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| Tel. direct: +41 22 791 35 98  Fax direct: +41 22 791 47 30  E-mail : vanzyla@who.int  In reply please  refer to: P5-447-3/AvZ/VCR/1  Your reference: | Address |
|  | Date |

Dear …,

**WHO Prequalification of Medicines**

As you already know the World Health Organization (WHO), on behalf of the United Nations and other partners, manages prequalification of high-priority health products.

One component of the evaluation procedure of medicines involves inspection the manufacturing sites of finished pharmaceutical products and active pharmaceutical ingredients, and of sites at which efficacy/bioequivalence studies are conducted, to assess compliance with Good Manufacturing Practices (GMP), Good Clinical Practice (GCP) or Good Laboratory Practice (GLP), as appropriate. Only products and manufacturing sites that meet WHO norms and standards are listed in the WHO List of Prequalified Medicines Products or WHO List of Prequalified Active Pharmaceutical Ingredients.

Cooperation with well-resourced national medicines regulatory authorities (NMRAs), and capacity building of staff from NMRAs with limited resources for sustainable evaluation and monitoring of the quality of medicines used in their countries, is one of the WHO Prequalification Team’s (PQT) key strategies. The capacity building activities have also been found to be effective catalysts for harmonization of medicine regulation.

PQT’s capacity building efforts include targeted involvement of inspectors from NMRAs of low-income countries and other interested WHO Member States in its inspections, and sharing of inspections-related information in order to avoid duplicative inspections, promote work sharing and facilitate harmonization of the norms and standards applied during inspections. Further details of this collaborative procedure for inspections, and details of how to participate, can be found on the PQT: medicines web site at [www.who.int/prequal](http://www.who.int/prequal) (under About Us, What We Do, Inspections).

I would like to take this opportunity, to thank you for your support for this important area of WHO activity.

Yours sincerely,

Mr Deus Mubangizi

Coordinator

Prequalification Team