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MPP INTERVENTION AT THE OPEN SESSION OF THE WHO COMMITTEE ON THE SELECTION AND USE OF ESSENTIAL MEDICINES

APRIL 1, 2019

PATENTED MEDICINES SUBMITTED TO WHO EML IN 2019

- Several patented medicines have been submitted for inclusion in the WHO EML in 2019:
  - An **HIV** combination
  - A **hepatitis C** treatment
  - Several **cancer** medicines
  - **Novel oral anticoagulants**
  - Drugs for **multiple sclerosis**
  - Heat-stable carbetocin for **post-partum hemorrhage**
  - New **antibiotics**
  - Some **insulin analogues**
  - Additional formulations/indications of patented HIV, TB or cancer medicines

LICENSING THROUGH MPP ONE WAY TO FACILITATE AFFORDABLE ACCESS

Established in 2010 to increase **access** to new HIV medicines in LMICs…

…and to facilitate the **development of new formulations** (e.g. combinations)

Operates through **voluntary licences** to allow entry of **generic manufacturers**

Expanded to work on **hep C**, **TB** and other **patented essential medicines**

MPP's HIV, Hepatitis C and TB activities are funded by Unitaid

Unitaid
Innovation in Global Health

Seed funding for initial work on other patented essential medicines provided by SDC and Wellcome Trust

Schweizerische Eidgenossenschaft
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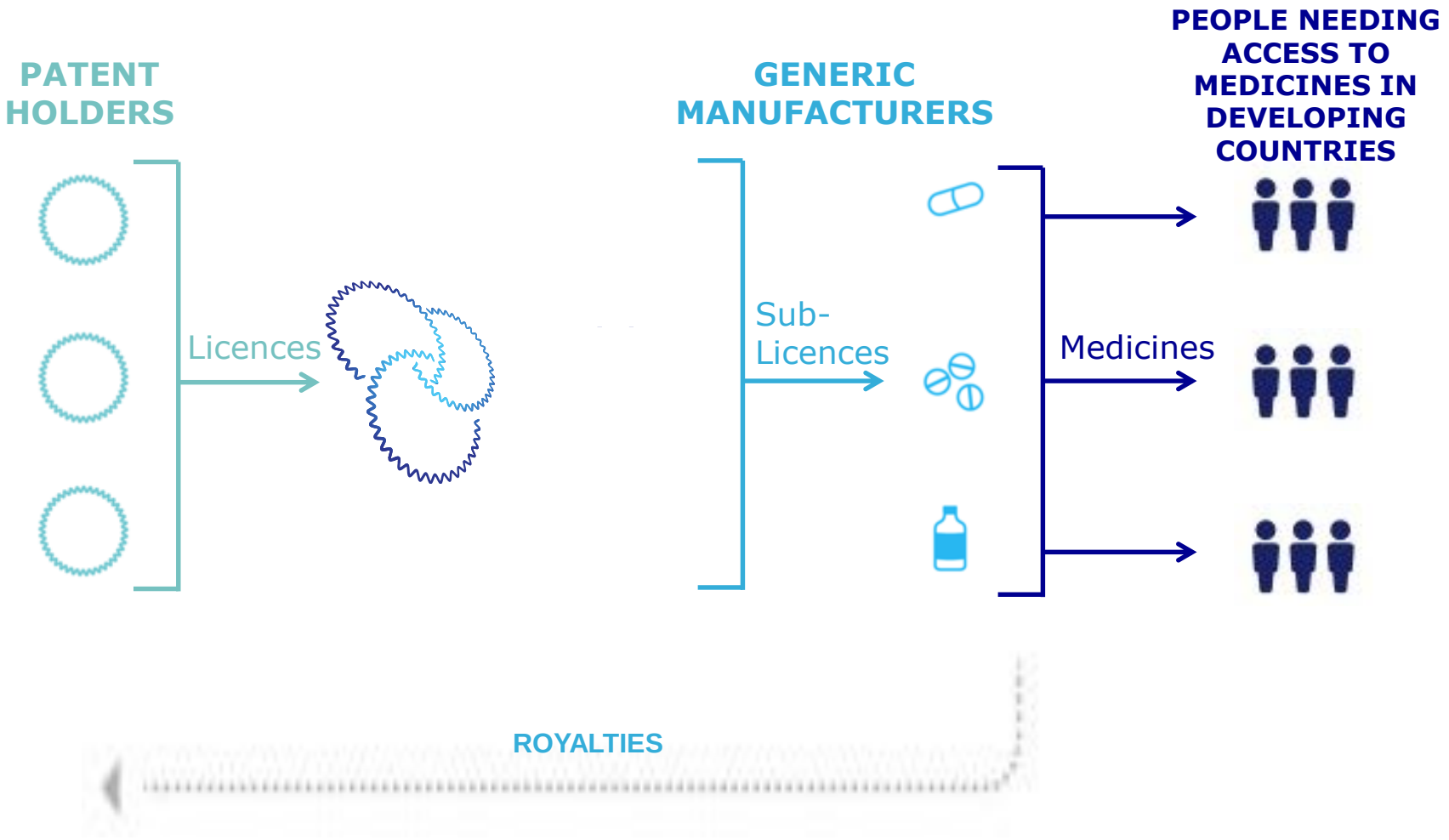
Swiss Agency for Development and Cooperation SDC

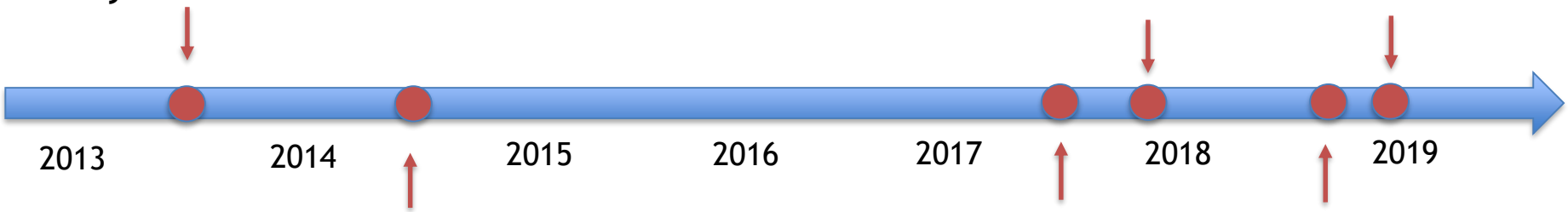
wellcome

A STYLIZED VIEW OF THE MPP MODEL



CASE OF HIV COMBINATION TENOFOVIR / LAMIVUDINE / DOLUTEGRAVIR (TLD)

TLD is a combination first developed by MPP licensees thanks to the licence with ViiV Healthcare.



August 2013: Dolutegravir first approved by US FDA

April 2014: MPP license with ViiV Healthcare. Covers countries home to 94% of people with HIV in LMICs

August 2017: First US FDA approval of TLD combination

Sept 2017 Unitaid et al announce price of USD 75 for TLD

December 2018 TLD already filed or approved in 41 countries and sold in 27

2019: TLD submitted to the WHO EML

CASE OF HEPATITIS C MEDICINE: GLECAPREVIR / PIBRENTASVIR (G/P)

- Approved by USFDA in August 2017
- In July 2018, G/P became one of three pan-genotypic regimens **recommended by WHO**
- In November 2018, MPP signs **licence** with AbbVie
- The licence allows the development of generic versions for sale in **99 LMICs and territories**
- As with previous directly acting antivirals, it is expected that it would take 3 to 4 years for generics to file for WHO Prequalification

CALLS FOR MPP EXPANSION TO OTHER PATENTED ESSENTIAL MEDICINES

- In 2016, the **World Health Organization (WHO)** recommended that consideration be given to:

  "***the expansion of the MPP to […] all patented essential medicines on the WHO EML (Essential Medicines List)***."

- Similar recommendation made by the **Lancet Commission on Essential Medicines Policies**

- **GSK** announced intention to license essential medicines for lower MICs and to include cancer pipeline in patent pool

- **UK AMR Review** and other reports proposed role for MPP in relation to new antibiotics

- The MPP received funding from the **Swiss Agency for Development and Cooperation** to undertake a feasibility study

OVERVIEW OF AREAS COVERED BY THE FEASIBILITY STUDY

Study sought to understand the feasibility and potential public health impact of the MPP expanding beyond HIV, HCV and TB

Categories	Case studies
1. Patented medicines included in the **WHO EML**	*Medicines for chronic myeloid leukemia*
2. Patented medicines with likely **relevant clinical benefits** but **needing additional data**	*New oral medicines for type 2 diabetes*
3. Patented medicines with **clinical benefits**, not meeting **comparative cost-effectiveness** criteria	*Novel oral anticoagulants (NOACs)*
4. Medicines needing a **therapeutic area review** by a separate working group	*Medicines for breast, lung and prostate cancer, and multiple myeloma*
5. New **antibacterials**: recently approved or currently under development	*New antibiotics*

KEY CONCLUSIONS OF FEASIBILTY STUDY

- **Strong case for MPP to expand** its mandate and facilitate access to patented essential medicines in LMICs
- Patented medicines added to the **WHO EML** at each revision could be natural candidates for in-licensing
- Medicines with **relevant clinical benefits** that are not added partly due to **cost** or **because more data or more detailed analysis needed** could also be considered.
- MPP could focus initially on licensing of **small molecules**, given greater complexity in biologics
- Work with patent holders to build confidence in model in new areas and find **win win solutions** with strong public health impact
- **Partnerships** with governments / CS and others will be key for access to licensed products
- Suitable **regulatory pathway** for MPP licensed medicines will be key

MPP'S EXPANSION INTO PATENTED ESSENTIAL MEDICINES

The MPP Board agreed to expand the mandate of the Medicines Patent Pool to treatment areas beyond HIV, Hepatitis C and TB.

*"The Board notes that the MPP should make a **phased expansion**, initially into **small molecules** listed in the **WHO Model List of Essential Medicines** as well as medicines with **strong potential for future inclusion** in view of their clinical benefits and potential for public health impact in low and middle-income countries."*

NEXT STEPS

- **MPP currently completing a framework** for prioritising medicines for licensing
- In particular, the MPP stands ready to **explore the licensing of patented medicines** that the WHO Expert Committee considers to be important.
- MPP licences could contribute to **accelerating the development and availability of generic versions** for use in resource limited settings. Where **new combinations/formulations** are needed MPP licences could also facilitate that.
- In relation to **new antibiotics**, licences would need to take into consideration the AWaRe categorization and balance **access needs with stewardship considerations**

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THANK YOU

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