

Agreement
on
Usage of
Common European Submission Portal
(CESP)

between the

Health Products Regulatory Authority

and

Czech Republic: Czech State Institute for Drug Control

Agreement on use of the Common European Submission Portal (CESP)

THE PARTIES

This agreement is made between the **HEALTH PRODUCTS REGULATORY AUTHORITY**, a statutory body incorporated under the Irish Medicines Board Act, 1995, as amended, having its principal office at Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland (hereinafter the '**HPRA**'), of the one part

AND

STATE INSTITUTE FOR DRUG CONTROL, having its principal office at Šrobárova 48, 100 41 Prague 10 (hereinafter the '**Competent Authority**'), of the other part (each a '**Party**' and together the '**Parties**') (hereinafter the '**Agreement**').

WHEREAS:

- (a) CESP is a file transfer portal which was developed by the HPRA to support its regulatory activities as a competent authority under EU legislation regarding the healthcare sector, including under Directive 2001/82/EC regarding veterinary medicinal products and Directive 2001/83/EC regarding human medicinal products, (hereinafter '**EU healthcare legislation**'). In particular, CESP was designed to support the delivery and acknowledgement of healthcare related submissions, simultaneously, to one or more competent authorities.
- (b) An essential aim of the rules set out by EU healthcare legislation is to safeguard public health. EU healthcare legislation requires compliance with regulatory procedures, including authorisation procedures, by competent authorities within specified time limits.
- (c) In the interests of complying in an expeditious manner with regulatory procedures set out by EU healthcare legislation, the Competent Authority wishes to use CESP.
- (d) In consideration for payment of the requisite Contribution-Towards-Costs and under the terms and conditions set out in this Agreement the HPRA is willing to make CESP available for use by the Competent Authority.

(e) The Annexes to this Agreement shall be deemed to be incorporated in and form part of the overall arrangement between the HPRA and the Competent Authority, regarding the Competent Authority's use of CESP.

IT IS HEREBY AGREED AS FOLLOWS:

1. Definitions

In this Agreement:

'Business Day' means any day that is not a Saturday, Sunday or public holiday in the Republic of Ireland;

'CESP' means Common European Submission Portal, the file transfer portal designed and developed by the HPRA to support the delivery and acknowledgement of healthcare related submissions, simultaneously, to one or more competent authority;

'Contribution-Towards-Costs' means monetary contribution to the HPRA with respect to the costs regarding the operation of CESP;

'HMA' means the Heads of Medicines Agencies, the network of the Heads of the national competent authorities whose organisations are responsible for the regulation of medicinal products for human and veterinary use in the European Economic Area;

'Intellectual Property Rights' means all copyright and other intellectual property rights, howsoever arising and in whatever media, whether or not registered, including (without limitation) patents, trademarks, service marks, database rights, moral rights, trade names, registered designs and any applications for the protection or registration of these rights and all renewals and extensions thereof throughout the world;

'Transaction' means a receipt or a delivery of information via CESP; and

'year' means a twelve month period.

2. Interpretation

Unless the context indicates otherwise:

- 2.1 Words in the singular include the plural and vice versa;
- 2.2 Words in the any gender include all genders;
- 2.3 References to any law include amendments and replacements;
- 2.4 References to a day mean a calendar day, unless otherwise indicated; and
- 2.5 References to a month mean a calendar month, unless otherwise indicated.

3. Obligations of the HPRA

- 3.1 The HPRA shall assist the Competent Authority to connect to CESP.
- 3.2 In consideration of the Competent Authority's payment of Contribution-Towards-Costs to the HPRA, the HPRA shall permit the Competent Authority to use CESP.
- 3.3 The HPRA shall use its best endeavours to ensure that CESP functions properly. CESP shall be deemed to be functioning properly when it fulfils at least the requirements set out in the **Technical Annex** to this Agreement.
- 3.4 Each year the HPRA shall provide the Competent Authority with an estimated Contribution-Towards-Costs for the forthcoming billing period. The billing period is set out in the **Financial Annex** to this Agreement. It is the HPRA's intention for this estimate to be provided to the Competent Authority approximately three months prior to the commencement of the relevant billing period, however this is subject to change for operational reasons. The estimate shall be based on the Competent Authority's Transaction level in the preceding billing period, in accordance with the activity level bands set out in the **Financial Annex** to this Agreement. The Contribution-Towards-Costs paid by the Competent Authority shall be reconciled at the end of the relevant billing period on a pro-rata basis, if over-payment or under-payment has been made.
- 3.5 The HPRA shall elaborate on all documents in relation to the use of CESP when requested by the Competent Authority, including with regard to CESP system functionalities.
- 3.6 Where the Competent Authority proposes a modification or further development of CESP (hereinafter the '**Competent Authority's Proposal**'), the HPRA shall:
 - 3.6.1 notify all other competent authorities that have an agreement with the HPRA to use CESP, of the Competent Authority's Proposal;

- 3.6.2 consider the Competent Authority's Proposal and any comments received from other competent authorities which the HPRA notified in accordance with clause 3.6.1;
- 3.6.3 provide the Competent Authority with a feasibility report with respect to the Competent Authority's Proposal including an estimate of the Contribution-Towards-Costs which the Competent Authority would be required to make if it were implemented;
- 3.6.4 notify the competent authorities notified in accordance with clause 3.6.1 of any action that will be taken with respect to the Competent Authority's Proposal;
- 3.6.5 where action is to be taken with respect to the Competent Authority's Proposal, agree separately with the Competent Authority the related details and any Contribution-Towards-Costs required to be made by the Competent Authority in relation to same.
- 3.7 Subject to clause 5 (Confidentiality), the HPRA shall provide information to the HMA on the use of CESP with respect to issues of mutual interest to the healthcare regulatory network, as and when necessary or appropriate.
- 3.8 The HPRA shall have in place and use its best endeavours to maintain at all times security standards to protect the confidentiality, integrity and security of data managed via CESP.
- 3.9 The HPRA shall, as soon as practicable, inform the Competent Authority in the event of encountering any indication of breach of data security including but not limited to possible data loss, data corruption or inappropriate usage of CESP.

4. Obligations of the Competent Authority

- 4.1 The Competent Authority shall, within 30 days of receiving a payment request from the HPRA, pay the HPRA an annual Contribution-Towards-Costs, based on the HPRA's estimation of what the Competent Authority's usage will be for the forthcoming billing period.
- 4.2 If the Competent Authority fails to pay the Contribution-Towards-Costs as it becomes due the HPRA is entitled to suspend the Competent Authority's access to and use of CESP, having given 30 days' prior written notice of its intention to do so, unless the Competent Authority pays the Contribution-Towards-Costs to the HPRA during the 30 day notice period.
- 4.3 The Competent Authority shall use CESP in accordance with part 2 of the **Technical Annex** to this Agreement.
- 4.4 The Competent Authority shall be responsible for the provision of, and payment for, any translation services related to its own usage of CESP.

- 4.5 The Competent Authority shall be responsible for the marketing and communicating of CESP functionality to support its own operations, and any costs associated therewith.
- 4.6 The Competent Authority shall be responsible for the development of any documentation, training or registration material related to CESP specific to its own operations, and any costs associated therewith.
- 4.7 The Competent Authority shall be responsible for the management of its own internal organisational user configuration and access rights to CESP, and for ensuring that where organisational personnel change role or responsibility, or in the event that they leave the Competent Authority's organisation, that their access rights to CESP are removed with immediate effect.
- 4.8 The Competent Authority shall, as soon as practicable, inform the HPRA in the event of encountering any indication of breach of data security including but not limited to possible data loss, data corruption or inappropriate usage of CESP.
- 4.9 The Competent Authority shall be responsible for promptly notifying the HPRA of any unexpected or unusual usage or behaviour of which it becomes aware with regard to CESP.
- 4.10 The Competent Authority shall inform the HPRA promptly if it becomes aware of any infringement, potential infringement, or alleged infringement of any Intellectual Property Rights that subsist in CESP or that are connected with the Agreement.

5. Confidentiality

- 5.1 The HPRA and the Competent Authority shall keep confidential:
 - all information disclosed to them via CESP and all parts thereof and this Agreement; and
 - all information on software and all parts thereof, including subsequent modification or development of CESP, except:
 - 5.1.1 as may be legally required by court order or under legislation; or
 - 5.1.2 to give effect to clause 3.6; or
 - 5.1.3 if and to the extent that the other Party has given prior written consent to the disclosure; or
 - 5.1.4 if and to the extent the information has come into the public domain through no fault of that Party.

- 5.2 In the event that the Competent Authority becomes aware that it has distributed data via CESP in error or received data via CESP which is not intended for it, the Competent Authority shall immediately notify the CESP Helpdesk.
- 5.3 The HPRA and the Competent Authority shall take all reasonable steps to ensure the protection of confidential data and to ensure that only authorised users have access to CESP.

6. Liability

- 6.1 The HPRA shall not be liable to the Competent Authority for any damages, including compensatory, special, incidental, exemplary, punitive, or consequential damages connected with or resulting from this Agreement or the Competent Authority's use of CESP.
- 6.2 The Competent Authority shall defend and indemnify the HPRA and hold the HPRA harmless from all claims, losses, damages, complaints, or expenses connected with or resulting from the Competent Authority's use of CESP.

7. Data Protection

- 7.1 In using CESP or performing their obligations under the Agreement the Parties shall comply at all times with all applicable EU and Irish legislation relating to the processing of personal data and privacy (**'Data Protection Legislation'**).
- 7.2 Any alleged breach of Data Protection Legislation in connection with the Agreement shall immediately be notified by the Party concerned.

8. Commencement Date and Termination

- 8.1 This Agreement shall take effect upon the execution of it by both the HPRA and the Competent Authority (the **'Commencement Date'**) and shall have effect until terminated by either Party or both Parties.
- 8.2 Either Party may terminate this Agreement on not less than 3 months' prior written notice to the other Party.
- 8.3 Upon termination of this Agreement for any reason, unless otherwise agreed by the Parties in writing, the provisions of clause 4.10 (regarding Intellectual Property Rights), clause 5 (Confidentiality), clause 6 (Liability), clause 7 (Data Protection) and clause 13 (Governing Law and Jurisdiction) shall remain in force.

9. Validity and Amendment of the Agreement

- 9.1 This Agreement and the documents referred to in it supersede all previous representations, arrangements, understandings and agreements between the

HPRA and the Competent Authority about the subject matter of this Agreement and set out the entire agreement between the HPRA and the Competent Authority about the subject matter of the Agreement.

- 9.2 No amendment or variation to this Agreement shall operate to change or vary the terms, obligations or conditions hereof except upon mutual agreement by both Parties signed by an authorised representative of each Party.
- 9.3 Any amendment to the Annexes attached to this Agreement may be made in the form of an exchange of letters.
- 9.4 In the event that any term, condition or provision contained in this Agreement shall be held to be invalid, unlawful or unenforceable to any extent, such term, clause or provision will, to that extent, be omitted from this Agreement and the rest of this Agreement shall stand, without affecting the remaining clauses.

10. Force Majeure

- 10.1 Neither Party shall be liable for any delays or failures in performance, or breach of this Agreement, due to events or circumstances beyond that Party's reasonable control.

11. Notice

- 11.1 Any notice to be given or served under this Agreement shall be in writing, addressed to the relevant Party and expressed to be a notice or communication under this Agreement and may only be delivered by hand or be sent by registered post or by commercial courier or by email (where the Party has a valid and up to date e-mail address for a representative of the other Party), addressed to:
 - 11.1.1 The HPRA at its head office, at the address stated above; and
 - 11.1.2 The Competent Authority at the address stated above.
- 11.2 A notice shall be deemed to have been duly served or given:
 - 11.2.1 in the case of delivery by hand, at the time of delivery; or
 - 11.2.2 in the case of registered post, 9.00 a.m. on the second Business Day after posting; or
 - 11.2.3 in the case of delivery by commercial courier, on the date and at the time that the courier's delivery receipt is signed; or
 - 11.2.4 in the case of e-mail, upon receipt of confirmation that the e-mail has been received, or receipt of a delivery receipt, whichever is the earlier.

12. Governing Law and Jurisdiction

- 12.1 This Agreement shall be governed by and construed in accordance with the laws of the Republic of Ireland.
- 12.2 Any matter arising out of or in connection with this Agreement, including any question regarding its existence, validity or termination, which becomes the subject of a dispute between the HPRA and the Competent Authority shall be dealt with at a liaison meeting between a senior representative of the HPRA and a senior representative of the Competent Authority.
- 12.3 Where any dispute is not settled by the process outlined in clause 12.2 within a period of 30 days from the date of the liaison meeting or within such other period agreed between the Parties, the Parties submit to the exclusive jurisdiction of the courts of Ireland.

Done in two copies:

**For and on behalf of the Health Products
Regulatory Authority**

**For and on behalf of the Competent
Authority**

Signed:

Signed:

Position:

Position:

Date:

Date:

Technical Annex

1. Accessibility

- 1.1. The HPRA shall use its best endeavours to ensure that CESP is accessible to the Competent Authority between the hours of 9:00 and 17:00 CET.
- 1.2. The HPRA shall provide support to the Competent Authority through a helpdesk facility (the '**CESP Helpdesk**') between the hours of 9:00 and 17:00 CET.
- 1.3. The HPRA shall notify the Competent Authority of any scheduled CESP downtime and shall notify the Competent Authority when CESP becomes available again.

2. Technical Usage

- 2.1. The Competent Authority shall be responsible for testing the connectivity and operation of CESP for its regulatory purposes in a timely manner and shall promptly communicate any difficulties to the HPRA.
- 2.2. The Competent Authority shall, as soon as practicable, notify the HPRA in the event of encountering any problem with the operation of CESP.
- 2.3. The Competent Authority shall notify the HPRA in a timely manner of any change in the Competent Authority's usage of CESP that may result in an increased level of activity/throughput via CESP.

Financial Annex

1. Basis for Contribution-Towards-Costs for usage of CESP

Category	Activity Level	Contribution-Towards-Costs
15,000 + transactions per year	Level 1	35 000 €
10,000 -14,999 transactions per year	Level 2	25 000 €
6,000 – 9,999 transactions per year	Level 3	15 000 €
3,000 – 5,999 transactions per year	Level 4	10 000 €
2,000 – 2,999 transactions per year	Level 5	6 000 €
Below 1,999 transactions per year	Level 6	3 000 €

The amount of Contribution-Towards-Costs corresponding to each level shall be in accordance with the latest costs structure agreed by the HPRA and the Competent Authority.

2. Billing Period

The billing period shall be 1 April of a given year until 31 March of the following year inclusive.