Summary of Recommendations from the Twelfth Meeting of the WHO Advisory Committee on Safety of Medicinal Products (ACSoMP)

15-16 April 2015, Geneva

Specific recommendations:

- WHO should establish a strategic sub-group of the Committee to help align the ACSoMP Terms of Reference with the requirements of the reorganised Safety & Vigilance (SAV) Team in WHO and to guide the work of all five WHO Collaborating Centres[1] that support the work of WHO Safety & Vigilance Team.

- WHO/SAV should work with its Collaborating Centres to develop a pharmacovigilance (PV) strategy with a road map and an annual work plan for the programme; and manage and sustain resources for the activities.

- WHO and its Collaborating Centres should work with countries to strengthen PV systems, and to decrease the lag times between the general occurrence of a medicine-related adverse event and recording the event in VigiBase (the WHO global database of Individual Case Safety Reports (ICSRs).

- The WHO/SAV and its Collaborating Centres should meet regularly, co-ordinate and plan training programmes collectively to ensure they complement each other.

- The algorithm developed by the Uppsala Monitoring Centre (UMC) to detect substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products in large ICSR databases should be tested in regions such as the East African Community (EAC). A sub-committee should be established to work with WHO/SAV team and the EAC to take this forward and link with ongoing counter-SSFFC initiatives.

- WHO/SAV should develop a follow-on document to the WHO handbooks on Cohort Event Monitoring (CEM), to define and describe the criteria and various scenarios in which CEM could be used, together with examples of research questions in public health programmes that may be addressed by CEM. A working group from ACSoMP should review the value added with CEM, analyse the cost-benefit of CEM, and options for managing and analysing data from CEM.

- UMC should develop guidelines for national pharmacovigilance centres on how best to manage their PV data. Clear guidance should also be provided on the roles and responsibilities of various stakeholders involved in different aspects of data management.

- SAV to establish a sub-committee within ACSoMP to work with WHO/SAV and Neglected Tropical Disease (NTD) teams for integrating PV within neglected tropical disease prevention and treatment programmes.

[1] WHO Collaborating centres: WHO Collaborating Centre for International Drug Monitoring, *The Uppsala Monitoring Centre, Uppsala, Sweden*; WHO Collaborating Centre for Drug Statistics and Methodology, *Oslo, Norway*; WHO Collaborating Centre for Advocacy & Training in Pharmacovigilance, *Accra, Ghana*; WHO Collaborating Centre for Pharmacovigilance, *Rabat, Morocco*; Pharmacovigilance in Education and Patient Reporting, *s'Hertogenbosch, the Netherlands.*

- In 2012, WHO made a recommendation for the implementation of seasonal malaria chemoprevention (SMC) in areas of Sahel sub-regions where highly seasonal malaria transmission occurs. This consists of a combination of amodiaquine and sulfadoxinepyrimethamine (AQ + SP) which will be administered to children aged between 3 and 59 months at monthly intervals, beginning at the start of the transmission season, to a maximum of four doses during the malaria transmission season, provided both drugs retain sufficient antimalarial activity. The policy also recommends that PV should be strengthened where it exists, and where there is no PV, it should be instituted. ACSoMP recommends that all adverse events (both serious and non-serious events) should be collected in countries where SMC will be launched; WHO (SAV and TDR, the special programme for Research and Training in Tropical Diseases) should work with partners to ensure this. ACSoMP also recommends that an independent regional committee should be established by WHO TDR and its consortium of partners engaged in the SMC initiative, to review the safety data from the SMC initiative and to report to ACSoMP at its next meeting in 2016, or through other ad hoc meetings if needed. PV support for SMC should build on existing systems; in the absence of a PV system in a country, SMC should be leveraged to introduce PV within the country.

- The ACSoMP will remain prepared to advise, if needed, on the deployment of therapeutics, vaccines and health system strengthening initiatives in relation to the WHO response to Ebola Virus Disease (EVD). WHO/SAV should keep the Committee informed on current developments and WHO initiatives related to EVD-response.

- The African Medicines Regulatory Harmonization (AMRH) Initiative was established in 2009 following the efforts of WHO, the New Partnership for Africa's Development (NEPAD), World Bank and others. AMRH aims to improve the access to safe and effective medicines in Africa through regulatory harmonization in the continent. Pharmacovigilance has been included as a component within the AMRH initiative. WHO has reviewed and discussed the PV proposal with ACSoMP. ACSoMP will guide WHO/SAV in drafting a document to highlight the importance of including pharmacovigilance in the AMRH initiative, clarifying the vision and priorities for PV within the initiative, incorporating lessons learnt from other harmonization models, and building on good science, existing systems and networks.

- WHO/SAV routinely receives requests from WHO Member States from individuals working in pharmacovigilance in low- and middle- income countries for learning opportunities in PV through exchange visits with well-resourced regulatory agencies such as the US FDA, MHRA, EMA etc. SAV will follow up with a strategy to manage such requests and facilitate learning opportunities through various mechanisms including bilateral cooperative agreements with selected regulatory agencies.

General Recommendations

- Early involvement of WHO/SAV in WHO public health programmes is recommended, commencing already at the planning stage of the programme, together with relevant resources for SAV, to better plan and support PV requirements and applications within these programmes.

- Risk management plans should be an inherent part of all public health programmes.

- Public health programmes can learn from each other, hence it is recommended that public health programmes share what they are doing in PV, for example, through a conference day on PV, facilitated by the SAV team, to discuss common PV needs and shared solutions.