



Action Items from the 2010 Survey of Manufacturers

PQP concluded a comprehensive survey among manufacturers in 2010 to assess its level of service. It identified a number of issues for review and possible follow-up action. These are outlined below. An article on the development, implementation and conclusions of the survey can be found at:

http://www.who.int/medicines/publications/druginformation/issues/DrugInformation2010_Vol24-4/en/index.html

ISSUE	ACTIONS
<p>Question 7A.1 In responding to the statement, "when it comes to the length of time taken to review and reply to applicants during the dossier assessment process", manufacturers have indicated that PQP does not meet their minimum expectations.</p>	<p>Most assessment occurs at Copenhagen assessment sessions which are held every 2 months. This may cause slight delay but is managed so as to minimize this as far as possible. PQP's new IT system, that is under development, will be web based and will facilitate access to and flow of information between assessors, and enable better process monitoring. Implementation is expected later this year.</p>
<p>Question 7A.3 In responding to the statement, "when it comes to providing the same assessors throughout the assessment process for a product dossier", manufacturers have indicated that PQP does not meet their minimum expectations.</p>	<p>As far as possible, the same assessors are involved in the review of a particular dossier. External assessors also work for national regulatory authorities and may not always be available to assist PQP. A different assessor is involved only if there is no other option.</p>
<p>Question 7A.4 In responding to the statement, "when it comes to providing direct access to assessors to address technical questions or deficiencies", manufacturers have indicated that PQP does not meet their minimum expectations.</p>	<p>It is not considered appropriate to provide manufacturers with direct access to assessors. Technical questions are managed centrally by PQP and directed to the most appropriate assessor (internal and/or external). In this way, consistency of responses can be assured. In addition, external assessors are not always available outside their periods of contract with WHO.</p>
<p>Question 7B.1 In responding to the statement, "when it comes to making applicants aware of opportunities for in-person meetings with assessors during the</p>	<p>WHO's PQ procedure provides for meetings before or during dossier assessment.</p>

<p>assessment process", manufacturers have indicated that PQP does not meet their minimum expectations.</p> <p>Question 7B.2 In responding to the statement "when it comes to providing an appropriate number of in-person review meetings during the assessment process", manufacturers have indicated that PQP does not meet their minimum expectations.</p>	<p>Improved guidance about in-person meetings and how manufacturers can request these have been posted on the PQP website.</p> <p>Note: Updates on progress with specific dossier assessments are handled by email correspondence rather than in-person meeting.</p>
<p>Question 7B.4 In responding to the statement, "when it comes to providing an efficient process to resolve issues and questions raised during the assessment of product dossiers", manufacturers have indicated that PQP does not meet their minimum expectations.</p>	<p>WHO's PQ procedure states, "In the event of any disagreement between an applicant and WHO, an SOP [standard operating procedure] established by WHO for the handling of disagreements will be followed to discuss and resolve the issue.</p> <p>A new paragraph advising manufacturers what action they can take in the event of a disagreement has been added to each assessment and inspection report letter.</p>
<p>Question 7D.5 In responding to the statement, "when it comes to including inspectors from your country or region on the inspection team", manufacturers have indicated that PQP does not meet their minimum expectations.</p>	<p>Inspectors from the local national regulatory authority are always invited and encouraged to participate in inspections as observers. This opportunity is not always taken, however.</p>
<p>Question 18.7 When asked how strongly they agree or disagree with the statement, "WHO GMP requirements are more stringent than EU or US FDA GMP requirements", the majority of manufacturers indicated that they were more stringent</p>	<p>In principle, PQP does not wish to be perceived as more stringent than a stringent regulatory authority.</p> <p>Comments from manufacturers in the survey did not help PQP identify the reasons for the perception. For this reason an agenda item to discuss this was included in a meeting on good manufacturing practice with manufacturers on 5 April 2011. At this time no specific areas of stringency were identified. In fact, PQP was commended for having guidelines to clarify GMP requirements. This is seen as helpful to manufacturers. In the absence of specific information, no further action is proposed.</p>