WHO statement following issue of EU Statement of Non-compliance with EUGMP to North China Pharmaceutical Group Semisyntech Co., Ltd active pharmaceutical ingredient manufacturing facility in Shijiazhuang, Hebei, P.R. China.

A recent Good Manufacturing Practice (GMP) inspection carried out by the French National Agency for Medicines and Health Products Safety (ANSM - Agence nationale de sécurité du médicament et des produits de santé) has identified serious deficiencies concerning documentation and data integrity at:

North China Pharmaceutical Group Semisyntech Co., Ltd
No. 8 Xingye Street,
Shijiazhuang Economic & Technological Development Zone,
Hebei,
052 065 P.R. China

This site was formally known as Hebei Huari Pharmaceuticals Co., Ltd.

Following the inspection, and in consultation with the European Union (EU) Network of National Medicines Regulatory Authorities (NMRAs) for Human and Veterinary medicines, ANSM has issued an EU Statement of Non-compliance (SoNC) with EUGMP for Active Pharmaceutical Ingredients (APIs). The EU statement and its recommendations to EU NMRAs have been posted on the EUDRAGMP website.1

The APIs named in this SoNC are:
- Benzylpenicillin benzathine, 1% lecithine, 0.2% polysorbate 80, 9.2% sodium citrate (sterile)
- Benzylpenicillin procaine (sterile)
- Benzylpenicillin enzylpenicillin procaine +1% lecithin (sterile)

Are any WHO Prequalified Finished Pharmaceutical Products (FPPs) manufactured using any API manufactured by North China Pharmaceutical Group Semisyntech Co., Ltd?

WHO has NOT prequalified any APIs, or FPPs that authorize the incorporation during manufacture of any API manufactured by North China Pharmaceutical Group Semisyntech Co., Ltd, at the facility named in the EU SoNC.

NMRAs and procurement agencies should note that the North China Pharmaceutical Group is a very large group, with over 25 subsidiary and affiliated companies manufacturing a wide range of APIs and intermediates, mainly in the Shijiazhuang area of China. Therefore, when performing risk assessments

1 http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPNonCompliance.do
relating to products manufactured by North China Pharmaceutical Group, care must be taken to avoid confusing companies and sites.

WHO has prequalified the Active Pharmaceutical Ingredient capreomycin (WHOAPI-187) manufactured by another NCPC Group company, North China Pharmaceutical Huasheng Co., Ltd., which is also located within the Shijiazhuang Economic & Technological Development Zone. The most recent inspection of this company was performed in collaboration with the European Directorate for the Quality of Medicines (EDQM) in September 2014. This collaborative inspection with EDQM covered the manufacture of capreomycin and streptomycin sulfate.

The WHO prequalification status of capreomycin (WHOAPI-187) remains unchanged, and is not directly related to the SoNC issued in the EU for North China Pharmaceutical Group Semisyntech Co., Ltd.

Further information:

Dr Deus Mubangizi, Group Lead, Inspections, WHO Prequalification Team — email: mubangizid@who.int