The Global Accelerator for Paediatric Formulations (GAP-f)

Accelerating the development and uptake of the most needed drug formulations for children

Sébastien Morin1, Jennifer Cohg2, Marissa Vicari3, Paul Domanico3, Linda Lewis3, Melynda Watkins3, Fernando Pascual4, Janice Lee5, Nandita Sugandhi6, Martin Eisenhauer7, Carmen Pérez Casas8, Martin Auton9, George Siberry10, Carlo Giaquinto11, Martina Penazzato12, On behalf of GAP-f partners

INTRODUCTION

Limited treatment options and sub-optimal formulations have contributed to poor adherence and outcomes for children living with HIV. Despite the need for expanded and improved options for paediatric treatment, significant structural and technical barriers to ensuring that the most needed formulations are developed for children remain.

FINDING SOLUTIONS

To move the field forward, we need:

• Smarter coordination between existing processes to reduce the lag time between steps
• A portfolio approach to coordinate efforts on overall treatment needs across different product lifecycles
• Donor engagement to share the manufacturers’ risk for niche products
• Market analytics to support decisions at various stages of programme lifecycle, with product commercialization plans and means for implementation.

THE GLOBAL ACCELERATOR FOR PAEDIATRIC FORMULATIONS (GAP-f)

The GAP-f is a collaborative framework that aims to expedite development and uptake of priority paediatric formulations for key disease areas facing similar market challenges, such as HIV, TB and viral hepatitis [1]. The GAP-f, as a facilitating platform, will prioritize product development within clinical priorities indicated by WHO-led expert groups to improve the treatment portfolio.

It will support pre-approval processes by enabling the work needed to incentivize formulation development (or reformulation of existing drugs); facilitating the alleviation of intellectual property barriers; generating clinical evidence that can meet regulatory requirements; working towards achieving prioritized commitments from originators and helping them develop flexible PIP/PSPs; providing market analytics to support decisions across all stages; and promoting prioritization within regulatory approval processes required to achieve full uptake of new formulations.

The GAP-f will also support post-approval processes by accelerating product introduction through early engagement with ministries of health; providing tools for demand generation with healthcare workers and community advocates; promoting national approval processes; incentivizing manufacturers; and coordinating procurement to facilitate uptake.

IMPLEMENTING THE GAP-f IN A THREE STAGE PROCESS [2]

Stage 1 – Development of a strategic framework as well as promotion of key regulatory efficiencies (through increased coordination of the PIP/PSP processes in the EU and US) and visibility on the future market of individual priority products

Stage 2 – Testing of the acceleration model for feasibility and results, building on the work of existing platforms such as the Paediatric HIV Treatment Initiative (PHTI) and including innovative approaches to incentivize generic drug development

Stage 3 – Launch of the GAP-f as a fully functioning, sustainable structure informed by the evaluations of Stages 1 and 2

GLOBAL PAEDIATRIC HIV COMMUNITY COMMITMENTS

In November 2017, a High-Level Dialogue on Scaling Up Early Diagnosis and Treatment of Children and Adolescents took place (see: http://bit.ly/2tCAdL). Key principles of the GAP-f set the basis of discussion, which led to an action plan including an impressive list of commitments from industry, regulators, UN agencies and other stakeholders.

The commitments from the Rome action plan promote three key principles: Focusing on priority paediatric drugs and formulations; Accelerating development, review, and introduction of paediatric formulations; Collaborating to expedite the development and introduction of paediatric products.

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For more information, please contact sebastien.morin@iasociety.org.

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[6] ICAF, USA
[7] World Health Organization, Switzerland
[8] UNITAID, Switzerland
[9] The Global Fund to Fight AIDS, Tuberculosis and Malaria, Switzerland
[10] Office of the U.S. Global AIDS Coordinator, USA
[11] Paediatric European Network for Treatment of AIDS, Italy