

ePQS Terms and Conditions of use (4 October 2023)

Access to the ePQS is limited to registered users. By registering and using ePQS, users agree to comply with the following Terms and Conditions.

1. Definitions

In the present Terms and Conditions, unless the context requires otherwise:

“Materials” includes, but is not limited to:

- Procedural application forms and declarations
- Technical data, information and summaries necessary to support the assessment of a new or changed product, laboratory, site, clinical trial, or relevant procedure. Including, but limited to, confidential and non-confidential information regarding the preparation, function, safety, quality, efficacy, stability of a product, laboratory, site or clinical trial.
- Information leaflets, any product-related information, and photos

“Personal Data” means information which can be used to identify an individual, either directly or indirectly, such as name or national identification number, passport number, telephone number, residential address, bank account number, employee number, Internet protocol (IP) address, or some other unique identifier pertaining to an individual or any information that when combined, can be used to identify an individual.

“Purpose” means, (i) for WHO external experts: to gain access to information necessary to complete their application assessment duties, e.g. related assessment reports, manufacturer dossiers, etc. ; (ii) for NRA experts: to conduct their assessment and consider the registration of the product within their regulatory system

“Site” means the ePQS portal.

“User” means any authorized user of ePQS website including vendors, external WHO experts, WHO implementing partners and National Regulatory Authorities (NRAs) who submitted the Registration Form.

“ePQS” means the Salesforce community portal and the associated Box or Extedo Documentation Management System repositories.

2. General Rules

2.1. By registering to the Site, the User commit to comply with the present ePQS Terms and Conditions of use with respect to the use of the Site.

2.2. The rights and obligations concerning the use of the Site and its Services are personal to the User, and are not transferable to any other person or entity.

2.3. The User acknowledges and agrees to apply relevant procedures for prequalification.

2.4. No waiver by a User to the present ePQS Terms and Conditions of use or any of its provisions, or any breach or default of the ePQS Terms and Conditions of use, shall be deemed to be a waiver of any preceding or subsequent breach or default.

3. Changes to the terms and conditions

3.1. WHO reserves the right, at its discretion, to make changes to the present ePQS Terms and Conditions of use at any time. All changes and modifications will be notified to the User by being posted on the Site, or sent to the User via email, and it is their responsibility to read these changes and modifications. They will come into effect immediately upon being posted, unless otherwise stated in the notice.

3.2. The User's use of the Site, or continued use following the notification of any changes or modifications of these Terms and Conditions of use, will constitute a binding acceptance by the User of such changes or modifications.

4. Username and Password

4.1. Upon registration, the User will provide their email address, which will be their username (Username). The User will be sent a site activation link via email using the email address provided and a password (Password) of their own choice can be created. The user should choose a strong password with a minimum password length of eight characters including at least uppercase, lowercase number and special characters. The User may not (i) use a name of another person with the intent to impersonate that person; (ii) use a name subject to the rights of any other person without authorization; or (iii) use a name that ePQS, at its sole discretion, deems offensive.

4.2. The User will be solely responsible for protecting the confidentiality of their Username and Password, and solely liable for any harm resulting from disclosing or allowing disclosure of any Password.

4.3. The User must notify WHO immediately of any known or suspected unauthorized use of their Username or Password, or any known or suspected breach of security, including loss, theft, or unauthorized disclosure of their Password. Any fraudulent, abusive or otherwise illegal activity may be grounds for termination of their account, at WHO sole discretion.

5. Use of the ePQS Site and confidentiality

5.1. At all times, the User shall be responsible for all use of the Site under their authorized account, and the User will be solely responsible for ensuring that any use of their account complies fully with the present Terms and Conditions of use of ePQS.

5.2. The User is permitted to download or print extracts of the Materials on the Site for their personal use only, and for lawful purposes only, provided that the User protects all copyright and other notices contained in the Material and agree to abide by all additional copyright notices, information, or restrictions contained in such Material. None of the material on the Site may be used for any commercial or public use, and no part of such material may be reproduced or stored in or transmitted to any other website.

5.3. No material on the Site may be disseminated in any form, either electronic or non-electronic, or included in any retrieval system or site without the prior written permission of WHO. Any request for such permission shall be sent to the attention of Manager, Prequalification Unit.

5.4. The User shall not send unsolicited e-mails to any e-mail addresses obtained through ePQS. No information provided by WHO to the User shall be communicated in any fashion to any third party or used to contribute towards any other Services.

5.5 Users agree to treat any information, documentation and Material available on the Site (“Information”) as strictly confidential and proprietary to the Applicant, parties collaborating with the Applicant and/or reference SRA as relevant. Thus, the User undertakes to maintain the Information in strict confidence, and to take all reasonable measures to ensure that:

- The Information shall not be used for any purpose other than the Purpose;
- The Information shall only be disclosed to persons who have a need to know for the aforesaid Purpose and are bound by confidentiality undertakings in respect of such information and documentation, which are no less stringent than those contained herein.

The User warrants and represents that it has adequate procedures in place to ensure compliance with its aforesaid obligations.

The obligations of confidentiality and restrictions on use contained herein shall not cease on completion of the Purpose.

The obligations of confidentiality and restrictions on use contained herein shall not apply to any part of the Information which the User is clearly able to demonstrate:

- Was in the public domain or the subject of public knowledge at the time of disclosure by the Applicant on the Site; or
- Becomes part of the public domain or the subject of public knowledge through no fault of the User receiving the Information; or
- Is required to be disclosed by law, provided that the User shall in such event immediately notify the Applicant in writing of such obligation and shall provide adequate opportunity to the Applicant to object to such disclosure or request confidential treatment thereof.

Upon completion of the Purpose, the User shall cease all use and make no further use of the Information disclosed to it under the Procedure, and shall promptly destroy the Information received from the Applicant, which is in tangible or other form and is not archived in accordance with archival procedures established by the User. The Purpose for each product shall be deemed to be completed as soon as:

- The Applicant discontinues participation in the Procedure for the particular product;
- The product is deregistered by the NRA and/or ceases to be authorized by reference SRA.

6. Intellectual Property Rights

6.1. Except for Materials submitted by User, WHO owns all intellectual property rights in all text, graphics and other material on the Site, and the User shall take no action which is inconsistent with WHO’s rights as owner of the rights in the Site. No Material may be reproduced, modified, stored, transmitted, published, distributed, performed, displayed, sold or exploited in whole or in part, as a derivative work, or in any form, language or by any media, electronic or otherwise, throughout the world, except as outlined below.

6.2. The name, emblem, logo and official seal of the World Health Organization (WHO) are protected by law worldwide, and the User is not permitted to use or reproduce, or allow anyone to use or reproduce

this name or logo for any purpose. The User is not permitted to use the name, emblem or official seal of the World Health Organization, or any abbreviation thereof, for any purpose.

6.3. All intellectual property and other property rights, including but not limited to copyrights and trademarks, in all countries, with regard to the Materials shall remain the sole property of WHO.

7. Disclaimer

7.1. The User expressly acknowledges and agrees that any and all use of the Site is at their sole risk. Neither WHO, or any of their respective employees, agents, third-party content providers, or licensors warrant that access to and use of the Site will be free from interruptions or free from errors; nor do they make any warranty as to the results that may be obtained from use of the Site. The User waives and discharges any and all claims against WHO arising out of related access or lack thereof.

7.2. WHO may improve, change, suspend or discontinue any aspect of the Site at any time without notice, including the availability of any Site feature, database or content. WHO may also impose limits on certain features and services, or restrict the User's access to parts or all of the Site without notice or liability.

7.3. The User further expressly acknowledges and agrees that information, text, graphics, and hyperlinks provided through the Site and located on other Sites throughout the combined global electronic networks known as the internet and the World Wide Web are provided solely as a resource and a convenience to the User. Such hyperlinks to other sites are not an endorsement by WHO of those sites. WHO makes no warranty, either expressed or implied, and shall not be held responsible as to the accuracy, reliability, or content of such information, text, graphics, and hyperlinks. WHO does not represent or endorse the accuracy or reliability of any advice, opinion, statement or other information displayed, uploaded or distributed through the Site. WHO has not tested any software located on other sites and does not make any representations as to the quality, safety, reliability or suitability of such software.

7.4. The designation employed and the representation of content on the Site, including maps and other illustrative materials, do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area, or of its authorities, or concerning the delineation of frontiers and borders. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

7.5. The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned.

7.6. Inclusion in the PQS database does not constitute an endorsement, or warranty of fitness, of any product for a particular purpose, including in regard to its safe and appropriate use in immunization programmes. WHO does not furthermore warrant or represent that: 1) the database is complete or error free and/or that 2) the products that have been found to meet the standards recommended by WHO, will continue to do so and/or that 3) the products listed have obtained regulatory approval for use in every country of the world or that its use is otherwise in accordance with the national laws and regulations of any country, including but not limited to patent laws. In addition, WHO wishes to alert procuring UN agencies that the improper storage, handling and transportation of products may affect their quality, efficacy and safety. WHO disclaims any and all liability and responsibility for any injury, death, loss, damage or other prejudice of any kind whatsoever that may arise as a result of, or in connection with the procurement, distribution and use of products included in the list.

8. Limitation of Liability and indemnification

8.1. WHO shall not be liable for any direct or indirect loss, injury, claim, liability, or damage of any kind (whether involving negligence or otherwise), which may be incurred by the User resulting from:

- (a) The User's use of the Services or Materials or the Site (regardless of whether the User received any assistance from WHO in using the Services);
- (b) Any reliance placed by the User on the completeness, accuracy, timeliness or existence of any Materials or the Site, or as a result of any relationship or transaction between the User and any party who's Materials appears on the Services;
- (c) Any changes which WHO may make to the Services or the Site;
- (d) The unavailability or interruption of the Site or any feature thereof or any Materials;
- (e) Any permanent or temporary cessation in the provision of the Site (or any features therein);
- (f) The deletion of, corruption of, or failure to store, any Materials and other data maintained or transmitted by or through the User's use of the Site;
- (g) The User's failure to provide WHO with accurate account information;
- (h) The User's failure to keep its password or account details secure and confidential; and/or
- (i) Any delay or failure in performance by WHO.

8.2. Accordingly, WHO shall not be liable for any incidental, special or consequential damages or for any loss of business or profits which may be incurred by a User in connection with the Site, even if WHO was previously advised of the possibility of such damages, including, but not limited to, reliance by any User on any information obtained by way of the Site, or that may result from mistakes, omissions, interruptions, deletion of files or E-mail, errors, defects, viruses, delays in operation or transmission, or any failure of performance, whether or not limited to natural disasters, communications failure, theft, destruction or unauthorized access to WHO's records, programs or Services. This shall include any loss of:

- (a) Profit (whether incurred directly or indirectly);
- (b) Revenue;
- (c) Anticipated savings;
- (d) Business;
- (e) Goodwill or business reputation; and/or
- (f) Loss of data which may be incurred or suffered by the User.

8.3. Without limiting the generality of paragraph 8.2 above, WHO shall not be liable for any loss, injury, claim, liability, or damage of any kind (whether involving negligence or otherwise).

8.4. The User acknowledges and agrees that the delivery system used for the Site (i.e., the Internet, the World Wide Web) is unpredictable and may, from time to time, impede access to the Site. The User acknowledges and agrees that WHO is in no way responsible whatsoever for any interference with their use of, or access to, the Site, and he/she expressly waives and forever discharges and releases any and all claims against WHO in connection therewith.

8.5. By using this Site, the User agrees to defend at their own expense, indemnify and hold harmless WHO, and their respective officials and employees from and against all claims, suits, demands and liability of any nature, including costs and expenses associated therewith, and attorneys' fees, arising out of the use of the Site by the User or anyone having gained access to the Site by use of their Username and Password, including officers, agents, servants, employees, subcontractors or independent contractors.

9. End of access to the Site

9.1. Access to the Site will take effect when the User registers and continues until either the User or WHO suspends or ends their access to the Site as an authorized User.

9.2. Suspension or end of access to the Site or all of its features may be done by WHO for any reason, including, without limitation, any conduct which WHO, at its sole discretion, believes is in breach of the present ePQS Terms and Conditions of use, or is harmful to WHO's interests.

9.3. End of access may also be done by WHO if the User is sanctioned for proscribed practices.

9.4. The User's request to end their access to the Site does not imply the removal of their name and details from the Site, in particular if the User has been suspended by the UN or other UN agencies for proscribed practices.

9.5. In the event of an end of access, clauses 5, 6, 7, 8, 9, 11, 12 and 13 will remain binding on the parties.

10. Sanctions

10.1. Should the User not comply with the present ePQS Terms and Conditions of use, WHO reserves its right to take all appropriate measures deemed necessary to remedy the situation. It may include the temporary or permanent suspension of the User account.

11. Data Protection

11.1. WHO ensures that Personal Data are processed in accordance with international standards.

11.2. The following principles shall govern the processing of Personal Data entered by Users on ePQS. Personal Data hosted by WHO shall be:

11.2.1. obtained and used fairly and legitimately;

11.2.2. processed exclusively for the purpose of performing the tasks set out under the Agreement;

11.2.3. adequate, relevant and not excessive for the purpose for which they are obtained;

11.2.4. accurate and kept up to date where required;

11.2.5. kept in a form that permits identification of the data subjects concerned for no longer than is necessary for the purposes of performing the tasks set out under the Agreement;

11.2.6. subject to reasonable security safeguards and processed in a manner that ensures appropriate security of the personal Data, including protection against unauthorized or unlawful use and accidental loss, destruction or damage, using appropriate technical or organizational measures, including the

pseudonymisation and encryption of Personal Data and preserving the ongoing confidentiality, integrity, availability and resilience of processing systems and services.

11.3. The use of all Data, by Users of the Site is restricted exclusively to the purpose of this Internet service of WHO.

11.4. Use of Personal Data collected by the User for internal research or for marketing or promotional purposes is also strictly prohibited.

11.5. The User shall be responsible for providing timely and accurate information about any change to their Personal Data, including User's legal name, address, telephone number, and an e-mail address. The User must notify WHO within 30 days of any changes in such Data.

11.6. The User may serve a notice on ePQS, by sending it by e-mail to [please insert contact details]. WHO may serve a notice on the User by sending it to their e-mail address, or to the postal address provided upon registration.

11.7. By registering and using the Site, the User agrees to the dissemination to and the processing of their Personal Data by WHO within the context of the ePQS activities.

11.8. Failure to comply with the provisions of Clause 11 may constitute a breach of the present ePQS Terms and Conditions of use resulting in possible measures being taken unilaterally by WHO against the User's account, at WHO's sole discretion, shall this breach not have been remedied within 10 business days.

12. Privileges and Immunities

12.1. Nothing in or relating to the present ePQS Terms and Conditions of use shall:

- be deemed a waiver of any of the privileges and immunities of WHO in conformity with the Convention on the Privileges and Immunities of the Specialized Agencies approved by the General Assembly of the United Nations on November 21, 1947 or otherwise under any national or international law, convention or agreement; and/or

- be construed as submitting WHO to any national court jurisdiction.

13. Settlement of disputes

13.1. Any matter relating to the interpretation of the ePQS Terms and Conditions of use which is not covered by its terms shall be resolved by reference to Swiss law. Any dispute relating to the interpretation or application of the ePQS Terms and Conditions of use shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the rules of arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

Site security summary information

ePQS consists of three cloud-based systems integrated together to ensure the functionalities related to the submission, uploading and storage of documents related to users' applications are achieved. The three cloud-based systems used are: 1) Salesforce, which provides the overall database and community portal functionality; 2) Box used for the managing and storing of documents; and 3) EURNext System for the management and storage of electronic common technical document(eCTD) dossiers. All three systems are built with security at their core to ensure applicants data are secured and protected.

Authentication

Single Sign-On (SSO) is used as the authentication method to ensure a user securely logs into the ePQS portal without requiring multiple credentials for access to all three systems. This allows the user to securely access all three systems with the same username and password provided when they logged into the ePQS portal for the first time. After login, secure access to those resources they have permission to access, is controlled by WHO's Microsoft Azure Active Directory, which ensures only authorized users with the right username and password are granted access to the ePQS portal and all related systems.

Data Access

After successful authentication and login via SSO, a User is automatically assigned a profile and added to the right permissions set and public groups for all three systems. This ensures the given user, based on their access rights, only sees the data and documents that they are permitted to see. With multiple-level based access control enforced, data privacy and confidentiality is achieved when using the ePQS portal.

Data Storage

Data stored in the ePQS is safe and secure. All three cloud-based systems employ a strong encryption scheme that ensures data at rest or transmitted is not in danger of being exposed. In addition, all three-cloud providers provide redundancy mechanism to ensure stored data is available always without any interruption