INNOVATIVE DELIVERY SYSTEMS FOR PAEDIATRIC MEDICINES

TECHNOLOGY LANDSCAPE

Unitaid
Innovation in Global Health

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Innovative delivery systems for paediatric medicines:
technology landscape

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FOREWORD

There has been tremendous progress towards reducing morbidity and mortality from the major infectious disease killers including HIV, tuberculosis, and malaria. This is due in part to the introduction of innovative treatments and diagnostic tools which have contributed to greater efficiencies of care, moving us closer to our targets for eliminating these diseases as a public health problem. However, significant gaps in the global response remain and progress continues to be slower in key and vulnerable populations, including infants and children. Still over 5 million children are dying before reaching their fifth birthday, mostly in low and middle-income countries, and mostly from conditions that are readily preventable or treatable.

Medicines recommended for the prevention or treatment of diseases in babies and children are frequently legacy medicines which may not be the most effective, and/ or are delivered as non-palatable complicated dosage forms eventually leading to poor adherence and inadequate dosing of the prescribed treatment. Many challenges affect the investigation, development and access of appropriate medicines for children including weak market incentives with limited prospectus of market revenue; logistical, operationaland technical barriers; and complex evaluation and regulatory pathways.

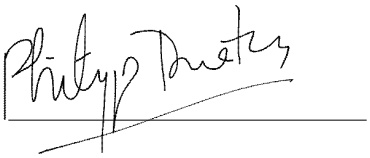
Over the last years, several global stakeholders have worked towards accelerating access to optimal paediatric formulations, whose availability historically have lagged up to 10 years behind that of the adult treatments. The World Health Organization (WHO), at the heart of such collaborative efforts, organized the first Paediatric Antiretroviral Drug Optimization (PADO) meeting in 2013 in Dakar to examine gaps in HIV-paediatric formulations to ensure best recommendations on the use of antiretroviral drugs could be implemented for treating and preventing HIV infection in infants and children, as well as to support the investigations and development of more simplified, less toxic drug regimens. Since then, paediatric drug optimization has expanded to other disease areas promoting prioritization and adaptation of key drugs and regimens for tuberculosis and hepatitis. The establishment of the Global Accelerator for Paediatric Formulations (GAP-f), launched in 2018 and now formally recognised as a WHO-led network, provides an opportunity to reinforce and innovate the mechanism needed to ensure that priority optimal paediatric formulations are investigated, developed and made available to children in a timely manner. Within malaria, revisions were made to the co-payment structure of Affordable Medicines Facility – Malaria (AMFm) to favour paediatric packs for therapies in March 2011. Since the revisions, measures have been put in place for managing orders to give preference to child-packs – which had an immediate impact on uptake of these medicines for children in affected regions. In addition, key research and development efforts have played a major role in bringing in more competition with the entry of multiple generic products pushing down prices for malaria medicines, both for adults and children.

In recent years, various improved child-friendly formulations have come to market, as a result of a multi-stakeholder approach, for critical medicines for HIV (e.g., ritonavir-boosted lopinavir oral pellets), malaria (e.g.., dispersible sulfadoxine--pyrimethamine + amodiaquine) and tuberculosis (e.g., dispersible fixed dosed combinations for first-line treatment). These more effective formulations and regimens are lessening the burden for

health providers and caregivers administering the medicines and offering more adapted and acceptable treatment options for children taking the medicines. Furthermore, they are demonstrating greater tolerability in young children and infants and leading to better health outcomes. Unitaid has been at the forefront of these efforts with over US$1 billion direct investments since its inception put towards improving and accelerating therapeutic innovations for children affected by HIV, tuberculosis, and malaria in low- and middle-income countries.

Much more remains to be done. Innovative delivery tools hold promise in facilitating cost-effective fit-for-purpose products that meet the unique needs of children in low-resource settings around the world. These tools could further simplify administration, improve adherence and ultimately lead to better health outcomes in children. This potential needs to be fully tapped starting with thorough landscaping to identify opportunities to accelerate research and development for the maximum impact. We cannot let infants and children be left behind and suffer and die from treatable conditions; we cannot accept the status quo and need to ensure that the most vulnerable, the small children, are at the forefront of our efforts in scientific and technical innovation.

Signatures



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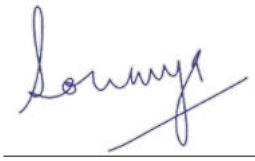

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