensure access to key health products that meet global standards of quality, safety and efficacy/performance, in order to optimize use of health resources and improve health outcomes.
- Today, there are almost 1,500 WHO prequalified products in vitro diagnostics (IVDs), male circumcision devices, medicines, vaccines, immunization devices and cold chain equipment, and vector control products — that have assisted in improving public health in low- and middleincome countries (LMIC).

• WHO prequalification has become a trusted and reputed symbol for *safety*, World Health *Quality and efficacy* across stakeholders. Organization

### **Cancer medicines in PQ**

- Eols are disease area-focused (except for trastuzumab/rituximab and insulin which are product-focused)
- There has never been an Eol in PQ focusing on cancer as a therapeutic area.
- Up to Nov 2010 certain medicines against cancers associated with HIV/AIDS were invited in the HIV/AIDS EoI (etoposide, bleomycin, vincristine, vinblastine) but these medicines were subsequently dropped from the EoI. Two products (vincristine and vinblastine) were prequalified in 2002 but were later withdrawn by the company. Palliative therapies continued to be invited for a while, but not any longer.



### The prequalification of rituximab and trastuzumab Background to pilot

BTP/SBPs quality, safety and efficacy, product handling and post-prequalification requirements differ greatly compared to small molecules. Trastuzumab and rituximab were selected as model biotherapeutics in the pilot for the below reasons.

- Disease prevalence, evidence of efficacy and safety, and comparative costeffectiveness
- One of the first monoclonal antibody therapies listed in the WHO Model List of Essential Medicines
- Existence of established WHO technical guidance for evaluation of biotherapeutic protein products prepared by recombinant DNA technology and on evaluation of MAbs
- Some SRAs have extensive experience in evaluating these molecules.

Pilot for PQ of rituximab & trastuzumab and their corresponding SBPs: EOI published on 5 July 2018 (first dossier received on 24 Oct 2018)



### Access to medicines: prequalification & registration (provisional)

### After identification of supplier and product: In-country Registration of the product

 All pharmaceutical products should be used in a country only after approval by the national or regional authority. (WHA Resolutions: WHA 67.20 (2014); WHA 67.21 (2014); WHA63.12 (2010))



2. Identification of supplier and product

3. Registration of the product in the country by the NRA (National Regulatory Authority)

- Depending on the nature of product and supplier, the National Regulatory authority (NRA) of each country may follow one of the following regulatory pathways to accept the introduction of the product in the country:
  - One-time waiver or only Import Permit for the first allocations, particularly if those are small allocations: Country to decide on the acceptability of this pathway. NRA to inform on the requirements for the supplier to meet and to issue the regulatory clearance – No product registration, regulatory clearance only
  - Collaborative Registration Procedure (CRP) for full registration/approval or marketing authorization of the product: WHO supports the NRA to get access to the relevant product data to accelerate the assessment and registration of a product (within 90 working days)
    - SRA CRP: products approved by SRAs
    - PQ CRP: products prequalified by WHO
  - 3. Mix of the 2 above Import waiver + CRP (in parallel): NRA and WHO

National registration pathway: Accelerated or standard registration pathway following NRA timelines (sometimes above 2000) 2000 and 2000 a

Access to medicines: prequalification & registration (provisional)

**CRP Process (PQ CRP or SRA CRP)** 

Vorld Health

)rganization



PQ has been proven as an effective mechanism for facilitating access to quality assure health products

□ Key findings of the independent external impact assessment:

(https://www.who.int/medicines/news/2019/report\_Impact-assessment\_WHO-PQ-Reg-systems.pdf?ua=1)

- ✓ WHO Prequalification (PQ) programme <u>enables a core market of</u> <u>approximately US\$3.5 billion</u> with the majority coming from vaccines
- ✓ WHO PQ has a <u>Return on Investment of 30-40 to 1</u> for the PQenabled donor-funded market (US\$ million)
- Most donors and procurers and implementing partners view <u>PQ</u> <u>approval as equivalent to approvals by stringent regulatory</u> <u>authorities</u>
- ✓ <u>340-400 million more patients have access</u> thanks to resources freed up by PQ
- National regulatory authorities (NRAs) relying on Collaborative Registration Procedure (CRP) have <u>achieved significant</u> <u>acceleration of approval timelines</u> vs pre-CRP registrations





 $\rightarrow$ 



#### **WHO Listed Authorities**

A new concept introduced to replace SRAs



assessment



#### **WHO Listed Authorities**

#### ...and to promote reliance



• **LISTING** can be achieved by ML3 and ML4 NRA/RRS and implies ADVANCED PERFORMANCE

i.e., **consistent** adherence to international standards and guidelines, as well as **good regulatory practices**, by ensuring the attainment of **key regulatory outputs** over time



#### **Definition of a WHO Listed Authority** Adopted by the ECSPP in October 2020, TRS 1033

A WHO Listed Authority (WLA) is a regulatory authority or a regional regulatory system which has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an

established benchmarking (GBT) AND a Performance Evaluation process





#### **Objectives of WLA initiative**

To provide a transparent and evidencebased pathway for RAs to be globally recognized

To promote access and the supply of safe, effective and quality medical products



To optimize use of limited resources by facilitating reliance

#### <u>Policy document</u>: Describes the purpose, definitions and high-

*level operating principles related to the evaluation and public listing of authorities* 



Link: https://www.who.int/publications/i/item/9789240023444