



## Work instructions

Title: New Standard Term requests to EDQM		
Applies to: QRD Secretariat and PTLs/PMs in the H, P and V Units		
<b>PUBLIC</b>		Document no.: WIN/EMA/0108
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### 1. Changes since last revision

New WIN.

### 2. Records

All Standard Term requests are saved electronically in the folder:

*EDMS\Meetings\Scientific Meetings\Q R D - P I Q\16 QRD Issues\04 Standard terms issues & EDQM*

### 3. Instructions

EDQM: European Directorate for the Quality of Medicines and Health Care

PTL: Product Team Leader

PM: Project Manager

QRD: Quality Review of Documents

QWP: Quality Working Party

SPC: Summary of Product Characteristics



<b>Step</b>	<b>Action</b>	<b>Responsibility</b>
<b>1</b>	<p>During pre-submission meeting (or at the latest by day 110), identify new Standard Term or new combination of existing Standard Terms proposals.</p> <p>For <u>new</u> Standard Term proposals go to step 2</p> <p>For new <u>combination</u> of existing Standard Terms proposals go to step 11</p>	PTL/PM
<b>2</b>	Ask company to submit to the PTL/PM a request, together with the appropriate documentation (i.e. full justification and proposed SPC), for a new Standard Term.	PTL/PM
<b>3</b>	Forward company request to QRD Secretariat.	PTL/PM
<b>4</b>	<p>Send company request to QRD members (advisory role) for review via written procedure.</p> <p>Inform PTL/PM if timing adjacent to a QRD Plenary meeting and request to be discussed during the meeting.</p> <p>At the meeting, PTL/PM will present the issue to QRD members for discussion.</p>	<p>QRD Secretariat</p> <p>QRD Secretariat</p> <p>PTL/PM</p>
<b>5</b>	If QRD review is via written procedure, inform PTL/PM about QRD position	QRD Secretariat
<b>6</b>	<p>Inform (via written procedure) the QWP (advisory role) about the request for a new Standard Terms and circulate QRD position.</p> <p>Inform QRD Secretariat if timing adjacent to a QWP meeting and request to be discussed during the meeting.</p> <p>QRD Secretariat will participate to the meeting and PTL/PM will present the issue to QWP members.</p>	<p>PTL/PM</p> <p>PTL/PM</p> <p>QRD Secretariat PTL/PM</p>
<b>7</b>	If QWP review is via written procedure inform QRD Secretariat about QWP position.	PTL/PM
<b>8</b>	<p>Send request to EDQM (deciding body) together with the Agency (QRD+QWP) position.</p> <p><i>In case of QWP and QRD divergent positions these should both be sent to EDQM.</i></p>	QRD Secretariat
<b>9</b>	Forward to PTL/PM (after EDQM 1 month consultation period) the EDQM position.	QRD Secretariat
<b>10</b>	Send EDQM position to company.	PTL/PM
<b>End of Procedure</b>		
<b>11</b>	<p>Liaise with QRD Secretariat to assess* the proposal for a new combination of existing Standard terms.</p> <p>If proposal accepted by common position go to step 13</p> <p>If no agreement reached go to step 12</p> <p>If proposal rejected go to step 13</p>	<p>PTL/PM</p> <p>QRD Secretariat</p>

<b>Step</b>	<b>Action</b>	<b>Responsibility</b>
	<i>*PTL/PM together with QRD Secretariat to decide whether it is necessary to consult EDQM.</i>	
<b>12</b>	Seek advice from QRD Group (via written procedure) go to step 4	QRD Secretariat
<b>13</b>	Send the Agency/QRD conclusion to company.	PTL/PM
<b>End of Procedure</b>		