Discussion Such scientific opinions on the quality, safety and efficacy of the medicines are provided by the EMA’s Committee for Medicinal Products for Human Use (CHMP). Prior to this, it is recommended to agree on the data to be generated through scientific advice. The opinions are based on the same standards as used for those approved for Europe, with considerations for local conditions of use. To promote reliance on EMA scientific outputs and awareness of the procedure, two training events with regulators from Southern and from Western Africa are organised in partnership with WHO, NEPAD and local regulators in June 2018.

Conclusion We have shown that this ‘article 58’ procedure has a true impact and we encourage applications by companies developing medicines, aimed to prevent or treat diseases of significant public health interest, to be marketed outside the EU. This will ensure timely access of medicines by patients in target countries all over the world.
Background Although minority HIV-1 drug-resistant HIV-1 variants may be selected under antiretroviral pressure, leading to therapy failure, their clinical significance remains controversial. This is particularly relevant in the case of prevention of mother-to-child transmission (MTCT), where transmitted drug resistance can affect treatment outcomes.

Methods An ultrasensitive HIV-1 genotyping assay based on deep sequencing (DEEPGENHIV) with a 1% mutation frequency sensitivity, was used to quantify MTCT drug-resistant variants in 38 prenatally HIV-infected children experiencing (Group I, n=27) or not (Group II, n=11) virologic failure 12 months after initiating first-line antiretroviral therapy (ART) as part of a paediatric cohort in Uganda.

Results Infants were infected with subtype A(n=20), D(n=16) or C(n=2) HIV-1 strains, distributed equally between both patients’ groups. Similarly, no significant difference was observed in intra-patient HIV-1 diversity among viruses obtained from Group I or II individuals at baseline. DEEPGENHIV was able to detect all the mutations originally detected in samples obtained from four control patients in Group II, where drug resistance was identified at baseline using Sanger sequencing, e.g. K65R (78% mutation frequency), K103N (47%), or M184V (85%). More importantly, a series of low abundance (<20% detection limit of Sanger) primary and compensatory mutations associated with resistance to PIs (D30N, Q48V), NRTIs (D67N, K219Q), or NNRTIs (L100I, K103N) were identified in both groups of patients, although just a few seem to have been selected and became majority variants after 12 or 24 months of ART.

Conclusion DEEPGENHIV improves the detection of minority viral variants in infants following MTCT; however, most of the emergent HIV-1 drug resistance mutations were not present at low frequency at baseline in subjects failing ART, most likely being generated and selected following exposure to therapy. Further studies, using this or other ultrasensitive assays, are needed to better understand the transmission, dynamics and overall evolution of minority drug-resistant viruses in MTCT.

Methods The target population for this study was 5000 asymptomatic individuals in seven communities in the Pakro subdistrict in Ghana. A community register was developed following a census. Community volunteers conducted quarterly house-to-house testing (using RDTs) and treating positive cases with ACTs. Between interventions HBM was conducted.

Results In those tested, asymptomatic malaria parasitaemia reduced from 1795 (36.3%) in July 2017 to 942 (23.1%) in March 2018. In eight months, parasitaemia declined by 43.5% and 37.3% in children under 15 and under 5, respectively. Coverage was 98.8% in July 2017 and 81.4% in March 2018. One of the challenges that surfaced was the fact that decrease in hospital attendance had a negative effect on money generated by the health facility. The district and subdistrict services, though appreciating the work, indicated that the negative effect on the health system may be serious and that measures need to be taken to address alternative financing for the health system.

Conclusion This study has demonstrated that combining MTTT and home-based management of malaria could reduce prevalence in under-15 children and that using community volunteers could ensure effective coverage at lower cost. There is need to start looking at financing of the health system without malaria.