World Health Organization

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In reply please refer to: P5-447-3/JS/ADV

Your reference:

Dr J.C. Hoogvliet
Qualified Person
Synergy Health Utrecht B.V.
Pharmaceutical Laboratories (SHPL)
Reactorweg 47A
3542 AD Utrecht
Pays-Bas

23 September 2014

Dear Dr Hoogvliet,

WHO Prequalification Team
Prequalification of Quality Control Laboratories

Synergy Health Utrecht B.V., Pharmaceutical Laboratories (SHPL), The Netherlands

This is in reference to the letter dated 7.7.2014 expressing interest of the Synergy Health Utrecht B.V., Pharmaceutical Laboratories (SHPL), The Netherlands to participate in the Procedure for assessing the acceptability, in principle, of quality control laboratories for use by United Nations agencies.

Thank you for submitting the data and information requested during the procedure and further cooperation.

We are pleased to inform you that the Synergy Health Utrecht B.V., Pharmaceutical Laboratories, The Netherlands (Chemical-pharmaceutical laboratory, Reactorweg 47A, 3542 AD Utrecht and Microbiological laboratory, Morsestraat 3, 6716 AH Ede) are considered to be operating at an acceptable level of compliance with WHO Good Practices for Pharmaceutical Quality Control Laboratories (GPCL) and will be included in the list of prequalified quality control laboratories together with the areas of expertise inspected and considered prequalified (see Annex 1).

You can access the information on the prequalification procedure, General Notes and Disclaimer, as well as the list of prequalified quality control laboratories, on the website www.who.int/prequal.

ENCLS: (2)

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According to the procedure, each prequalified Quality Control Laboratory should after its prequalification, be re-evaluated on a routine, as well as a non-routine basis. Therefore, each laboratory listed is requested to submit a brief annual report on its activities related to quality control of medicines within a calendar year by the end of March of the following year to the following address (your first report should be submitted by the end of March 2015):

Dr Jitka Sabartova
World Health Organization
HIS/EMP/RHT
20 Avenue Appia
1211 Geneva 27
Switzerland
Email: prequallaboratories@who.int

Please find attached (Annex 2) the outline of the content of the above-mentioned report that is required. Should any changes be implemented that may have significant impact on the prequalification of the laboratory, WHO should be informed without delay.

We should like to take this opportunity to thank you for your cooperation.

Yours sincerely,

Dr Lembit Rägo
Acting Coordinator, Prequalification Team
Regulation of Medicines and other Health Technologies

The Quality Control Laboratory and contact details	Date of last inspection[1]	Final outcome	Date of prequalification	The area of expertise inspected and considered prequalified		
				Type of analysis	*Finished products*	*Active pharmaceutical ingredients*
Synergy Health Utrecht B.V., Pharmaceutical Laboratories (SHPL)[2] Reactorweg 47A 3542 AD Utrecht The Netherlands Tel: +31 30 2843010 Fax: +31 30 2843011 e-mail: utrecht@synergyhealthplc.com	18.12.2012 and 4.9.2013 Dutch Healthcare Inspectorate inspections	Compliant with WHO recommended standards		Physical/Chemical analysis	pH, density, refractive index, optical rotation, viscosity, water content, loss on drying, conductivity, neutralizing capacity, tablet hardness, dimensions, friability, disintegration, dissolution, uniformity of dosage units (mass, content), particulate matter test (visible and sub-visible)	pH, density, refractive index, optical rotation, viscosity, water content, loss on drying, conductivity, particle size, melting point, freezing point, drop point, boiling point, distilling range
				Identification	FTIR, (HP)TLC, (U)HPLC (UV-VIS, PDA, RI detection), GC (FID detection), UV-VIS spectrophotometry, fluorimetry, AAS/AES, basic tests	FTIR, (HP)TLC, (U)HPLC (UV-VIS, PDA, RI detection), GC (FID detection), UV-VIS spectrophotometry, fluorimetry, AAS/AES, basic tests
				Assay, impurities and related substances	(U)HPLC (UV-VIS, PDA, RI detection), GC (FID detection), (HP)TLC, UV-VIS spectrophotometry, fluorimetry, polarimetry, AAS/AES, gravimetric analysis, volumetric titrations, potentiometry, nitrogen determination, residual solvents, ethylene oxide residual analysis	(U)HPLC (UV-VIS, PDA, RI detection), GC (FID detection), (HP)TLC, UV-VIS spectrophotometry, fluorimetry, polarimetry, AAS/AES, gravimetric analysis, volumetric titrations, potentiometry, nitrogen determination, residual solvents, ethylene oxide residual analysis, oxygen flask combustion, composition of fatty acids
				Microbiological tests	Sterility test, microbial limit tests, identification of microorganisms, preservative efficacy test, bacterial endotoxins test (LAL), microbial assay of antibiotics	Sterility test, microbial limit tests, identification of microorganisms, bacterial endotoxins test (LAL), microbial assay of antibiotics
				Stability studies	ICH conditions	ICH conditions

[1] Date of last inspection performed by WHO unless otherwise indicated.

[2] The laboratory has been included on the list based on the WHO assessment, which utilized the results of inspections performed by the Healthcare Inspectorate, Ministry of Public Health, Welfare and Sport of The Netherlands. Therefore no WHO Public Inspection Report is published in this case.

Outline of the content of an annual report on activities of a prequalified laboratory

According to the "Procedure for assessing the acceptability, in principle, of quality control laboratories for use by United Nations agencies" (published as Annex 12 to WHO Technical Report Series No. 961, 2011), each prequalified Quality Control Laboratory should, after its prequalification, be re-evaluated on a routine basis at regular intervals (annually) or earlier, when information requiring re-evaluation is obtained by WHO. To enable the WHO Prequalification team to perform the re-evaluation, all laboratories listed in the WHO List of Prequalified Quality Control Laboratories are requested to submit a brief annual report on their activities.

A report should cover activities related to quality control of medicines within a calendar year and should be submitted by the end of March of the subsequent year. The following items should be included in the report:

- Summary of services provided to UN agencies, other public health organizations procuring medicines and other customers.
- Summary of number of samples analysed, differentiating between compliant and non-compliant samples.
- List of analytical methods used.
- Summary of complaints concerning results of analysis performed by the laboratory received from customers.
- Brief details of any proficiency testing schemes (organizing party, methods involved, outcomes and, if appropriate, adopted corrective measures).
- Listing of inspections and audits performed by external parties, identifying the party and scope of the inspection or audit.
- In the case that changes have been implemented, which have an impact on the content of the LIF (such as changes to facility, equipment or key personnel), a summary of these changes should be included in the report and an updated LIF should be attached.