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.

OC 8432 EVALUATION OF AN ANTIBODY-DETECTING POINT-OF-CARE TEST FOR THE DIAGNOSIS OF *TAENIA SOLIUM* TAENIASIS AND NEUROCYSTICERCOSIS/CYSTICERCOSIS IN AN ENDEMIC AREA

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Background *Taenia solium* taeniasis/(neuro)cysticercosis is a neglected parasitic zoonosis with significant economic and public health impacts. Neurocysticercosis is responsible for 30% cases of acquired epilepsy in endemic areas. Diagnosis and case management of neurocysticercosis/taeniasis in resource-limited endemic countries is challenging. Reliable, inexpensive and easy to use diagnostic tools with sufficient sensitivity and specificity are currently not available. A new point-of-care (POC) test based on recombinant rT24H and rES33 proteins developed by the Centre for Disease Control in Atlanta (US) which combines diagnosis of taeniasis and cysticercosis has been developed, however, its performance at community level is not known. The aim of this study is therefore, to evaluate the diagnostic performance of this test in a community setting.
Methods The study site is Mtandaza community, Sinda district, Eastern Province of Zambia. The diagnostic accuracy is being evaluated for taeniasis and (neuro) cysticercosis in 1200 randomly selected participants in a community-based study. The performance characteristics (sensitivity and specificity) for neurocysticercosis will be computed by cross-tabulating of POC results with those of the 'neurocysticercosis diagnosis' while a Bayesian approach will be used for cysticercosis and taeniasis to compare the performance of the index test with reference tests (enzyme-linked immuno-electrotransfer blot (EITB), B158/B60 Ag-ELISA, Ab-ELISA, Copro-Ag ELISA, PCR).
Results Preliminary results of 505 POC tests so far conducted show that 0.8% were positive for taeniasis, 9.1% for cysticercosis and, 4.6% were invalid or unclear. Except for Copro-Ag and B158/B60 Ag-ELISA for taeniasis and cysticercosis respectively, reference tests are yet to be conducted.
Conclusion Results will show the diagnostic value of the POC test and its applicability for use at community level in endemic areas. If successful, implementation of the tool will enable early detection of taeniasis and suspected neurocysticercosis cases and lead to improved patient management and treatment outcomes.

OC 8435 MULTI-BIOMARKER TEST STRIP FOR POINT-OF-CARE SCREENING FOR ACTIVE TUBERCULOSIS: A FIVE-COUNTRY MULTI-CENTRE TEST EVALUATION

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Background Inexpensive rapid screening tests that can be used at the point-of-care (POC) are vital to combat tuberculosis. Particularly, less invasive non-sputum-based biomarker tests for all TB forms can help controlling transmission. Availability of such tests would significantly accelerate and streamline diagnostic approaches, improve cost-efficiency and decrease unnecessary costly GeneXpert referrals.
Methods Multi-biomarker test (MBT) devices measuring levels of selections of up to six serum proteins simultaneously on a single lateral flow (LF) strip were produced. The strip contains individual capture lines for a biomarker selection allowing discrimination of TB-patients from other respiratory diseases (ORD). Only biomarkers successfully evaluated with singleplex strips (single biomarker tests) were applied to the MBT device. Quantitative signals are recorded with a low-cost handheld reader compatible with the applied luminescent up-converting particle (UCP) label. Biomarker selection and algorithms used to distinguish potential-TB and ORD are flexible.
Results Results obtained with MBT strips containing multiple test lines correlate well with singleplex LF strips. Using LF tests for 5 selected biomarkers a sensitivity of 94% and specificity of 96% could be achieved with a confirmed South African selection of 20 TB and 31 non-TB samples. Patients were designated TB positive when scoring a value above the cut-off threshold for at least 3 out of 5 biomarkers. Serum samples of potential TB patients collected at five medical research institutes (Ethiopia, Namibia, South Africa, The Gambia, Uganda) were tested locally with MBT strips comprised of CRP, SAA, IP-10, Ferritin, ApoA-I and IL-6 and results analysed to obtain an overall pan-Africa applicable signature.
Conclusion Evaluated POC applicable UCP-LF devices detecting serum biomarker signatures can help to distinguish active TB from other respiratory diseases and as such can prioritise highest-risk patients for further care. Ongoing prospective studies evaluate the MBT strip with fingerstick blood and do not require a laboratory or trained phlebotomist anymore.

OC 8450 ABSENCE OF MINORITY HIV-1 DRUG-RESISTANT VARIANTS FOLLOWING MOTHER-TO-CHILD TRANSMISSION DOES NOT PREDICT VIROLOGIC SUCCESS OF FIRST-LINE ANTIRETROVIRAL THERAPY

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