

1 **PRIVACY STATEMENT OF THE EUROPEAN PHARMACOPOEIA**

2 The European Directorate for the Quality of Medicines & HealthCare (hereinafter “EDQM”)
3 is committed to respecting the right of all individuals taking part in the work of the European
4 Pharmacopoeia (Ph. Eur.) to the protection of their personal data. These individuals are (see
5 also §5 of the Code of practice for the work of the European Pharmacopoeia):

- 6 • the Chair of the European Pharmacopoeia Commission (EPC),
- 7 • the Vice-Chairs of the EPC,
- 8 • delegations and observers of the EPC,
- 9 • members (chairs, experts, *ad hoc* specialists and Observer members) of groups of
10 experts and working parties of the EPC
- 11 • substitutes for experts (as defined in the *Guide for work*).

12 This Privacy statement explains how the EDQM collects and uses personal data for purposes
13 related to Ph. Eur. activities (see §2.).

14 The *Privacy statement of the European Pharmacopoeia* is to be read in conjunction with the
15 *Rules of procedure of the European Pharmacopoeia Commission*, the *Guide for the work of*
16 *the European Pharmacopoeia* and the *Code of Practice for the work of the European*
17 *Pharmacopoeia*.

18 *All references in this document to functions, titles or positions shall be construed as applying*
19 *equally to men and women.*

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2 **1 Definitions**

3 ‘Data subject’ means a person who has provided their data to EDQM for the purposes of Ph.
4 Eur. activities.

5 ‘Data protection regulation’ means either Regulation (EU) 2018/1725 on the protection of
6 natural persons with regard to the processing of personal data by the Union institutions,
7 bodies, offices and agencies and on the free movement of such data, the enhanced Convention
8 108 or any other data protection regulation as applied by the Council of Europe.

9 **2 Purpose of data processing activities**

10 Data processing activities are a necessary part of the organisation and management of EPC
11 sessions and groups of experts/working parties meetings as well of as the elaboration, revision
12 correction or suppression of Ph. Eur. texts.

13 In this context, they include:

- 14 • managing the lists of invitations and participants, and of meetings (e.g. preparation of
15 name cards or badges);
- 16 • maintaining contact details and mailing lists;
- 17 • managing document access rights;
- 18 • distributing information, reports, publications and other documents;
- 19 • arranging follow-up meetings and actions;
- 20 • sharing meeting content via various communication channels (e.g. Extranet);
- 21 • managing the data required for the organisation of hotel and travel arrangements, for
22 reimbursement of hotel and travel expenses (if applicable).

23 **3 Personal data concerned**

24 The EDQM processes personal data either collected and sent, to the EDQM, by a Contracting
25 Party to the Convention on the elaboration of a Ph. Eur., an observer of the EPC or provided
26 directly by individuals interested in taking part in the work of the Ph. Eur. (usually via the
27 EDQM helpdesk).

28 Such data may include, but are not limited to, the following:

- 29 • First and second names, gender (to ensure the right title is used), profession,
30 organisation represented, citizenship, postal and email addresses, telephone number
31 and date of birth (for access to the EDQM building).
- 32 • In the case of the Chair of the EPC (or any other individual whose travel expenses are
33 to be reimbursed): identification or passport number, date of birth, nationality,
34 information on transport dates and costs, bank account details.

35 **4 Collection of personal data**

36 Personal data is collected for all individuals interested in taking part in the work of the Ph.
37 Eur. (*either at the EDQM premises or via participation in virtual event*):

- 1 • In the case of individuals from Ph. Eur. Member States, the data are collected by the
2 Contracting Party and then sent (via a nomination form, a curriculum vitae and a
3 declaration of interests) to the EDQM.
- 4 • In the case of individuals from non-Ph. Eur. Member States, the data are sent by the
5 individual to the EDQM via the Helpdesk. They are also collected via a nomination
6 form, a curriculum vitae and a declaration of interests.

7 Data processing starts as soon as the nomination form, curriculum vitae and declaration of
8 interests are received by the EDQM.

9 The nomination form, curriculum vitae and declaration of interests will only be used for the
10 purposes of:

- 11 1. Deciding on the eligibility of the candidate to take part in the work of the Ph. Eur.
12 according to the principles laid down in the *Rules of procedure of the European*
13 *Pharmacopoeia Commission* and the *Guide for the work of the European*
14 *Pharmacopoeia*.
- 15 2. Updating the EDQM databases to allow for appropriate exchanges of data and
16 information (e.g. invitation to meetings, access to agendas, reports and other
17 documents issued by the EDQM).
- 18 3. In the case of email addresses, carrying out mailing activities by the EDQM (i.e.
19 sharing of information on recruitment, or on Ph. Eur. related activities that might be of
20 interest to the individuals).

21 The EDQM Director may choose to decline the appointment of any individual refusing to
22 provide the personal data required for Ph. Eur. activities.

23 **5 Handling of nomination forms, curriculum vitae and declaration of interests and** 24 **access to data**

25 *5.1 Chair and Vice-Chairs of the EPC*

26 A *curriculum vitae*, declaration of interest and statement of motivation are to be sent to the
27 Secretariat for every application. The *curriculum vitae* and the statement of motivation are
28 provided either electronically or in paper form to the EPC, to allow the latter to take an
29 informed decision when electing the Chair and Vice-Chairs.

30 *Curriculum vitae*, statements of motivation and declarations of interests are kept by the
31 EDQM. They may be consulted at the EDQM premises, in Strasbourg (France). Such requests
32 must be made via the EDQM Helpdesk system.

33 *5.2 Delegations of the EPC*

34 Members and alternates are appointed by the Contracting Parties. The Secretariat receives a
35 covering letter, *curriculum vitae* and declaration of interest for each delegate or alternate. The
36 appointment of the delegates to the EPC is not subject to approval or evaluation neither by the
37 EDQM nor by the EPC (sovereignty of the Contracting Party, according to the Convention on
38 the elaboration of a European Pharmacopoeia).

1 *Curriculum vitae* and declarations of interests are kept by the EDQM. They may be consulted
2 at the EDQM premises, in Strasbourg (France). Such requests must be made via the EDQM
3 Helpdesk system.

4 *5.3 Members of groups of experts and working parties of the EPC*

5 The nomination form, *curriculum vitae* and declaration of interests are collected by
6 Contracting Parties (usually by National Pharmacopoeia Authorities, NPA) and sent to the
7 EDQM. Individuals from non-Ph. Eur. Member States showing interest in participating in the
8 work of the Ph. Eur. send these documents to the EDQM via the Helpdesk.

9 The nomination form and the *curriculum vitae* of candidates are provided to and reviewed by
10 the EDQM (Ph. Eur. Department) and by the Presidium. A list of individuals who meet the
11 selection criteria as defined in the *Terms of Reference* document is proposed to the EPC for
12 the latter to confirm the appointment of all proposed individuals to the respective groups of
13 experts and working parties. The declarations of interests are not usually provided to the
14 Presidium or the EPC, but can be made available upon their request as also stated in the *Code*
15 *of practice for the work of the Ph. Eur.* (available on the EDQM website).

16 If more than one application is received for the chairmanship of a group of experts or working
17 party, an election is organised. To this end, the *curriculum vitae* of candidates is provided to
18 the EPC either electronically or, in the event of face-to-face sessions, in paper form. The
19 declarations of interests are not usually provided to the Presidium or the EPC, but can be
20 made available upon their request as also stated in the *Code of practice for the work of the Ph.*
21 *Eur.* (available on the EDQM website).

22 On request the *curriculum vitae* and the declaration of interests of experts and *ad hoc*
23 specialists might also be provided to Chairs of Groups of Experts or Working Parties.

24 *Curriculum vitae* and declarations of interests are kept by the EDQM. They may be consulted
25 at the EDQM premises, in Strasbourg (France). Such requests must be made via the EDQM
26 Helpdesk system.

27 *5.4 Substitutes for Experts (as defined in the Guide for work).*

28 A *curriculum vitae* and a declaration of interests, collected by the Contracting Party, is sent
29 by the latter to the EDQM. A list of substitutes who attended meetings is provided to the EPC
30 for transparency.

31 *Curriculum vitae* and declarations of interests are kept by the EDQM. They may be consulted
32 at the EDQM premises, in Strasbourg (France). Such requests must be made via the EDQM
33 Helpdesk system.

34 *5.5 Publication of personal data*

35 The list of individuals taking part in the work of the Ph. Eur. (except substitutes) is published
36 in the Ph. Eur. This list contains the first and second names of the people concerned.

37 The following data are provided in the EDQM handbook that is sent to the Chair and Vice-
38 Chairs of the EPC, the delegates to the EPC, to NPAs and to EDQM staff members:

- 39 • Delegates and observers to the EPC, chairs of the groups of experts and working
40 parties: first and second names, gender (to ensure the right title is used),

1 organisation/Contracting Party represented, postal and email addresses and telephone
2 number, Group(s) in which they have been appointed.

- 3 • Experts and appointed *ad hoc* specialists of the groups of experts and working parties:
4 first and second names, gender (to ensure the right title is used),
5 organisation/Contracting Party represented, Group(s) in which they have been
6 appointed.

7 **6 Storage of nomination forms, curriculum vitae and declaration of interests and of** 8 **personal data**

9 Nomination forms, *curriculum vitae* and declarations of interests are stored by the EDQM in a
10 database that is only accessible to EDQM staff members (EDRMS).

11 Personal data - taken from these documents - are also stored in various databases that are only
12 accessible to EDQM staff members.

13 **7 Retention period**

14 Personal data are kept for as long as is necessary for the purposes of processing for Ph. Eur.
15 activities.

16 Personal data such as first and second names and gender (to ensure the right title is used) are
17 part of meeting reports or session records, for example, and will therefore be kept as long as
18 the reports or records are kept. As such data (specifically the first and second names) are part
19 of the Ph. Eur., they are kept as long as is necessary for the purposes of processing.

20 The data subject may request removal of personal data from EDQM databases (including
21 suppression of the nomination form, *curriculum vitae* and declaration of interests from
22 EDQM databases) at any time, by sending an email to the EDQM. It should be noted that it
23 may be necessary to terminate the Ph. Eur. mandate of the data subject making the request.

24 **8 Lawfulness and legal basis of the processing**

25 The EDQM has a legitimate business interest in processing the personal data provided in
26 nomination forms, *curriculum vitae* and declaration of interest forms for purposes related to
27 Ph. Eur. activities.

28 Appropriate protection and governance will be applied as described in the data protection
29 regulation as applied by the Council of Europe, the *Guide for the work of the European*
30 *Pharmacopoeia* and the *Code of Practice for the work of the European Pharmacopoeia*.

31 The processing of an individual's data related to the setting up and maintenance of EDQM
32 databases (such as Extranet) is necessary for the tasks carried out by the Ph. Eur. in the public
33 interest (such as assigning appropriate access rights). This is particularly important for
34 exchanges of data and information.

35 EDQM may also process personal data to meet legal obligations where appropriate.

1 **9 Data subject rights**

2 Individuals whose data are processed by EDQM for the purposes of Ph. Eur. activities have
3 the following rights:

- 4 • The right to object to processing – data subjects have the right to object to the
5 processing of their data by the EDQM although this right is not absolute and certain
6 exemptions may apply, such as the removal of personal data from already published
7 content by EDQM.
- 8 • The right of access to information – this is the right to request information about how
9 personal data is being processed, and the right to be allowed access to that data and to
10 be provided with a copy of it.
- 11 • The right to rectification - in the event that a data subject identifies inaccuracies or
12 incompleteness in their personal data, they have the right (i) to ask the EDQM to
13 rectify or delete such inaccuracies; or (ii) to supplement the personal data, as
14 appropriate, for completeness.