

## GENERAL TERMS AND CONDITIONS FOR THE USE OF COMBISTATS

### **Glossary:**

GTC: General Terms and Conditions of the Software Licence Agreement for the use of 'CombiStats'.

CombiStats: Statistical software developed by the European Directorate for the Quality of Medicines and HealthCare of the Council of Europe hereinafter referred to as 'Council of Europe', based on the statistical chapter 5.3 of the European Pharmacopoeia

Licensee: the person (or entity) named in the order form, who shall have subscribed to CombiStats.

Authorised user: An authorised user is defined as a current employee of the licensee where the licensee is a non-educational organisation, as a current employee or registered student of the licensee where the licensee is an educational organisation, and as the licensee where the licensee is an individual person.

### **§ 1 Subject Matter and Contents of Agreement**

1. The Council of Europe shall use all reasonable efforts to make CombiStats available to the Licensee via the Internet.
2. The type and extent of the online access services offered by the Council of Europe are based on the currently prevailing technical, legal, and commercial umbrella conditions of the networks used. The place of transfer of the software and data is the interface between the server hosting CombiStats and the Internet. The responsibility of the Council of Europe for the data transmission shall end at this point.
3. The present GTC shall apply exclusively. Other terms and conditions shall not become part of the Licence Agreement, even if the Council of Europe does not expressly object to them. Amendments and modifications of the Licence Agreement shall only become effective if they have been agreed between the Council of Europe and the Licensee in writing.

### **§ 2 Access Authorization**

1. By acquiring the CombiStats software, the Licensee shall obtain the non-exclusive right from the Council of Europe to install and use the software on one (1) computer, solely in accordance with the present "general terms and conditions of the licence agreement".
2. The Licensee is not allowed to install and/or access any of the functions of the software in a network configuration. Notwithstanding the forgoing, the Licensee is not licensed to use the Software in order to provide services of any nature to third parties.
3. The Licensee shall register with the Council of Europe a single user licence.
4. The Licensee shall receive a user ID from the Council of Europe and a password for a single user licence.

5. The Licensee, in order to receive domain access, shall ensure that access from the Licensee's domain is only available from the Licensee's institution.

6. If the Licensee wants to install and use CombiStats on more than one (1) computer, a separate licence must be acquired for each computer.

### **§ 3 Technical Requirements**

1. The Council of Europe shall provide CombiStats in data formats that are supported by current, usual informatic equipment (hard- and software). The Licensees shall provide the technical requirements for the use of the service offered at their expense and risk. Information on technical requirements shall be provided on the CombiStats Internet -site, which shall be continuously updated.

2. The Council of Europe reserves the right to change the technical requirements. The Council of Europe shall attempt to minimize technical changes. If changes are unreasonable for the Licensee, the Licensee may terminate the Agreement pursuant to § 10 par. 2.

### **§ 4 Rights**

1. The Licensee acknowledges that all copyrights and other intellectual property rights, in particular, rights to the use of CombiStats as well as of parts thereof (individual texts, articles, excerpts thereof, in particular abstracts, figures, and tables, etc.) are the sole and exclusive property of the Council of Europe and that the Licence Agreement does not convey to the Licensee any right, title, or interest therein except for the right to use CombiStats in accordance with the present GTC.

The Licensee shall notify the Council of Europe promptly of the facts and circumstances surrounding any unauthorised possession or use of CombiStats or any portion thereof.

2. The Licensee shall receive the following rights to the CombiStats information service and the parts thereof:

#### *Single user licence:*

i. The Licensee is authorized to download CombiStats in order to conduct statistical analysis for him-/herself and for his employer in accordance with the rules defined in the GTC and to copy a selection of the licensed software into his computer's RAM.

ii. The Licensee may, only for his/her own use, permanently store the licensed software mentioned in paragraph i and make hard copies thereof (downloading and printout). The transfer of the licensed data in whole or in part - regardless of whether by electronic data carrier, remote data transmission or in the form of hard copies - as well as granting access to the stored data to third parties, the feeding of the data into an intranet and commercial information brokerage, as well as any use of the licensed data for commercial purposes, are not permitted.

iii. Translations, editing, arrangement, and other changes - such as (a) disassembling, decompiling or otherwise deriving source code from the Software, (b) reverse engineering the Software, (c) modifying or preparing derivative works of the Software, (d) copying the Software, except to make a single copy for archiving purposes only, (e) renting or leasing the

Software, (f) using the Software in an online system, (g) using the Software in any manner that infringes on the intellectual property or other rights of another party, (h) transferring the Software or any copy thereof to another party, (i) remotely accessing the Software from a computer or workstation in a network configuration, or (j) continuing to use the Software after the licence has been terminated - to the licensed software and the public communication, representation or performance thereof are prohibited.

### Installation

*For a period of 60 days from the date of acquisition of the software by the Licensee, the Council of Europe will use all reasonable efforts to provide technical support to help solve specific problems concerning installation of the Software. Such technical support shall be in the form of limited consultation via the EDQM helpdesk. The Council of Europe does not guarantee that it will solve every problem or correct every bug or error, or that the Software will meet the Licensee's requirements, or that the operation of the Software will be uninterrupted or error-free. The Council of Europe does not provide any support of an experimental/statistical/mathematical/computational nature to help the Authorised Users use the software.*

3. The Council of Europe reserves the right to investigate occurrences of suspected unauthorized use or other contract violations and to take appropriate action or to deny the Licensee or individual users access to the service. The Council of Europe reserves the right to terminate this Agreement for cause or to claim damages.

### **§ 5 Service Changes**

1. If the technical, legal and commercial umbrella conditions for use of the networks used change and if thereby the provision of contract services by the Council of Europe is materially impaired, the Council of Europe may change or discontinue the offered services, or change (increase) the fees for the offered services.

2. The Council of Europe shall immediately inform the Licensee by e-mail or letter, if due to the above reason(s) parts of the services in their present form can no longer be offered from a certain date or only at an increased fee. The Licensee shall be entitled to terminate the Licence Agreement within four weeks after the announcement of the change, effective from the date of change. Any other rights of the Licensee are excluded.

### **§ 6 The Licensee's Duties**

1. The Licensee shall only use CombiStats for his/her proper purposes. The Licensee shall in particular:

- not abuse the access to the service, in particular in violation of § 4, and the Licensee shall omit illegal acts;
- comply with the recognized principles of data security for the purpose of data protection;
- immediately inform the Council of Europe of any indications of illegal use.

2. The Licensee shall within his/her possibilities ensure the proper implementation of the access to the licensed data.

The Licensee shall hold the Council of Europe harmless from and against all claims, suits, proceedings, losses, liabilities and damages which the Council of Europe incurs on account of contract violations by the Licensee or the Authorised Users or due to third party claims arising from contract violations of the Licensee or the Authorised Users. The Licensee shall at the Council of Europe's option either defend the Council of Europe against the claims or satisfy the claims or support the Council of Europe in the enforcement of its rights and pay the costs of legal action.

### **§ 7 Liability**

The Software is licensed on an "AS IS" basis without any warranty of any nature. The software is not an official extension of the texts adopted by the European Pharmacopoeia Commission and no rights can be derived from the output of the software. In particular, the Council of Europe cannot guarantee that the software will always be in agreement with future revisions of official texts in the European Pharmacopoeia.

SAVE AS PROVIDED IN § 8 BELOW, THE COUNCIL OF EUROPE DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE (E.G. THE RELEASE OF MEDICINES). THE COUNCIL OF EUROPE SHALL NOT BE LIABLE FOR ANY DAMAGE OR LOSS OF ANY KIND ARISING OUT OF OR RESULTING FROM THE LICENSEE'S POSSESSION OR USE OF, OR INABILITY TO USE COMBISTATS (INCLUDING, WITHOUT LIMITATION, DATA LOSS OR CORRUPTION, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING FROM ITS USE OR INABILITY TO USE THE SOFTWARE, EVEN IF THE COUNCIL OF EUROPE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES), SAVE FOR CASES WHERE SUCH LIABILITY IS BASED ON A VIOLATION BY THE COUNCIL OF EUROPE OF ONE OF ITS UNDERTAKINGS UNDER THE PRESENT AGREEMENT.

UNDER NO CIRCUMSTANCE SHALL THE COUNCIL OF EUROPE'S LIABILITY TO THE LICENSEE ARISING OUT OF ANY KIND OF CLAIM IN ANY WAY CONNECTED WITH THE USE OR INABILITY TO USE COMBISTATS EXCEED THE AMOUNT OF THE LICENCE FEES PAID BY THE LICENSEE FOR COMBISTATS. The REMEDIES AVAILABLE TO THE LICENSEE AGAINST THE COUNCIL OF EUROPE UNDER THIS AGREEMENT ARE EXCLUSIVE.

### **§ 8 Third Party Rights**

Notwithstanding the limitation of liability in § 7 above and without prejudice to its privileges and immunities, the Council of Europe warrants that the transfer and use of the licensed data in accordance with the Licence Agreement does not violate any third party rights. In case third parties allege any claims against the Licensee which arise out of any act or omission by the Council of Europe that constitutes a breach of the Council of Europe's warranties hereunder, the Council of Europe shall at its option either defend the Licensee against the claims or indemnify him.

## **§ 9 Confidentiality**

The Licensee shall ensure that unauthorized third parties shall not gain access to the access authorization of CombiStats, nor to possession of the reproductions of CombiStats or portions thereof - regardless of what type - made by the Licensee or Authorized Users. The Licensee shall respect strict confidentiality in respect of the contents of CombiStats and shall take the necessary measures to prevent unauthorised third parties from gaining knowledge of the contents of CombiStats. The Licensee shall inform the Authorized Users in writing of these confidentiality obligations. The Licence Agreement is personal to and binding on the parties and neither the Licence Agreement nor any of the rights under it may be assigned or sublicensed.

## **§ 10 Term of Agreement**

1. The CombiStats Licence Agreement is subject to the same terms with regard to the advance notice for termination as the subscription agreement and shall terminate no later than the subscription agreement for CombiStats.
2. The right to terminate forthwith by serving a written notice on the other party for cause remains unaffected.
3. The notice of termination shall be in writing in order to be effective.
4. Any amendment of or variations to this Licence Agreement must be in writing and signed by both parties.

## **§ 11 Arbitration**

In accordance with the provisions of article 21 of the General Agreement on Privileges and Immunities of the Council of Europe, all disputes between the Council of Europe and the Licensee as regards the interpretation of the GTC and the application of the Licence Agreement shall be submitted, if a mutual agreement cannot be reached between the parties, to arbitration as laid down in Rule No 481 of the Secretary General, approved by the Committee of Ministers.