**User stories**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **1. Applicants to be able to submit an application for product registration** | | | | |
|  | **Who** | **What** | **Why** | **Priority**  H: High, M: Moderate, L: Low | **Acceptability tests** |
|  | Applicant | Create new account  (user name and password) | To get access to the system | H |  |
|  | Applicant | Fill the applicant details\* such as name, business address, postal address, country, email, phone number, and company details\* such as company name, plant address, postal address, website, phone number to create an account | To have full details of the applicant and use the information in latter processes | H |  |
|  | Applicant | Log in to the system | To submit and track applications | H |  |
|  | Applicant | Log out from the system (confirmation message before logging out) | To close and secure account | H |  |
|  | Applicant | Change passwords | To secure the account | H |  |
|  | Applicant | Reset passwords | To replace forgotten passwords | H |  |
|  | System | Introduce password control mechanisms (use of caps, alphabet, symbol, and number) while creating passwords | To strengthen the passwords | H |  |
|  | System | Grant access level only as applicant | To secure data sharing | H |  |
|  | Applicant | Ask further queries | To get additional information | H |  |
|  | Contact person (email) of the NMFA | View applicant queries | To address the queries | H |  |
|  | System admin (Supervisor) | Upload essential materials\* for registration which includes guidelines, application forms, bank details, list of local authorized agents | To provide access of the documents to the system users | H |  |
|  | System | Store essential material for registration | To provide access to applicant and assessor | M |  |
|  | All users with access to the system | View the materials | To refer and use the materials | M |  |
|  | All users with access to the system | Download the materials | To refer and use the materials | M |  |
|  | Applicant | Initiate application submission process by filling the application form\* | To submit the application form | H |  |
|  | Applicant | Import application details from excel sheet  *N.B: For offline mode, the supervisor should be able to upload excel sheet and put in the respective applications* | To upload the details to the system | H |  |
|  | System | Autosave application process after each step | To reduce loss of information | H |  |
|  | Applicant | Save and logout amid submission process | To be able to leave and resume process later | H |  |
|  | System | List out partially saved submissions | To continue partially saved processes | H |  |
|  | System | Provide prefilled information\* (ENLM, field instructions) to the applicant while filling the details | To ease the application process | H |  |
|  | System | Allow entry of other medicines outside ENLM | To provide special route of registration | H |  |
|  | System | Provide alert (color code) to the supervisor/assessor for medicines outside of the ENLM | To help the assessor to take informed decision | H |  |
|  | System | Remember applicant details for future use | To ease the application process | M |  |
|  | System | Check and verify completeness of submissions\* (check filling of the mandatory fields) | To ensure completeness | H |  |
|  | System | Alert the applicant for unfilled mandatory fields | To lock passing to the next step without filling the mandatory fields | H |  |
|  | System | Remind applicant for partially saved submissions every 5 days via email to the applicant and contact person | To remind the applicant to complete submission at the earliest possible time | H |  |
|  | System | Delete partially saved/incomplete submissions that lasts longer than 30 days | To minimize system overload | H |  |
|  | Applicant | Upload dossier in PDF format  *N.B: For offline mode, the supervisor should be able to upload the dossiers and put in the respective applications* | To upload the dossiers to the system | H |  |
|  | Applicant | Submit the application | To complete the submission process | H |  |
|  | System | Generate application number\* according the PERU SOP | To create proper referencing and unique identification | H |  |
|  | System | Send notification for successful submission to the applicant and supervisor | To ensure completion of submission and proceed with further process | H |  |
|  | System | Sort application unique ID by date, manufacturer, product | To easily view and generate report | H |  |
|  | System | Notify assessor to process applications of each product every 10 days via database notification until completion of preliminary screening | To remind pending submission | H |  |
|  | Applicant | View the status of all submissions (partially saved, in progress applications, and finalized applications) in the dashboard after each log in | To ensure transparency | H |  |
|  | System | Track fully submitted applications (Application number and Name) | To ensure transparency | H |  |
|  | **2. Assessors to be able to screen submissions** | | | | |
|  | Supervisor | Create new account  (user name and password) | To get access to the system | H |  |
|  | Supervisor | Fill personal details\* such as name, business address, postal address, country, email, phone number, to create an account | To have full details of the supervisor | H |  |
|  | Supervisor | Upload CV in PDF format | To archive the document |  |  |
|  | Supervisor | Log in to the system | To review and track applications | H |  |
|  | Supervisor | Log out from the system (confirmation message before logging out) | To close and secure account | H |  |
|  | Supervisor | Change passwords | To secure the account | H |  |
|  | Supervisor | Reset passwords | To replace forgotten passwords | H |  |
|  | System | Introduce password control mechanisms (use of caps, alphabet, symbol, and number) while creating passwords | To strengthen the passwords | H |  |
|  | System | Grant access level as supervisor | To secure data sharing | H |  |
|  | Supervisor | Create account for the assessor, NMFA units, Director/PERC | To access, review, and track submissions | H |  |
|  | System | Provide option for the supervisor to assign access level during sign up | To secure data sharing | H |  |
|  | System | Notify the assessor, NMFA units, Director/PERC for the new user account | To remind the users on the new created account |  |  |
|  | System | Provide link to the users on the new account via email | To get access to the system and finalized the signing up process |  |  |
|  | Assessor, NMFA units, Director/PERC | Change passwords | To secure the account  To have full details of the assessor |  |  |
|  | Assessor, NMFA units, Director/PERC | Reset passwords | To replace forgotten passwords |  |  |
|  | System | Introduce password control mechanisms (use of caps, alphabet, symbol, and number) while creating passwords | To strengthen the passwords | H |  |
|  | Assessor, NMFA units, Director/PERC | Edit personal details\* | To provide detailed information of the users |  |  |
|  | Assessor | Upload CV in PDF format | To archive the document |  |  |
|  | NMFA units, Director/PERC | Upload CV in PDF format (optional) | To archive the document |  |  |
|  | Assessor, NMFA units, Director/PERC | Log in to the system | To access, review and track applications | H |  |
|  | Assessor, NMFA units, Director/PERC | Log out from the system (confirmation message before logging out) | To close and secure account | H |  |
|  | Supervisor | Assign application submission for preliminary screening | To grant access of the documents to the respective assessor |  |  |
|  | System | Notify the assessor of new assignment | To remind the assessor on the new assignment |  |  |
|  | System | Start clock and set deadline (14 days) | To track the timeline of the processes |  |  |
|  | System | Notify supervisor for reached deadlines | To remind the supervisor on the deadlines |  |  |
|  | System | Lock the activity after the deadlines is reached | To stop the assessor from continuing the process |  |  |
|  | Supervisor | Extend deadlines | To provide extra days for reasonable delays |  |  |
|  | Assessor | Access and view documents submitted by the applicant | To conduct preliminary screening |  |  |
|  | System | Remind the assessor every 5 days until report submission | To remind the incomplete assigned tasks |  |  |
|  | Assessor | Import screening report\* (Word format) to the system | To upload the report to the system |  |  |
|  | System | Check and verify completeness of report submissions\* (check filling of the mandatory fields) | To ensure completeness |  |  |
|  | Assessor | Submit screening report | To finalize submitting preliminary screening report |  |  |
|  | System | Stop clock and turn off reminders | To mute unnecessary reminders |  |  |
|  | System | Archive screening reports | To ensure proper documentation |  |  |
|  | Supervisor | Export report in printable format | To document the report in hard copy |  |  |
|  | Supervisor | Send queries to assessor if applicable | To communicate the mistakes/concerns with the assessor |  |  |
|  | System | Notify assessors for the queries from supervisor | To alert the assessor on the new message |  |  |
|  | System | Set deadline (2 days) | To track the timeline of the processes |  |  |
|  | Assessor | Send queries to applicants (if available) via email and system (Template x) | To respond to the queries |  |  |
|  | System | Notify the supervisor for query submitted by the assessor | To alert the supervisor on the new message |  |  |
|  | Note: if the queries have not been sent, the system should lock the activities and notify the supervisor | | | | |
|  | System | Notify the applicant of the queries issued by the assessor | To alert the applicant on the new queries |  |  |
|  | Applicant | View queries in dashboard | To ensure transparency |  |  |
|  | Applicant | Send response to queries | To reply to queries |  |  |
|  | Applicant | Upload response to queries document (Word or PDF format) when desired | To upload to the system |  |  |
|  | Assessor | View query response | To see the reply |  |  |
|  | Assessor | Issue acknowledgment of receipt of registration application (Template x) | To notify the applicant on the reception of the registration application |  |  |
|  | System | Notify the applicant of the incoming letter | To remind the applicant on the incoming letters |  |  |
|  | Applicant | View the letter | To be able to read the letter |  |  |
|  | Applicant | Download the letter | To archive and print the letter |  |  |
|  | Assessor | Issue invoice letter (template x) | To initiate the payment process |  |  |
|  | Applicant | View the letter | To be able to read the letter |  |  |
|  | Applicant | Download the letter | To archive and print the letter |  |  |
|  | System | Set deadlines for payment and samples submission (90 days) | To track the timelines |  |  |
|  | The deadline for the applicant should be shortened to 30 days and remind the applicant every 10 days. | | | | |
|  | System | Notify applicant every 30 days for due payment and sample | To remind the applicant on the upcoming deadline |  |  |
|  | System | Notify the applicant, assessor, and supervisor for the upcoming deadline (10 days before) | To remind them on the upcoming deadline |  |  |
|  | System | Lock the activity after the deadlines is reached | To stop the applicant from continuing the process |  |  |
|  | Supervisor | Extend deadlines | To provide extra days for reasonable delays |  |  |
|  | Supervisor  This role should be changed to the system | Clear/delete incomplete submissions (include the time limit) | To reduce burden of incomplete submissions on the system |  |  |
|  | Applicant | Upload Payment swift copy | To finalize the payment process |  |  |
|  | Applicant | Upload waybill (DHL/FedEx) |  |  |  |
|  | Assessor | Print the payment swift copy | To document and send the letter to the Finance department of MoH |  |  |
|  | Assessor | Upload fee receipt to the system | To archive the receipts |  |  |
|  | Assessor | Confirm payment reception | To ensure the payment is secured and pass to the next step |  |  |
|  | System | Generate financial (payment) notification letter to the applicant (Template x) | To ensure transparency |  |  |
|  | Assessor | Print financial notification letter and upload the scanned letter | To document the letter in hard copy |  |  |
|  | Applicant | View the letter | To be able to read the letter |  |  |
|  | Applicant | Download the letter | To archive and print the letter |  |  |
|  | Assessor | Confirm sample reception (waived for WHO – CRP) | To ensure the payment is secured and pass to the next step |  |  |
|  | System | Generate and send acknowledgement letter to the applicant for the completion of Preliminary assessment (Template X) | To ensure transparency |  |  |
|  | Assessor | Print the above letter | To document the letter in hard copy |  |  |
|  | Applicant | View the letter | To be able to read the letter |  |  |
|  | Applicant | Download the letter | To archive and print the letter |  |  |
|  | System | Notify the supervisor on the completion of the preliminary assessment | To remind and proceed to the next process |  |  |
|  | **3. Evaluation of dossiers** | | | | |
|  | System | Generate an automatic dossier reference number |  |  |  |
|  | System | Notify supervisor of incoming/new dossiers |  |  |  |
|  | Supervisor | Track already assigned dossiers for each assessor  **N.B.** *Status check by date, number of dossiers under assessment* |  |  |  |
|  | Supervisor | Assign dossiers to assessors |  |  |  |
|  | System**#** | Start clock (60 days for fast track, 130 days for standard review) |  |  |  |
|  | System | Notify assessors of dossiers assigned to them |  |  |  |
|  | Assessor | Access dossier files |  |  |  |
|  | Assessor | Send specific dossier sections to respective units/PERC (whenever required) |  |  |  |
|  | Assessor | Upload the specific dossier section |  |  |  |
|  | NMFA units/PERC | View and download the specific dossier sections |  |  |  |
|  | Assessor | Set deadlines for report submissions assigned to NMFA units/PERC (deadlines editable) |  | Reminder 10 days prior to the deadline |  |
|  | System | Notify respective personnel of assigned tasks via email and database system |  |  |  |
|  | NMFA units/PERC | Access assigned tasks |  |  |  |
|  | Assessor/NMFA units/PERC | View and fill assessment report form (template x) |  |  |  |
|  | Assessor/NMFA units/PERC | Save un-submitted or incomplete entries in the assessment report |  |  |  |
|  | Assessor/NMFA units/PERC | Export assessment report |  |  |  |
|  | System | Check and verify completeness of report submissions\* (check filling of the mandatory fields) | To ensure completeness |  |  |
|  | NMFA units/PERC | Upload the assessment report |  |  |  |
|  | NMFA units/PERC | Submit assessment report to assessor |  |  |  |
|  | System | Notify assessor of incoming reports |  |  |  |
|  | Assessor | Access reports from NMFA units/PERC |  |  |  |
|  | Assessor | View and download the submitted reports |  |  |  |
|  | Assessor | Send queries to NMFA units/PERC (if any) |  |  |  |
|  | System | Notify NMFA units/PERC for the incoming queries |  |  |  |
|  | NMFA units/PERC | Respond to the incoming queries |  |  |  |
|  | **3.1 Steps for sample testing** | | | | |
|  | Assessor | Issue letter for QC analysis to Inspection unit (Template) |  |  |  |
|  | NMFA units (Inspection unit) | Fill request form for QC analysis (Check mandatory fields) (Template) |  |  |  |
|  | NMFA units (Inspection unit) | Print the above request form |  |  |  |
|  | NMFA units (Inspection unit) | Set deadline (editable) for submission of QC analysis report |  | Remind one-third and two-third of the total time |  |
|  | System | Notify QC unit for the new request |  |  |  |
|  | NMFA units (QC) | View and print QC request form |  |  |  |
|  | NMFA units (QC) | View and fill QC analysis report (template x) |  |  |  |
|  | NMFA units (QC) | Upload QC lab analysis results (pdf format) |  |  |  |
|  | System | Notify the assessor and inspection unit for the incoming reports |  |  |  |
|  | System | Check and verify completeness of report submissions\* (check filling of the mandatory fields) | To ensure completeness |  |  |
|  | Assessor | Upload the assessment reports (word format) |  |  |  |
|  | Assessor | Submit report to supervisor |  |  |  |
|  | System | Notify the supervisor of the submitted assessment report |  |  |  |
|  | Supervisor | View and download the assessment report |  |  |  |
|  | Supervisor | Upload the commented assessment report |  |  |  |
|  | Supervisor | Forward/send comments to the assessor |  |  |  |
|  | Assessor | View and download the comments sent from the supervisor |  |  |  |
|  | Assessor | Issue query letter to the applicant (Template of the official letter)  (Template for the queries) |  |  |  |
|  | Assessor | Set deadline (editable) for submission of query responses |  | Remind 5 days prior to deadline |  |
|  | System**#** | Pause clock until responses are received |  |  |  |
|  | System | Notify the applicant for the incoming queries |  |  |  |
|  | Applicant | View queries |  |  |  |
|  | Applicant | Upload response files (field instruction) |  |  |  |
|  | System**#** | Start clock after the responses are uploaded |  |  |  |
|  | System | Notify the assessor for the incoming response |  |  |  |
|  | Assessor | View and download submission files (there might be multiple steps) |  |  |  |
|  | Assessor | Submit final assessment report to the supervisor |  |  |  |
|  | System | Notify the supervisor on the submission of the final report |  |  |  |
|  | Supervisor | View and download the final assessment report |  |  |  |
|  | Supervisor | Upload the commented final assessment report |  |  |  |
|  | Supervisor | Forward/send comments to the assessor |  |  |  |
|  | System | Notify the assessor of the forwarded comments |  |  |  |
|  | System | Remind the assessor for un-submitted tasks 10 days prior to the deadline via system database | To remind the assessor to complete submission at the earliest possible time |  |  |
|  | Assessor | View, download and edit the final report |  |  |  |
|  | Assessor | Upload and Submit the final revised report to the supervisor |  |  |  |
|  | System | Notify the supervisor of the incoming report and display list of reports awaiting decision for registration |  |  |  |
|  | System**#** | Stop clock |  |  |  |
|  | Supervisor | Extend deadlines (editable) for uncompleted tasks |  |  |  |
|  | Supervisor | Set deadline for registration decision |  |  |  |
|  |  |  |  |  |  |
|  | **Release three** | | | | |
|  | Supervisor | Send message to PERC members via email and system (template) |  |  |  |
|  | Supervisor | Send assessment reports to PERC members |  |  |  |
|  | PERC | Access assessment reports |  |  |  |
|  | Supervisor | Add PERC meeting date | To archive the date of decision |  |  |
|  | Supervisor | Upload PERC recommendation/meeting minutes (PDF) | To archive the decision of the committee | The page should provide three boxes to check either one. (Accepted, rejected, deferred) |  |
|  | **3.1 If the decision is “rejection”.** | | | | |
|  | System | Generate rejection letter (template) |  |  |  |
|  | Supervisor | Edit and send rejection letter to the applicant and local agent |  |  |  |
|  | Applicant | View the decision letter |  |  |  |
|  | System | Lock the application after two months of rejection (if appeal is not received) |  |  |  |
|  | Supervisor | Upload letter from Ministry of Health (letter of decision for the appeal) in the case of appeal. |  | The page should provide two boxes to check either one. (Acceptance vs rejection of the appeal) |  |
|  | System | Notify the supervisor for new dossier assignment |  | If the appeal is accepted and the supervisor checked the Acceptance box while uploading the letter.  N.B. the application number and dossier reference numbers remain the same. |  |
|  | Supervisor | Reassign the dossier for review to assessor |  | N.B. Repeat the steps that are covered in the release two. |  |
|  | System | Lock the application |  | If the appeal is rejected and the supervisor checked the Rejection box while uploading the letter. |  |
|  | **3.2 If the decision is “deferred”.** | | | | |
|  | System | Generate deferral letter (template) |  |  |  |
|  | Supervisor | Edit and send deferral letter to the applicant |  |  |  |
|  | Applicant | View the decision letter |  |  |  |
|  | Supervisor | Set deadline for the deferral (editable) |  |  |  |
|  | System | Remind the supervisor and applicant for the upcoming deadline (5 days before) |  |  |  |
|  | Applicant | Upload materials to respond the deferral decision |  |  |  |
|  | Supervisor | Extend deadline (editable) |  | N.B. If the applicant failed to upload or the uploaded material requests for deadline extension |  |
|  | System | Notify for the incoming message to the supervisor and the assessor |  |  |  |
|  | Assessor/  Supervisor | View the incoming message |  | N.B. Repeat the steps that are covered in the release two and three. |  |
|  | **3.3 If the decision is accepted.** | | | | |
|  | System | Generate Registration No. (Template) |  |  |  |
|  | System | Generate Certificate No. (Template) |  |  |  |
|  | System | Generate Marketing Authorization Certificate (Template) |  |  |  |
|  | Supervisor | Print Market Authorization Certificate |  |  |  |
|  | Supervisor | Upload signed and sealed Market authorization certificate |  |  |  |
|  | System | Archive the Market authorization certificate |  |  |  |
|  | System | Send the certificate to the Applicant (including Local agent) via system and email |  |  |  |
|  | Applicant/Local agent | View and download the Market authorization certificate |  |  |  |
|  | System | Update the list of registered products. (Template) |  |  |  |
|  | System | Lock the application |  | The timeline for product registration should stop here. |  |
|  | **Release four: Post-marketing Evaluation** | | | | |
|  | **4.1 Re-registration** | | | | |
|  | System | Notify MAH 6 months prior to expiration of application |  | Continue the notification every month |  |
|  | System | Notify the supervisor 3 months prior to the expiration of application |  |  |  |
|  | System | Color code (red) the expiration notification alert |  |  |  |
|  | System | Lock the registered application after expiry |  |  |  |
|  | System | Notify the supervisor and applicant of expired registration status |  | Allow the applicant to express interest for reregistration even after the registration application is locked |  |
|  | Supervisor | Extend the deadline for reregistration, if applicable (max. 3 months) |  |  |  |
|  | System | Permanently locks the application after 3 months of extension |  |  |  |
|  | Applicant | Choose an option to reregister in the already registered application |  | The options provided should be;  Variation, PSUR, Withdraw, Renew |  |
|  | Applicant | Fill new application form (Template4 R1) |  |  |  |
|  | Applicant | Submit/Attach relevant documents for reregistration (Template) |  | This template is the same as the template containing field instructions for submission of dossiers |  |
| Repeat user stories from 15-35, 58-214 except include the below changes; | | | | | |
|  | Change template for preliminary screening (Template2 R4) | | | | |
|  | Change the dossier reference numbering system (Template3 R4) | | | | |
|  | Change template for evaluation of re-registration (Template4 R4) | | | | |
|  | The clock should be similar to fast track | | | | |
|  | **4.2 Before expire of registration** | | | | |
|  | **Receive PSUR and alert notification from an applicant and NMFA director, respectively** | | | | |
|  | Applicant | Choose an option to submit PSUR of the already registered application |  |  |  |
|  | Applicant | Upload the PSUR along with the cover letter (Template5 R4) |  |  |  |
|  | NMFA director | Choose an option to submit alert notifications of the already registered application |  |  |  |
|  | NMFA director | Upload the alert notification |  |  |  |
|  | System | Assign PSUR reference no. (Template6 R4) |  |  |  |
|  | System | Notify the supervisor of the incoming PSUR/alert notification |  |  |  |
|  | System | Send acknowledgment letter to applicant for receipt of PSUR (Template7 R4) |  |  |  |
|  | Supervisor | Relay the PSUR to the PERC (select specific NMFA unit) |  |  |  |
|  | Supervisor | Set a deadline for the submission of PSUR report (editable) |  |  |  |
|  | System | Send reminder to the supervisor and PERC member 10 days prior to the deadline |  |  |  |
|  | PERC member and supervisor | View and download PSUR |  |  |  |
|  | PERC member | Upload review report of PSUR (Template8 R4) |  |  |  |
|  | System | Notify the supervisor for the incoming review report |  |  |  |
|  | Supervisor | Subject PSUR/alert notification to decision, if applicable |  |  |  |
|  |  | | |  |  |
|  | **Suspension/Withdrawal/Cessation of registered product** | | | | |
|  | Supervisor | Choose an option to suspend the already registered application |  | The options provided should include;  Suspend, cease/revoke |  |
|  | Supervisor | Upload any supplementary material to support the decision |  |  |  |
|  | Supervisor | Set a time period for the suspension (editable) |  |  |  |
|  | System | Send letter of suspension to the applicant (Template9 R4) |  |  |  |
|  | System | Update the list of suspended products |  |  |  |
|  | System | Notify the applicant and NMFA director of the suspension decision |  |  |  |
|  | Applicant | Upload response letter against the suspension decision and other supplementary materials (Template10 R4) |  |  |  |
|  | System | Notify the supervisor for the incoming message |  |  |  |
|  | Supervisor | Upload letter from Ministry of Health (letter of decision for the appeal) in the case of appeal. |  |  |  |
|  | Supervisor | Choose an option to un-suspend application |  | The options provided should include;  Un-suspend, cease/revoke |  |
|  | System | Update the list of registered products |  |  |  |
|  | Supervisor | Choose an option to cease the already registered application |  |  |  |
|  | Supervisor | Upload any supplementary material to support the decision |  |  |  |
|  | System | Send a cessation letter to the applicant (Template9.1 R4) |  |  |  |
|  | System | Update the list of ceased products |  |  |  |
|  | System | Notify the applicant of the incoming letter |  |  |  |
|  | Supervisor | Upload letter from Ministry of Health (letter of decision for the appeal) in the case of appeal. |  |  |  |
|  | Supervisor | Change the cessation decision |  | If the appeal has been accepted |  |
|  | System | Update the list of registered medicines |  |  |  |
|  | Applicant | Choose an option to withdraw the registered product |  |  |  |
|  | Applicant | Upload supplementary materials to support the applicant’s request |  |  |  |
|  | System | Notify the supervisor and the NMFA director of the incoming message |  |  |  |
|  | System | Update the list of withdrawn products |  |  |  |
|  |  |  |  |  |  |
|  | **Variation submission** | | | | |
|  | Applicant | Choose an option to submit variations of the already registered application |  |  |  |
|  | Applicant | Upload the variations documents along with the cover letter (Template) |  | If and only if the file size is small. |  |
|  | Supervisor | Choose an option to upload variations of the already registered application (in case of WHO-CRP, and manually received variations) |  |  |  |
|  | System | Assign variation reference no. (Template) |  |  |  |
|  | System | Notify the supervisor of the incoming variations |  |  |  |
|  | System | Send acknowledgment letter to applicant for receipt of variations (Template) |  |  |  |
|  | System | Notify the applicant of the incoming acknowledgment letter |  |  |  |
|  | Supervisor | Assign the variation application to an assessor |  |  |  |
|  | Supervisor | Set deadline for assessment of variation (editable) |  |  |  |
|  | System | Notify assessor of the assigned variation application |  |  |  |
|  | Assessor | Send queries to the applicant, if applicable |  |  |  |
|  | Loop between number 75 and 82 | | | | |
|  | System | Send reminder 10 days prior to the deadline |  |  |  |
|  | Assessor | Upload and send assessment report |  |  |  |
|  | System | Notify the supervisor of the incoming assessment report |  |  |  |
|  | Supervisor | Upload and forward decision letter to the applicant (Template) |  |  |  |
|  | System | Notify the applicant of the incoming letter |  |  |  |
|  | System | Update the list of accepted and rejected variations |  |  |  |
|  | Supervisor | Upload letter from Ministry of Health (letter of decision for the appeal) in the case of appeal. |  |  |  |
|  | Supervisor | Change the decision on the rejection of the variation |  | If the appeal has been accepted |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

N.B. Sealed letter (electronic signature or manual)

* Create new user stories and templates for WHO-CRP (appendix for access request to MedNet, communicating decision to WHO)

**Progress note display format**

**Percentage of weight for standard review**

Preliminary screen (10%)

QOS/QIS assessment (20%)

Quality assessment (60%)

After the first query is issued (30% increase)

After sample testing result is received (10% increase)

After final assessment report is submitted (20% increase)

Registration decision and certification (10%)

**Percentage of weight for fast track review**

Preliminary screen (20%)

Quality assessment (60%)

After the first query is issued (40% increase)

After final assessment report is submitted (20% increase)

Registration decision and certification (20%)

**Kanban Board**

Assigned tasks

In progress (progress report in line with the above classification)

Completed tasks (stay on the list for 3 months and permanently stored then after, there must be option for deleting the list)

**Interface of the database**

**Page 1**

**Possible users of the software**

**Applicants**

Marketing authorization holders (Manufacturers & Suppliers)

Local Authorized agents

**Assessors** **Supervisor** **NMFA Units** **NMFA Director Members of the registration committee**

The system

Procuring agencies

Visitors

Functions of the software

Application reception

Goal:

**1. Submit an application for product registration**

**Applicant**

Request any queries (application form)

Download essential materials

Submit application

Application form

Payment

Dossiers

Samples

**Assessor**

Preliminary screening of the submitted applications

Submit and issue report

Attach fee receipt

**The system**

Notification to both the applicant and assessor

Acknowledgement letter issuing that is approved by the assessor

Starting the clock 90 days (if there is any queries) [cancellation of the process] and relay the decision to the assessor

Allow extensions of preset deadlines

Allow to see ENLM

Instruction for filling each field box when required

Issue financial notification to local agent and applicant

Issue invoice letter

Create user account, change and reset password

Generate application number

Reminder to partially saved application and delete if incomplete submission longer than one month.

Import files from excel to the software

**2. Track the application submission process**

Partially saved

Fully saved