World Health Organization

# ACT-A Therapeutics

## Therapeutics Allocation
## Briefing to Member States

# ACT-A Therapeutics Partnership Structure

**Global Stewardship**

**Facilitation group to oversee and report progress, mobilize resources and engage with stakeholders**
Public sector and private not-for-profit partners, including:
- EU, Canada, France, Germany, Italy, Japan, Norway, Spain, UK
- BMGF, WEF, Wellcome Trust, coordination hub from WHO

Health Systems Connector

**R&D**
↕
**Manufacturing**
↕
**Procurement**
↕
**Deployment**

**Vaccine Partnership**
Co-conveners: GAVI, CEPI
WHO lead on product allocation
- Research
- Foundations
- International organizations
- Industry
- Funders
- Regulators

**Therapeutics Partnership**
Co-conveners: Therapeutics Accelerator, Unitaid
WHO lead on product allocation
- Research
- Industry
- Regulators
- Funders
- International organizations

**Diagnostics Partnership**
Co-conveners: FIND, Global Fund
WHO lead on product allocation
- Research
- Industry
- Regulators
- Funders
- International organizations

**WS1:** Rapid evidence assessment
Co-leads: Gates/Wellcome

**WS2:** Market preparedness
Co-leads: Unitaid

**WS3:** Procurement & Deployment
Co-leads: Global Fund, WHO

Tx Allocation Team within Procurement & Deployment workstream

*Dynamic view as of Nov 24th*

# **Recall** | Novel antivirals and monoclonal antibodies are priority Tx that require allocation; began with mAbs, as they are furthest along in development process

| | Clinical trial read-out | Likely use case | Potential demand[1] | Worldwide supply | ACT-A supply |
|---|---|---|---|---|---|
| Dexa-methasone | n/a | Severe/ Critical | 12 m | High | **2.9 m + 360 k** (UNICEF SD, Unitaid, Advanced purchase + WHO current stock) |
| Repurposed antivirals | Sof/Dac: Dec | Mild Moderate | 103 m | High | *tbd* |
| | Favipiravir: Dec | Moderate Severe/ Critical | 57 m | Medium | |
| ***Our focus – require allocation*** | | | | | |
| Novel antivirals | MK-4482: Dec (Ph2 final)<br>AT-527: Dec (interim) | Mild | 58 m | *Low - tbd* | *Tbd – Licensing and tech transfer* |
| Monoclonal antibodies (mAbs)[2] | LY-CoV 5555: Jan (final)[5]<br>REGN-CoV2: Jan (final)[5]<br>AZD7442: Q3 2020 (interim)<br>VIR-7831: Jan (interim) | Mild, Moderate | 103 m | 10-25[3] m | At least **2-4 m**[4] (2021 Fuji max capacity reservation)<br>*Tbd – Further work with developers & CDMOs* |

1. LIC, LMIC, UMIC (excl. China), based on likely use case – note does not consider target population 2. mAb supply estimate derived based on bioreactor capacity 3. BioTRAK capacity estimates and expert interviews. 4. Assuming single dose; range due to uncertainty in final dose and formulation 5. Both LY and REGN mAbs have received FDA EUA
Note: Demand and supply in treatment courses.

# **Recall** | Overarching principles to ensure equitable access to health products in the context of COVID-19

**Solidarity**: Joining forces to confront this unique challenge together and overcome this pandemic

**Accountability**: Clearly defined roles and responsibilities to ensure procedural justice

**Transparency:** To build and maintain trust

**Responsiveness to public health needs**: Health products are carefully selected and allocated to address the public health need

**Equity and fairness:** to inform the allocation process together with public health needs

**Affordability:** Consideration is given to pricing and procurement strategies to improve affordability of health products

**Collaboration**: Collaborative efforts amongst relevant global and national stakeholders is enhanced to accelerate and scale-up the response

**Regulatory and procurement efficiency**: Agile and comprehensive regulatory and procurement approaches are incorporated to improve timely access to safe, efficacious and quality health products for all countries in need


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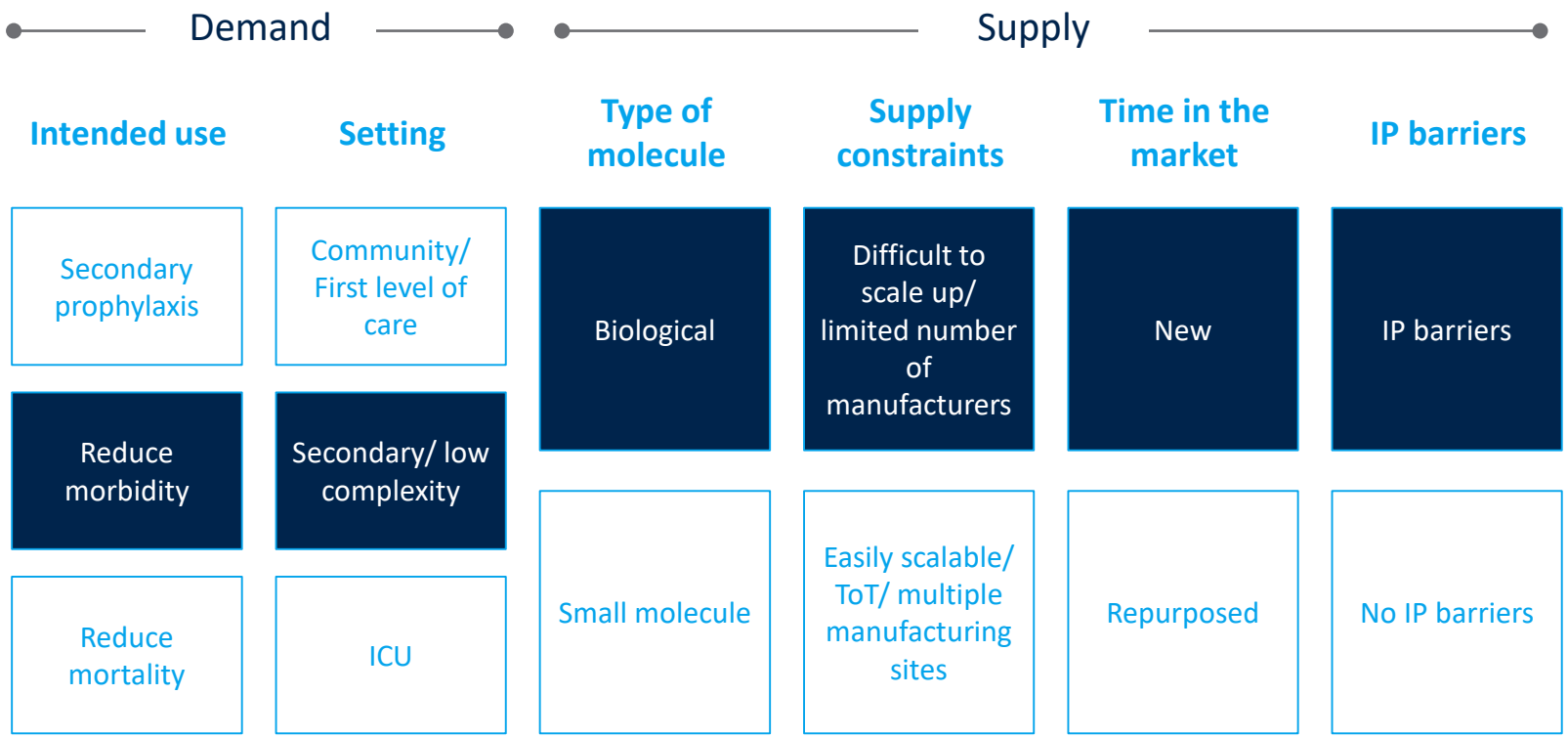
# Decision on whether an allocation mechanism is needed is based on comparison of demand vs. supply

| | Demand | Supply | Allocation mechanism |
|---|---|---|---|
|  **Monoclonal antibodies** | Expected to be **high** | **Low** | Required |
| | | *First priority – furthest along in product development process* | |
|  **Novel antivirals** | Expected to be **very high** | **Low to moderate** | Required |
|  **Repurposed therapeutics** | TBC, product dependent | **High –** TBC, product dependent | Likely not required |

**Detail** | Decision on whether an allocation mechanism is needed is based on comparison of demand vs. supply

| Demand | | Supply | | | |
|---|---|---|---|---|---|
| **Intended use** | **Setting** | **Type of molecule** | **Supply constraints** | **Time in the market** | **IP barriers** |
| Secondary prophylaxis | Community/ First level of care | Biological | Difficult to scale up/ limited number of manufacturers | New | IP barriers |
| Reduce morbidity | Secondary/ low complexity | Small molecule | Easily scalable/ ToT/ multiple manufacturing sites | Repurposed | No IP barriers |
| Reduce mortality | ICU | | | | |

# In the case of mAb, an allocation mechanism is needed



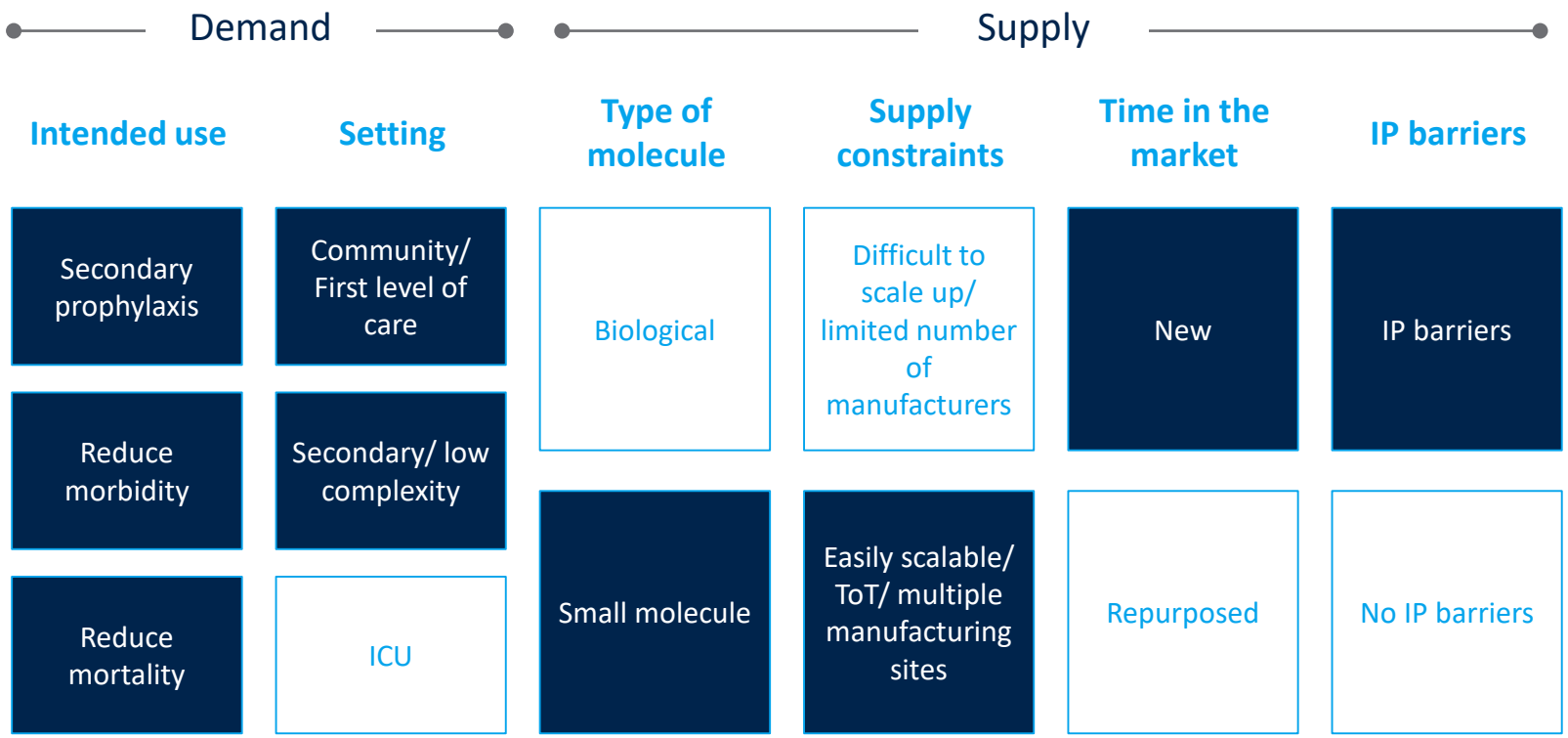

mAb supply will be constrained due to limited worldwide capacity, and complex manufacturing making scale up difficult

New molecules imply IP barriers and thus potentially higher price

Usage to reduce morbidity (ie. mild / moderate cases) means demand can be significant

New medicine - uncertainties on safety profiles and no established supply chain and other life cycle considerations; requires appropriate PV and reporting after authorization

# In the case of novel AV, an allocation mechanism will be needed



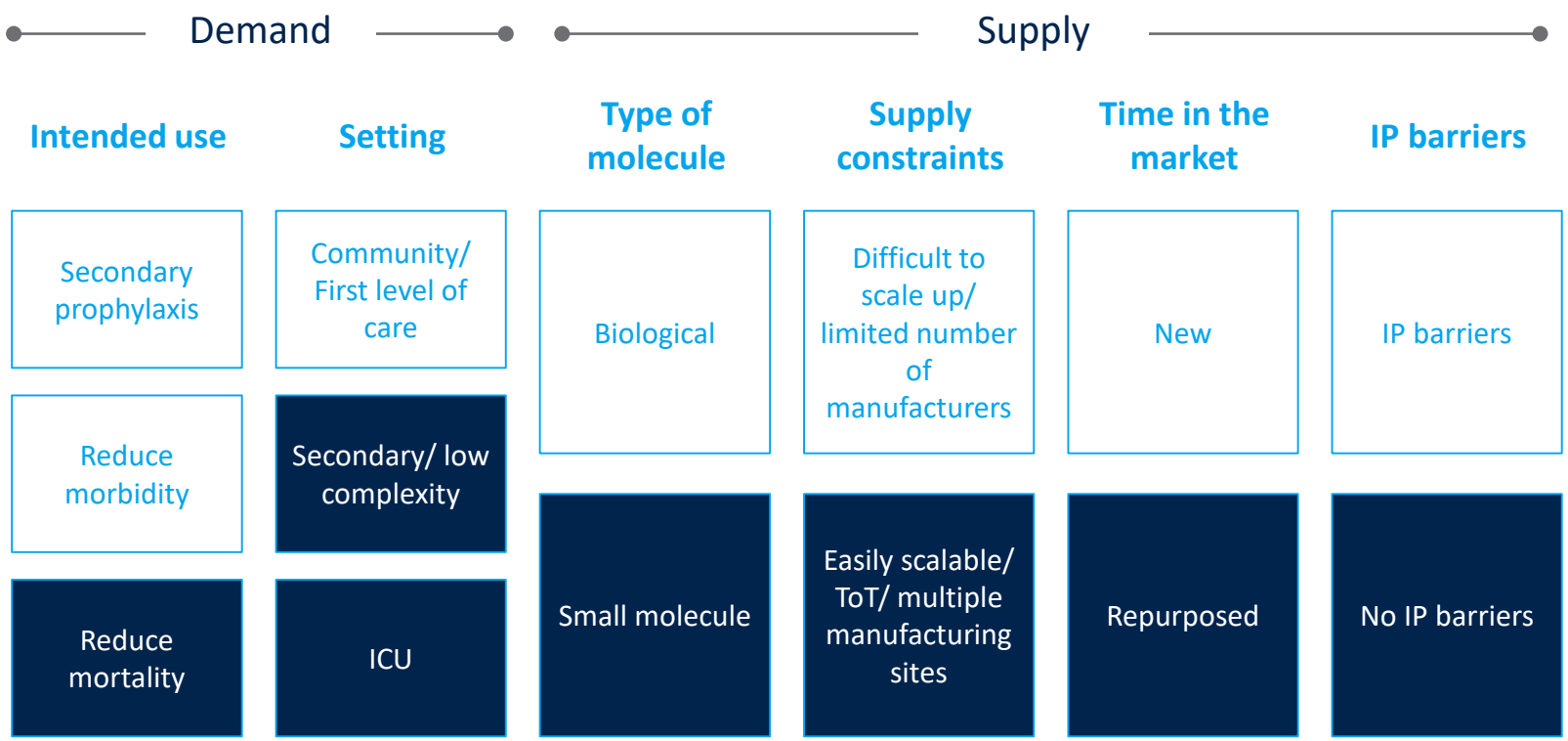

Potential for broad use and suitable for all care settings – demand may be very high

Small molecule – potentially easy to scale up manufacturing, depending on API availability among other factors

New therapeutic – manufacturing scale up may take time, and IP may pose affordability issues; supply may be constrained in near-term

New medicine - uncertainties on safety profiles and no established supply chain and other life cycle considerations; requires appropriate PV and reporting after authorization

# In the case of dexamethasone, an allocation mechanism is not needed




Reserved for severe use case – demand may be relatively low

Small molecule, repurposed therapeutic; manufacturing capacity at scale, with a well-established global supply chain – supply may be relatively abundant

No IP barriers should facilitate affordability

# **Recall |** Major elements of the Global Allocation Framework for COVID-19 products

### Goals

What are the overarching goals of the response?

### Target groups

Which target groups should receive products in priority to help achieve this goal?

How should specific products be allocated given their characteristics?

### Timing

At what pace will countries receive products given:

- their vulnerabilities (health systems and population factors)
- the dynamic nature of the threat?

### Boundary conditions

What other factors will impact the allocation of specific products given to countries:

- Product characteristics
- Country context?

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**Framework is product-agnostic – Tx Allocation Team now working on applying this to relevant therapeutics**

Work in progress

# Defining elements of the allocation framework for **monoclonal antibodies** (I/II)

| **Potential goals**<br>*Potential goals in Tx deployment include* | **Target groups**<br>*Target groups follow from specific goals for mAbs deployment* | **Focus for mAbs**<br>*Given the current context for of mAbs, what are objectives & target populations* |
|---|---|---|
| Reduce mortality | Severe or critical cases | Given clinical data, not currently key objective & target population[1] |
| Reduce morbidity | Mild or moderate cases among those at risk of progression to severe & critical | Key objective given clinical data; given supply constraints, focus on high risk population (over 65, or with underlying conditions) |
| Preserve health care system | Mild or moderate cases among frontline HCWs; to avoid overwhelming system, mild & moderate cases among high-risk groups | Key objective for mAb, as it will prevent disruptions in essential health services and is in accordance with principle of reciprocity |
| Reduce economic impact | Mild and moderate cases among essential workers | Given supply constraints, not currently a key objective & target population |

1. Given that data shows efficacy in mild & moderate cases only, unable to confirm efficacy in reducing mortality

*Work in progress*

# Defining elements of the allocation framework for **monoclonal antibodies** (II/II)

## Timing

Allocation will be conducted on an ongoing basis as more supply becomes available

In each cycle

- Prioritize countries for allocation based on need/epidemiology
- Re-allocate supply as necessary following assessment of country demand[1]

## Boundary conditions

Boundary conditions to be considered in an effort to ensure efficacy of mAb allocation

Considerations include:

- Regulatory hurdles
- Health system infrastructure
- Supply chain capabilities
- Diagnostics deployment
- Minimum and/or maximum volume thresholds

1. Actual country demand may differ from initial allocation

# Where do we stand…

Launched Tx Allocation Team, includes representatives across ACT-A partners

Developed approach to determining when an allocation mechanism is needed (so far, **monoclonal antibodies** & **novel antivirals**)

Began developing a mechanism for allocation of monoclonal antibodies

# …and next steps

Refine application of Global Allocation Framework to monoclonal antibodies & novel antivirals

Continue developing mechanism for the allocation of monoclonal antibodies

*Work in progress*

**Friday 4th December**

Please share any feedback on this presentation

**Friday 18th December**

We will share a working draft of the write up of the therapeutics allocation mechanism

**TBD**

Next Member States Briefing

Please share any feedback with the WHO lead on Access and Allocation, ADG Mariângela SIMÃO via ACTaccelerator@who.int