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Subject:	Proposal for a Regulation on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC *- Examination of the Presidency compromise text*

Delegations will find in Annex a compromise text prepared by the Presidency on the above-mentioned subject to be examined in the Working Party on Public Health on 6 October 2023.

New changes compared to the Commission proposal (on sections not yet discussed) and new changes compared to previous versions of the compromise (made either on the Commission proposal or on the Presidency text) are in **bold and underlined** and in ~~strikethrough~~ and highlighted in light grey shading.

Text marked in **bold and underlined** and in ~~strikethrough~~ without grey shading reflects changes made to the Commission proposal which were already presented in previous versions of Presidency text.

The Presidency is presenting the text of the following Chapters and the related definitions:

CHAPTER I (General Provisions): Articles 1, 2, 3, 4;

CHAPTERS III, IV & V and related recitals and definitions organised by sections:

Section VII – Authorisation of SoHo preparations: Recitals 27, 28, 29, 30; Articles 3(12), 3(22), 3(22a), 3(25), 3(39), 3(43), 3(57), 3(58), 3(59), 20, 21, 22, 22a, 23, 24, 40, 41;

CHAPTER VI (SoHO Donor Protection): Definitions 8, 9a, 13, 13a, 14, 23, 59, 64, 65; Articles 52, 53, 54, 55, 56 ;

CHAPTER X (Union Activities): Articles 69, 69a, 70, 71, 72 ;

CHAPTER XI (EU SoHO Platform): Recitals 41, 42, 43 ; Articles 3(31), 73, 74.

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CHAPTER I (General Provisions): Articles 1, 2, 3, 4

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CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation establishes measures setting high standards of quality and safety for all substances of human origin ('SoHO~~s~~') intended for human application and for activities related to those substances in order to ensure a high level of human health protection, in particular for SoHO donors, SoHO recipients and offspring from medically assisted reproduction. ~~This Regulation is without prejudice to national legislation which establishes rules relating to aspects of SoHOs other than their quality and safety and the safety of SoHO donors.~~

Article 2

Scope

1. This Regulation shall apply to:

(a) SoHO ~~intended for human application, to~~**and** ~~SoHO preparations~~ **intended for human application**~~,~~ **and** to **SoHOs used to manufacture** products**,** **defined in other Union legislation,** ~~manufactured from SoHOs and~~ **and** intended for human application;

(b) SoHO donors**,** ~~and~~**SoHO** recipients **and offspring from medically assisted reproduction;** ~~, and to the following SoHO activities;~~

1a.(c)~~This regulation shall also apply to~~ SoHO activities that have a direct impact on the safety~~, or~~ quality, ~~including, or~~ or effectiveness of SoHO ~~or SoHO preparations~~, as follows:

(**i**~~a~~) ~~SoHO~~ donor ~~recruitment~~**registration**;

(**ii**~~b~~) ~~SoHO~~ donor history review **or and medical examinations** ~~and~~ **for** ~~eligibility assessment~~;

(~~c~~**iii**) ~~SoHO~~ testing ~~of~~ **SoHO** ~~donors for eligibility~~ **assessment** or ~~matching purposes,~~ **or of persons, from whom SoHOs are collected for autologous application, for safe storage**;

(~~d~~**iv**) collection ~~of SoHOs from donors or patients~~;

(~~e~~**v**) processing ~~of SoHOs~~;

(~~f~~**vi**) quality control ~~testing of SoHOs~~ **or SoHO preparations**;

(~~g~~**vii**) storage ~~of SoHOs~~ **or SoHO preparations**;

(~~h~~**viii**)~~SoHO~~ release **of SoHOs or SoHO preparations**;

(~~i~~**ix**) distribution ~~of SoHOs~~ **or SoHO preparations**;

(~~j~~**x**) import ~~of SoHOs~~ **or SoHO preparations**;

(**xi**~~k~~) export ~~of SoHOs~~ **or SoHO preparations**;

(~~l~~**xii**) human application ~~of SoHOs~~ **or SoHO preparations**;

(~~m~~**xiii**)~~SoHO~~ clinical outcome **monitoring registration** ~~monitoring~~.

~~1b~~1a. This Regulation shall not apply to:

(i) organs intended for transplantation within the meaning of Article 3, points (h) and (q), of Directive 2010/53/EU~~.~~;

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~~1ba This Regulation shall not apply to~~

(ii) breast milk when used exclusively for feeding the own child.

~~1e1b~~. **This Regulation is without prejudice to national legislation which establishes rules relating to aspects of SoHOs other than their quality and safety ~~which are not governed by the provisions of this Regulation. other than their quality and safety and the safety of SoHO donors~~.**

1ba. By way of derogation, the provisions of this Regulation concerning the publication of information, specifically the publication obligations in Articles 4(2), 8, 17, 21(3), 31, 33, 39, 44, 62, 63, 66, 77, 81(3) may not apply when such publication might imply a risk to public security or national security and defence.

2. In case~~s~~ of **SoHO intended for** autologous ~~use~~ **application use,** ~~of SoHOs~~ where:

(a) SoHO~~s~~ **~~or SoHO preparations~~** are ~~processed and~~ **processed or** stored before application, this Regulation shall apply in **full~~relevant parts~~**~~full~~;

~~(b) SoHOs are processed and~~ **but** ~~not stored before application,~~ **~~this Regulation shall apply in full, except for the provisions of this Regulation that are relevant to the SoHO activities referred to in paragraph (1a) points (a), (b), (c), (g), (h), (i), (j) and (k)~~** ~~only the provisions on vigilance referred to in Article 35, on SoHO rapid alerts referred to in Article 36, on SoHO entity registration referred to in Article 37, on SoHO preparation authorisation referred to in Article 40, and on activity data collection and reporting referred to in Article 44 shall apply;~~

(c) SoHO~~s~~ are not processed and not stored before application, this Regulation shall not apply.

~~(d) SoHOs are used to manufacture products in accordance with other Union legislation, as referred to in paragraph (3), only the provisions of this Regulation that are applicable to the SoHO activities referred to in Article 2(1) points (c) and (d) shall apply.~~

3. ~~For~~ **In case of** SoHOs ~~**or SoHO preparations**~~ that are used to manufacture products **regulated by**~~**defined in other**~~ ~~in accordance with~~Union legislation**,**~~on medical devices, regulated by~~ **in particular, medical devices, as defined in** Regulation (EU) 2017/745 ~~**(on medical devices)**~~, ~~**Regulation (EU) 2017/746 (on in vitro diagnostic medical devices),**~~ ~~on medicinal products, regulated by~~ **medicinal products, as defined in** ~~Regulation (EC) No 726/2004 and~~ Directive 2001/83/EC ~~**(on medicinal products)**~~, ~~including on advanced therapy medicinal products, regulated by~~ **advanced therapy medicinal products, as defined in** Regulation (EC) No 1394/2007 ~~**(on advanced therapy medicinal products)**~~, ~~**Regulation (EU) No 536/2014 (on clinical trials on medicial products)**~~, ~~or~~ ~~on food, regulated by Regulation (EC) No 1925/2006~~ ~~**(on food)**~~, ~~or as the starting and raw material thereof~~, ~~the provisions of~~ **the provisions of** this Regulation ~~**shall apply for all SoHO to the extent that the activities to which they the SoHOs used to manufacture such products are subjected, including the provisions of this Regulation that are**~~ **applicable to the SoHO activities referred to in paragraph (1a) point (~~hi~~), (iii), (~~j~~iii) and (~~k~~iv), shall apply in all cases. I~~i~~nsofar ~~are not regulated by~~ as the activities of SoHO referred to in paragraph (a) point (vii), (viii), (x) and (xi) relate to SoHO until their distribution to a manufacturer regulated by ~~the~~ other Union legislation referred to in this subparagraph, the provisions of this Regulation shall also apply.~~legislative frameworks is not applicable. Nonetheless~~By way of derogation, the provisions of this Regulation that are relevant applicable to the SoHO activities referred to in paragraph (1a) points (a), (b), (c) and (d) shall apply~~ ~~at all times~~in all cases.** ~~applicable to the activities of SoHO donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, and collection of SoHOs from donors or patients shall apply. Insofar as the activities of SoHO release, distribution, import and export relate to SoHOs prior to their distribution to an operator regulated by the other Union legislation referred to in this subparagraph, the provisions of this Regulation shall also apply.~~

~~By way of derogation from the first subparagraph, in cases where SoHOs, SoHO preparations, or products manufactured from SoHO~~**~~s or SoHO preparations~~**~~, as referred to in that subparagraph, are exclusively for autologous use, only those provisions of this Regulation that~~ **~~are relevant to the SoHO activity referred to in paragraph (1a) point (d)~~** ~~concern the collection of SoHOs from patients shall apply.~~

4. Where non-viable SoHOs or their derivatives, as defined in Article 2, point **(16) and** (17), of Regulation (EU) 2017/745, incorporate, as an integral part, a medical device, and where the action of the non-viable SoHOs or their derivatives is principal and not ancillary to that of the device, **this Regulation shall apply in full on** the non-viable SoHOs or their derivatives ~~shall be governed by this Regulation~~. If the action of the non-viable SoHOs or their derivatives is ancillary to that of the device and not principal, **the provisions of this Regulation applicable to the SoHO activities referred to in paragraph (1a) point (i), (ii), (iii) and (iv), shall apply in all cases. Insofar as the activities of SoHO referred in parragraph (1a) point (vii), (viii), (x) and (xi) relate to SoHO until their distribution to the manufacturer regulated by Regulation (EU) 2017/745, the provisions of this Regulation shall also apply.~~**~~this Regulation shall apply for all SoHO activities to which the non-viable SoHOs or their derivatives are subjected, insofar as the extent that the activities to which the SoHOs or their derivatives are subjected are not regulated by Regulation (EU) 2017/745 is not applicable and the final product shall be subject to the provisions of that Regulation. By way of derogation, the provisions of this Regulation that are applicable to the SoHO activities referred to in paragraph (1a) points (a), (b), (c) and (d) shall apply in all cases.~~** ~~the provisions of this Regulation, insofar as they concern donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, collection of SoHOs from donors or patients, shall apply~~.

4a. By way of derogation from paragraphs 3 and 4, when SoHO are used to manufacture products under other Union legislation for the exclusive therapeutic use on the person from whom SoHO are collected, only the provisions of this Regulation relating to the SoHO activities referred to in Article 2(1) (c) (iii and iv) shall apply.

Article 3

Definitions[1]

~~[(1) 'blood' means the liquid that circulates in arteries and veins carrying oxygen to and carbon dioxide from the tissues of the body;]~~

~~[(2) 'blood component' means a constituent of blood such as red cells, white cells, platelets and plasma, that can be separated from it;]~~

~~[(3) 'cell' means a mass of cytoplasm with or without a nucleus, that is bound externally by a cell membrane. Usually microscopic in size, cells are the smallest structural and functional unit of an organism;]~~

~~[(4) 'tissue' means a group of cells that function together as a unit;]~~

(5) 'substance of human origin' (SoHO) means any substance collected from the human body ~~in whatever manner~~, whether it contains cells or not and whether those cells are living or not**, including SoHO preparations resulting from the processing of that substance;** ~~For the purposes of this Regulation, SoHO does not include organs in the sense of Article 3, point (h), of Directive 2010/53/EU;~~

(6) 'human application' means inserted, implanted, injected, infused, transfused, transplanted, ingested, transferred ~~(as in transfer to the uterus or fallopian tube of a woman)~~**,** inseminated or otherwise added to the human body in order to create a biological~~, mechanical~~ [~~or physiological~~] interaction with that body;

(7) 'SoHO activity' means an action, or series of actions, that has a direct impact on the safety, quality or ~~efficacy~~ **effectiveness** of SoHOs, as listed in Article 2(1**c**);

(7a) 'Effectiveness' means the extent to which SoHO quality ensures that the intended ~~biological effect~~outcome is achieved in the recipient;

[1] Only definitions not revised along with the corresponding sections and chapters during ES PRES are included.

(15) 'processing' means any operation involved in the handling of SoHOs~~,~~ including**, but not limited to,** washing, shaping, separation, fertilisation, decontamination, sterilisation, preservation and packaging;**except for the handling of SoHOs for immediate application ~~within the sterile field~~ during a surgical intervention, without ~~here~~ these SoHOs being removed from the surgical field before they are applied ~~are either released or for autologous application;~~**

~~(15a) 'preservation' means modifying the conditions of SoHOs in such a manner as to prevent deterioration over time of certain properties critical for their safety or quality, including placing SoHOs in an environment where the temperature differs from ambient;~~

(17) 'storage' means the maintenance of SoHO~~s~~ under appropriate controlled conditions **until they are transferred to another ~~authorised~~ SoHO entity** ~~until distribution~~;

(19) 'distribution' means ~~transportation and delivery~~ **the procedures for providing**~~, within the Union, of~~**,within the Union,** released SoHO~~s~~**:**

(a) ~~or SoHO preparations~~ intended for human application **to a specific SoHO recipient in the same or another SoHO entity;**

(b) intended for human applications in general, without the prior identification of a specific recipient, in the same or another SoHO entity;

(c) ~~or~~ **intended** for the manufacture of products regulated under **other** ~~other~~ Union legislation, **as referred to in Article 2(3),** ~~or as the starting and raw material thereof,~~ **[*within the Union*]**~~including within the same organisation when SoHOs are delivered from a SoHO entity to a unit responsible for human~~ **application to a manufacturer of such products;**

~~[(30) 'non-viable' means having no potential for metabolism or multiplication.]~~

~~[(45) 'technical guidelines' means a description of a series of methodological procedures and parameters that, if followed, achieve a level of quality and safety of a SoHO activity or a SoHO preparation that is considered to be acceptable as a means to comply with regulatory standards;]~~

(61) 'reproductive ~~cells~~**SoHO'** means **human sperm, oocytes, ovarian ~~or~~and testicular tissue ~~and any preparation resulting from the processing of those SoHO, including embryos,~~** ~~all cells~~ intended to be used for the purpose of medically assisted reproduction. **For the purposes of this Regulation, embryos are also considered reproductive SoHO even if they are not collected from the human body;**

~~[(68) 'plasma for transfusion' means plasma separated from whole blood or collected by apheresis for the purpose of transfusion to a recipient;]~~

~~[(69) 'plasma for fractionation' means plasma separated from whole blood or collected by apheresis and used as the starting material for manufacturing of plasma-derived medicinal products;]~~

~~[(70) 'apheresis' means a process by which a specific blood component or type of stem cell is separated from whole blood during the donation, allowing the remaining blood components to be returned immediately to the donor.]~~

Article 4

More stringent Member State measures

1. Member States may maintain or introduce within their territories measures that are more stringent than the ones provided for in this Regulation on condition that those national measures are compatible with Union law, and are proportionate to the risk to human health.

2. Member States shall make available to the public details of **the more stringent** measures put in place in accordance with paragraph 1 without undue delay, including on the internet. The SoHO National Authority shall submit the details of any **such** more stringent measure**s** to the EU SoHO Platform ~~referred to in Chapter XI.~~

CHAPTERS III, IV & V and related recitals and definitions organised by sections:

Section VII – Authorisation of SoHo preparations: Recitals 27, 28, 29, 30; Articles 3(12), 3(22), 3(22a), 3(25), 3(39), 3(43), 3(57), 3(58), 3(59), 20, 21, 22, 22a, 23, 24, 40, 41

Recitals:

(27) Since SoHO preparations are subjected to a series of SoHO activities prior to their release and distribution, **SoHO** competent authorities should assess and authorise SoHO preparations to verify that a high level of safety, quality and **effectiveness** ~~efficacy~~ is achieved consistently by the application of that specific series of activities, performed in that specific manner. When SoHOs are prepared with newly developed and validated collection, testing or processing methods, consideration should be given to the demonstration of safety and **effectiveness** ~~efficacy~~ in **SoHO** recipients by means of requirements for clinical outcome data collection and review. The extent of such required clinical outcome data should correlate with the level of risk associated with the activities performed for that SoHO preparation and use. Where a new or modified SoHO preparation poses negligible risks for **SoHO** recipients (or offspring in the case of medically assisted reproduction), the vigilance reporting requirements provided for in this Regulation should be adequate to ~~demonstrate~~ **verify** safety and quality. This should apply for well-established SoHO preparations that are introduced in a new SoHO entity but have been robustly demonstrated as safe and effective by their use in other entities.

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(28) With regard to SoHO preparations that pose a certain level of risk (low, moderate or high), the applicant should propose a plan for clinical outcome monitoring that should fulfil different requirements appropriate to the risk indicated. The most up-to-date guidance of the European Directorate for the Quality of Medicines & HealthCare (EDQM, a Directorate of the Council of Europe) should be considered relevant in the design of clinical follow-up studies proportionate in extent and complexity to the identified level of risk of the SoHO preparation. In the case of low risk, in addition to the mandatory continuous vigilance reporting, the applicant should organise pro-active clinical follow-up for a defined number of **SoHO recipients** ~~patients~~. For moderate and high risk, in addition to the mandatory vigilance reporting and the clinical follow-up, the applicant should propose clinical investigation studies with monitoring of pre-defined clinical **endpoints** ~~end-points~~. In case of high risk, these should include a comparison with standard **therapy** ~~treatments~~, ideally in a study with **SoHO recipients** ~~subjects~~ allocated to test and control groups in a randomised manner. The **SoHO** competent authority should approve the plans before they are implemented and should assess the outcome data as part of a SoHO preparation authorisation.

(29) In the interests of efficiency, it should be permitted to conduct clinical outcome studies using the established framework in the pharmaceutical sector for clinical trials, as set out in Regulation (EU) No 536/2014 of the European Parliament and of the Council[2], when **SoHO entities** ~~operators~~ wish to do so. Whilst applicants can choose to record the clinical data generated during the clinical outcome monitoring themselves, they should also be permitted to use existing clinical ~~data~~ registries as a means of such recording when those registries have been verified by the **SoHO** competent authority, or are certified by an external institution, in terms of the reliability of their data **quality** management procedures.

[2] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

(30) In order to facilitate innovation and reduce administrative burden, **SoHO** competent authorities should share with each other information on the authorisation of new SoHO preparations and the evidence used for such authorisations, including for the validation of certified medical devices used for SoHO collection, processing, storage or application to **recipients** ~~patients~~. Such sharing could allow **SoHO competent** authorities to accept previous authorisations granted to other **SoHO** entities, including in other Member States and to thus significantly reduce the requirements to generate evidence.

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CHAPTER I

GENERAL PROVISIONS

Article 3

Definitions

(12) 'SoHO preparation' means a ~~particular~~ type of SoHO**,** that:

(a) has been subjected to one or more SoHO activities, **as listed in Article 2(1~~a~~), point c, ~~at least,~~** including processing, in accordance with defined quality**, ~~and~~** safety **and effectiveness** parameters **in this Regulation**; **and**

~~(b) meets a pre-defined specification; and~~

(c) is intended for application to a **SoHO** recipient for a specific clinical indication or is intended for distribution for manufacture of a product regulated by other Union legislation, **as referred to in Article 2(3)** ~~or as the starting and raw material thereof~~;

(22) 'clinical outcome ~~monitoring~~**registration**' means ~~**recording information on results from clinical outcome monitoring as referred in Article 41, including transferring such information to oter registries**~~ **evaluation of the health of a SoHO recipient for the purpose of following-up the results of a SoHO preparation application, maintaining care and demonstrating safety and effectiveness** ~~evaluation of the health of a SoHO recipient for the purpose of monitoring the results of a SoHO preparation application, maintaining care and demonstrating safety and efficacy]~~;

(22a) clinical outcome monitoring plan' means a programme for monitoring, including the lasting of monitoring safety, effectiveness and indicators of effectiveness;

~~(25) 'SoHO preparation authorisation' means the formal approval by a competent authority of a SoHO preparation, including the approval of the chain of activities carried out to obtain the SoHO preparation;~~

~~[(39) 'assessors' means personnel performing the assessment of SoHO preparations as referred to in Article 22;]~~

~~[(43) 'conditional authorisation' means the granting of permission by a competent authority to a SoHO entity to perform certain SoHO activities under specific conditions defined by that competent authority;]~~

~~[(57) 'process validation' means establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce results meeting predetermined specifications and quality attributes;]~~

~~[(58) 'equipment qualification' means establishing documented evidence that provides a high degree of assurance that a specific piece of equipment will consistently perform to predetermined specifications;]~~

~~(59) 'EDQM SoHO monograph' means a specification of the critical quality parameters of a particular SoHO preparation defined by the European Directorate for the Quality of Medicines and HealthCare of the Council of Europe;~~

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CHAPTER III

SoHO SUPERVISORY ACTIVITIES

Article 20

SoHO preparation authorisation system

1. **SoHO** ~~C~~**c**ompetent authorities shall establish and maintain a system for **granting** ~~receiving and processing requests for the~~ authorisation~~s~~ of SoHO preparations **to SoHO entities located on their territory.** The system **shall include the reception and processing of requests and the approval of clinical outcome monitoring plans for the generation of evidence required for authorisation, where necessary, and** shall allow for the suspension or withdrawal of authorisations.

2. **SoHO c**~~C~~ompetent authorities shall authorise SoHO preparations pursuant to Articles 21, 22 and, where applicable, Article 23.

3. SoHO preparation authorisations shall be valid throughout the Union for the period defined in ~~the terms of~~ the authorisation, ~~when such a time period has been defined~~, **pursuant to Article 21 (2), point (d)** or until ~~a~~ **the SoHO** competent authority has suspended or withdrawn the authorisation. Where a Member State has adopted a more stringent measure, in accordance with Article 4, which relates to a specific SoHO preparation, that Member State may decline to recognise the validity of the SoHO preparation authorisation of another Member State **until ~~it has verified~~ the SoHO entity authorised for the SoHO preparation has demonstrated to that Member State the compliance with that more stringent measure** ~~pending verification that the more stringent measure has been met.~~

~~4. The Commission may adopt implementing acts concerning the compatibility and comparability of the SoHO preparation authorisation system.~~

~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).~~

Article 21

Authorisation of SoHO preparations

1. **SoHO** ~~C~~**c**ompetent authorities shall ~~have procedures in place to allow that applications for the authorisation of SoHO preparations are submitted in accordance with Article 41. They shall~~ provide guidelines and templates for the submission of applications for SoHO preparation authorisation, **in accordance with Article 41, and ~~including those~~ for the design of clinical outcome monitoring plans proposed, in accordance with Article 22a ~~that are proportionate to the level of risk assessed by the applicant.~~** When developing these guidelines and templates, **SoHO** competent authorities **shall use the ~~models~~ templates and** shall **take into account** ~~consult~~ the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c). **SoHO** ~~C~~**c**ompetent authorities may establish simplified procedures for applications concerning modifications to previously authorised SoHO preparations.

SoHO competent authorities may use the secure communicaction channel on the EU SoHO Platform for the exchange, with the SoHO entity, of documents relating to the application and authorisation of SoHO preparations~~, including those for the design of clinical outcome monitoring plans that are proportionate to the level of risk~~.

2. Upon receipt of an application for the authorisation of a **SoHO** preparation, **SoHO** competent authorities shall:

   (a) acknowledge receipt of the application **without undue delay** ~~within 14 working days;~~

   (b) assess the SoHO preparation pursuant to Article 22 and examine agreements between the applicant ~~SoHO entity~~ and **other SoHO entities or** ~~any~~ third parties contracted ~~by~~ **to perform** ~~that SoHO entity concerning~~ SoHO activities, **in relation to the SoHO preparation** where applicable;

   (ba) request ~~to~~ the applicant ~~SoHO entity~~ to provide supplementary information, if needed;

(c) grant **or refuse the approval for** ~~a conditional authorisation for the use of the SoHO preparation in all cases where~~ clinical outcome **monitoring plans, as appropriate** ~~data is required for authorisation~~, pursuant to Article 22(4), points (d) and (e); **and indicate any conditions that ~~may~~ apply, as well as ~~and~~ a time limit for the applicant to submit the results of the approved clinical outcome monitoring;**

(d) **on the basis of the assessment performed in point (b), and the results of the clinical outcome monitoring referred to in point (c),** grant or refuse the authorisation for the SoHO preparation **and, if any**, ~~as appropriate,~~**~~taking into accout the assessment performd in point (b), and the results of the clinical outcome monitoring referred to in point (c), if required,~~ indicating which conditions apply~~, if any~~**.

3. **SoHO ~~C~~c**ompetent authorities shall submit information regarding **the** ~~granted~~ **authorisation of the** SoHO preparation ~~authorisations, including a summary of the evidence used to authorise each SoHO preparation~~, to the EU SoHO Platform ~~referred to in Chapter XI,~~ and, for each SoHO preparation, amend accordingly the authorisation **information** ~~status~~ of the SoHO entity **concerned** ~~to which the SoHO preparation is linked to in the EU SoHO Platform, including the name and contact details of the SoHO preparation authorisation holder.~~

4. **SoHO ~~C~~c**ompetent authorities shall conclude the SoHO preparation authorisation ~~steps~~, referred to in paragraph 2 of this Article, **~~whitout undue delay and~~** ~~within 3 months from receipt of the application,~~ **in accordance with national legislationi,** ~~excluding the time needed for clinical outcome monitoring or~~ **~~for the performance of additional validation or the gerneration of additional quality data as requested by the SoHO competent authority prior to the authorisation~~** ~~studies~~. **SoHO competent authorities** ~~They~~ may suspend this time limit for**:**

(a) the duration of the consultation processes referred to in Article 14(1)~~and~~**,** (2) **and (3),**

(b) **~~and in case of~~ a request for additional information to the SoHO entity,**

(c) the time needed to perform clinical outcome monitoring, or

(d) the performance of additional validation or the generation of additional quality and safety data as requested by the SoHO competent authority.

4a. For SoHO preparations that incorporate a medical device as an integral part, as referred to in Regulation (EU) 2017/745 Annex IX (5) (3) (1), and where the medical device has an action that is ancillary to that of the SoHO preparation, SoHO competent authorities shall verify ~~appropriate certification of~~ that the medical device has been certified by the competent body.

5. Upon receipt of a request for an opinion in course of the conformity assessment procedure pursuant to Article 52 of Regulation (EU) 2017/745,**of a medical device that incorporates a SoHO preparation as an integral part, and where the medical device has an action that is principal,** the **SoHO** competent authorities receiving the request shall **provide an opinion regarding compliance of the SoHO preparation part with the provisions of this Regulation, pursuant to Annex IX (5) (3)(1) of Regulation (EU) 2017/745** ~~follow the relevant procedure of that Regulation~~, and inform the SCB of the opinion provided.

6. **SoHO** Competent authorities may, in accordance with national legislation, suspend the authorisation of a SoHO preparation**, or the realisation of its clinical monitoring outcome plan, in circumstances where** ~~if~~ SoHO supervisory activities demonstrate or give reasonable ground for suspecting that **such SoHO preparation, or any activities performed for that preparation:**

(a) ~~such preparation, or any of the activities performed for that preparation,~~ do not comply with the conditions of its authorisation**;** or ~~the requirements of this Regulation; and~~

(b) **do not comply with the provisions of this Regulation; or~~and such~~**

(c) that non-compliance**, or suspected non-compliance,** impl**y**~~ies~~ **or might imply** a risk to the safety of SoHO donors, recipients or offspring from medically assisted reproduction **or ~~unnecessary~~ wastage of SoHO preparations.**

SoHO ~~C~~**c**competent authorities shall specify a period of time for the investigation of the suspected non-compliance and for SoHO entities to rectify a confirmed non-compliance, during which the suspension will remain in place.

7. In cases where SoHO **competent authorities have** ~~entities are not able to rectify~~ confirmed non-compliances referred to in paragraph 6 **and SoHO entities are not able to rectify** ~~**them**~~ in the specified time period, **SoHO** competent authorities shall, in accordance with national legislation, withdraw the authorisation of the SoHO preparation **from the SoHO entities** concerned.

8. **SoHO** ~~C~~**c**competent authorities may, in accordance with national legislation, withdraw the authorisation of a SoHO preparation if the **SoHO** competent authorities have confirmed that the SoHO preparation in question does not comply with ~~subsequently~~ updated criteria for authorisation or the SoHO entity has ~~repeatedly~~ failed to comply with the conditions of its authorisation, ~~**and**~~**or** ~~**that**~~ **a risk to SoHO donors, recipients or offspring from medically assisted reproduction is identified and that risk cannot be resolved during a suspension.**

9. In cases of authorisation suspension or withdrawal, as referred to in paragraphs 6, 7 and 8, **SoHO** competent authorities shall, without undue delay, amend accordingly the authorisation **information** ~~**for**~~ ~~status~~ of the SoHO entity concerned in the EU SoHO Platform ~~as referred to in Chapter XI.~~

9a. By way of derogation from this Article, SoHO competent authorities may authorise, at the request of a prescribing physician or the SoHO entity responsible for that application, the application of SoHO preparations for a defined group of SoHO recipients within their territory in cases where the procedures referred to in this Article have not been carried out, provided that:

(a) the use of those SoHO preparations is foreseen for a ~~**given**~~ **specific SoHO recipient, in cases where** ~~**that**~~ **the SoHO recipient has no therapeutic alternative, where treatment cannot be postponed or where the SoHO recipient's prognosis is life-threatening;**

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(b) the safety and effectiveness of the SoHO preparation is presumed on the basis of the available clinical data; ~~and~~

(c) there is ~~a~~ the conformity of the SoHO entity ~~establishment~~ responsible for the SoHO preparation; and

(d) the SoHO recipient concerned are informed of the scarcity of the available data and of the still experimental nature of the proposed treatment as well as its therapeutic objectives.

SoHO competent authorities shall indicate the period of time or a maximum number of SoHO recipients for which the application of those SoHO preparations is authorised ~~authorisation is granted~~.

SoHO competent authorities shall inform the SoHO National Authority of ~~the~~ that authorisation.

10. ~~Competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).~~

11. The Commission may adopt implementing acts concerning the procedures to authorise SoHO preparations pursuant to this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).

Article 22

Assessment of SoHO preparations

1. The assessment of a SoHO preparation~~,~~ shall include a review of all SoHO activities that are performed for that SoHO preparation and that might influence the safety, quality and **effectiveness** ~~efficacy~~ of the SoHO preparation.

2. The assessment of SoHO preparations shall be carried out by **SoHO preparation** assessors meeting the requirements set out in Article 24.

3. In cases where the SoHO preparation**,** subject to the application for authorisation pursuant to Article 21**,** has been duly authorised in another SoHO entity in the same or in another Member State **or by the transitional provisions referred to in Article 82**, **SoHO** competent authorities may authorise that SoHO preparation ~~in the applicant SoHO entity~~, provided that the **SoHO** competent authorities have verified that the SoHO activities performed **and the steps of the processing applied** for the SoHO preparation are carried out by the applicant ~~SoHO entity~~ in a manner such that the safety, quality and **effectiveness** ~~efficacy~~ results **of the SoHO preparation** will be equivalent to those demonstrated in the SoHO entity where the SoHO preparation was first authorised.

4. In cases where the SoHO preparation, subject to the application for authorisation pursuant to Article 21, has not been ~~duly~~ authorised in another SoHO entity, **or the SoHO competent authority chooses not to take SoHO preparation authorisation in another Member State into account, SoHO** competent authorities **shall**:

(a) ~~shall~~ assess **the adequacy of** ~~all~~ the information provided by the applicant pursuant to Article 41**(2) point (a);**

(b) ~~shall review the SoHO preparation dossier referred to in Article 41(2), point (a);~~

(c) ~~shall~~ initiate the consultation described in Article 14~~(1)~~, if during the review of the **information** ~~SoHO preparation dossier~~ referred to in point (~~a~~b), questions arise as to whether the SoHO preparation falls, in part or fully, within the scope of this Regulation or other Union legislation, taking into account the activities performed for the SoHO preparation and the intended human application;

(d) ~~shall review and~~ evaluate the **results of a benefit** risk assessment **carried out** ~~performed~~ by the applicant as pursuant to Article 41(2), point (b);

(e) shall evaluate the plan for clinical outcome monitoring and its proportionality to the level of risk of the SoHO preparation **according to Article 22a** ~~paraghap 4a~~ ~~as referred to in Article 41(3), points (a), (b) and (c), as applicable;~~

(f) ~~shall may~~ consult the SCB, pursuant to Article 68(1) on the evidence necessary and sufficient for the authorisation of a particular SoHO preparation **where the guidance referred to in paragraph 7 is not sufficient**;

(g) ~~shall~~ assess, in the case of **an approved clinical outcome monitoring plan** ~~a conditional authorisation~~ pursuant to Article 21(2), point (c), the results of **that plan** ~~that plan the clinical outcome monitoring~~ **upon submission by the applicant**.

~~**4a. When evaluating clinical outcome monitoring plans, as referred to in paragraph 4 point (e), SoHO competent authorities shall verify that the plan proposes clinical outcome monitoring as follows:**~~

~~**(a) in cases of low risk, pro-active clinical follow-up of a defined number of SoHO recipients;**~~

~~**(b) in cases of moderate risk, in addition to point (a), a clinical study of a pre-defined number of SoHO recipients assessing pre-defined clinical endpoints;**~~

~~**(c) in cases of high risk, in addition to point (a), a clinical study of a pre-defined number of SoHO recipients assessing pre-defined clinical endpoints with a comparison to standard therapy.**~~

5. When assessing the SoHO preparation pursuant to paragraph 4, points (e) and (g), **SoHO** competent authorities shall **verify** ~~consider~~, in the cases where the applicant has proposed to record, and recorded, the results of the clinical outcome monitoring in an existing clinical registry, that this ~~is an acceptable method, provided that those competent authorities have verified that the~~ registry has data quality management procedures in place that ensure **adequate** accuracy and completeness ~~of data~~.

6. **SoHO c**~~C~~ompetent authorities shall conduct the assessment ~~steps~~ referred to in paragraphs 3 and 4 of this Article by means of a remote document review. **SoHO c**~~C~~ompetent authorities may also, as part of the SoHO preparation assessment, carry out inspections pursuant to Articles 29, 30 and 31. **Member States shall ensure communication and cooperation between SoHO preparation assessors and inspectors pursuant to Article 13.**

7. When conducting the assessment steps referred to in paragraph 4 **and 4a** of this Article, **SoHO** competent authorities shall **take into account** ~~consult~~ the best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).

Article 22a

Clinical outcome monitoring plans

1. As a basis for the assessment of an authorisation for a new SoHO preparation a clinical outcome monitoring plan shall be approved by the SoHO competent authority.

2. The clinical outcome monitoring plan shall include:

(a) clinical outcome monitoring according to 22a (3) point c, where scientific data for clinical use are not available or sparse, where benefit and risk are not evaluable, or when a negative benefit-risk analysis based on current knowledge is confirmed.

(b) clinical outcome monitoring according to 22a (3) point a, in a case of a relevant risk despite a positive benefit-risk analysis.

3. The design of clinical outcome monitoring plan referred to in paragraph 1, shall be proportionate to the level of risk assessed by the applicant and shall take into account the guidance and templates provided by their SoHO competent authority, in accordance with Article 21(1).

4. The clinical outcome monitoring plan shall include the clinical outcome monitoring as follows:

(a) in cases of low benefit risk, pro-active clinical follow-up of a defined number of SoHO recipients;

(b) in cases of moderate benefit risk, in addition to point (a), a clinical study of a pre-specified number of SoHO recipients assessing pre-defined clinical endpoints;

(c) in cases of high benefit risk, in addition to point (a), a clinical study of a pre-specified number of SoHO recipients assessing pre-defined clinical endpoints with a comparison to standard therapy.

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5. To record the clinical data generated during the clinical outcome monitoring, the applicant shall record those data via their own registries or existing clinical registries. In cases where the applicant SoHO entity chooses to use existing clinical registries, those registries shall be verified by the SoHO competent authority, or shall be certified by an external institution, in terms of the reliability of their data quality management procedures.

6. In case where vigilance reports indicate a risk for SoHO donors, SoHO recipients or offspring from medically assisted reproduction, SoHO competent authorities may stop clinical outcome monitoring.

Article 23

Joint SoHO preparation assessments

1. At the request of one or more **SoHO** competent authorities, **via their SoHO National Authority to another SoHO National Autority, or a SoHO entity,** SoHO preparation assessments as referred to in Article 22 may be carried out by **SoHO preparation assessors assigned by** ~~competent authorities from~~ more than one Member State, as a joint SoHO preparation assessment.

2. **With the previous consent of the SoHO National Authority, t**~~T~~he **SoHO** competent authority receiving a request for a joint SoHO preparation assessment **shall make all reasonable efforts to accept such request, taking into account their available resources** ~~may accept such a request, and coordinate and support that assessment, where that competent authority agrees that there are reasonable grounds for conducting a joint assessment~~.

2a. The SoHO competent authority receiving a request for a joint SoHO preparation assessment and in charge of the authorisation of the SoHO preparation shall be the leader of the joint SoHO preparation assessment.

3. **The SoHO C**~~c~~ompetent authorities participating in a joint **SoHO preparation** assessment shall conclude a prior written agreement **to carry out** ~~on~~ the joint assessment. **Such written** ~~The~~ agreement shall **specify** at least ~~defines~~ the following:

(a) the scope of the joint assessment;

(b) the roles of the participating assessors during and following the assessment, ~~including the designation of an authority leading the assessment;~~

(c) the powers and responsibilities of each of the **SoHO competent** authorities **involved.**

The SoHO competent authorities participating in the joint SoHO preparation assessments shall commit themselves in that agreement to jointly accept the results of ~~the~~ that assessment.

The agreement shall be signed by all the participating SoHO competent authorities, including the respective SoHO National Authorities, according to the ~~requisites~~ requirements developed by the SCB.

4. Member States may set up joint **SoHO preparation** assessment programmes to facilitate frequent or routine joint assessments**. Member States may operate such programmes under a single written agreement as referred to** ~~In such cases, competent authorities may sign a single written agreement provided that agreement meets the requirements~~ in paragraph 3.

4a. For the purposes of coordinating and performing joint SoHO preparation assessments, as referred to in this Article, SoHO competent authorities shall take into account the relevant best practices agreed and documented by the SCB, as referred to in Article 68(1), point(c).

5. ~~On completion of a joint SoHO preparation authorisation, the competent authority in the territory where the SoHO preparation authorisation holder is based shall submit the information, as pursuant to Article 21(3), regarding the new authorised SoHO preparation in the EU SoHO Platform~~.

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Article 24

Specific obligations concerning SoHO preparation assessors

1. **SoHO preparation** ~~A~~**a**ssessors shall:

   (a) **be in** possess**ion of** a diploma, certificate or other evidence of formal qualifications in ~~the field of medical , **pharmaceutical** or **life** biological sciences~~ **a relevant field**, awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned;

   (b) have expertise in the processes being assessed ~~and~~ **or** the human applications for which the SoHO preparations will be used.

2. The assessment of SoHO preparations as referred to in Article 22 may be done jointly by a team of persons which collectively have the qualifications and experience set out in paragraph 1.

3. In exceptional cases, **SoHO** competent authorities may consider that a person's considerable and relevant experience may exempt this person from the requirements set out in paragraph 1.

4. Before **SoHO preparation** assessors take up their duties, **SoHO** competent authorities shall provide **SoHO preparation** assessors with a specific induction training on the procedures to be followed for the assessment of SoHO preparations in accordance with Article 22.

5. **SoHO** ~~C~~**c**ompetent authorities shall ensure that the specific induction training is complemented by specialised training for assessment of processing methods and technologies used for specific types of SoHO preparations and by continuous training, as appropriate, throughout the career of the **SoHO preparation** assessors. **SoHO** ~~C~~**c**ompetent authorities shall make all reasonable efforts to ensure that **SoHO preparation** assessors that participate in joint **SoHO preparation** assessments have completed the relevant Union training referred to in Article 69(1) and are included in the list referred to in Article 69(5).

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6. **SoHO preparation** ~~A~~**a**ssessors may be assisted by technical experts provided that **SoHO** competent authorities ensure that those experts comply with the requirements of this Regulation, in particular with the obligations set out in Articles 7, **75** and 76.

CHAPTER IV

GENERAL OBLIGATIONS ON SOHO ENTITIES

Article 40

SoHO preparation authorisation

1. SoHO entities shall not release or, in an autologous context **as referred to in Article 2(2)(a),** prepare and apply ~~immediately~~ to a **SoHO** recipient, SoHO preparations without prior SoHO preparation authorisation. ~~In cases where a SoHO entity modifies an activity carried out for an authorised SoHO preparation, it shall obtain an authorisation for that modified SoHO preparation.~~

2. SoHO entities may request **an opinion** ~~advice~~ from their **SoHO** competent authorities on the applicability of the authorisation requirements in this Regulation to their SoHO activities prior to submitting an application for a **SoHO** preparation authorisation.

3. SoHO entities may request to their **SoHO** competent authorities a derogation from the requirement for a SoHO preparation authorisation in ~~the~~ **emergency situations** ~~exceptional circumstances~~ referred to in Article 64.

Article 41

Application for ~~the authorisation of~~ SoHO preparation authorisation

1. SoHO entities shall send applications for ~~the authorisation of a~~ SoHO preparation **authorisation** to the~~ir~~ **SoHO** competent authorit~~y~~**ies** **of their territories**. ~~The applicant shall provide the name and contact details of the prospective SoHO preparation authorisation holder responsible for the application. This paragraph shall be without prejudice to Article 38(1).~~

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2. The **applications for SoHO preparation authorisation** ~~applicant~~ shall **include** ~~provide~~ the following:

(-a) the name and contact details of the ~~pro~~~~spective~~ applicant SoHO entity ~~preparation authorisation~~ responsible for the SoHO preparation authorisation;

(a) ~~a SoHO preparation dossier describing the~~ details of the SoHO activities performed for that SoHO preparation and including at least:

(-i) a description of the SoHO used for the preparation;

(i) **a summary of** ~~any specific~~ SoHO donor eligibility **~~or~~and** SoHO donor testing procedures;

(ii) **a summary of** ~~any specific~~ SoHO collection procedures **and any specific controls carried out on the collected SoHO prior to processing**;

(iii) a description of the **steps of the** processing applied including **details of relevant materials and equipment used, environmental conditions and the process parameters and controls at each step** ~~details s of the air quality standards maintained in the processing facilities and the rationale for the air quality standard applied;~~

(iv) a description of equipment, reagents and materials **coming into direct contact with the SoHO during processing** ~~used~~ and their certification status in accordance with Regulation (EU) 2017/745 **or Regulation (EU) 2017/746, when applicable, and, in the case of the use of in-house developed equipment, reagents or materials, a justification of the validation of their quality**;

(v) any specific storage **and transport** conditions and storage time limits **including validation of those conditions and limits**;

(vi) **a specification of the SoHO preparation including** ~~any~~ quality control and~~,~~ **~~where relevant,~~** release parameters;

(vii) data ~~concerning procedures performed for~~ **resulting from** process validation and equipment qualification;

(viii) details of any **SoHO entities or** third parties contracted ~~by the SoHO entity~~ to perform activities **or relevant steps of the processing applied** for the SoHO preparation;

(ix) the clinical indications for which the SoHO preparation is to be applied **and the ~~scientific rationale~~ clinical data justifying this indication**;

(b) the results of a **benefit-**risk assessment conducted on the combination of SoHO activities performed for the SoHO preparation, together with the intended clinical indication for which **application for authorisation is submited** ~~it is authorised intended~~ to be applied, taking into account:

(i) whether the SoHO preparation is described in, and aligned with, an EDQM SoHO monograph included in the technical guidelines referred to in Article 59(4), point (a) **or point (b)**;

(ii) whether the SoHO preparation meets the defined quality criteria in the EDQM SoHO monograph referred to in point (i) and is intended to be used for the indication and with the mode of application to which that monograph refers, where such details are provided in that monograph **or meets national requirements as referred to in Article 59(4) point (b)**;

(iii) information regarding previous use and authorisation of the SoHO preparation in other SoHO entities, as available in the EU SoHO Platform;

(iv) **where ~~available~~ applicable, clinical functionality** evidence generated as part of the process of certification, in accordance with Regulation (EU) 2017/745, of **a** certified medical device **that is critical to the specific processing** ~~used~~ for the SoHO preparation, where available;

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(v) documentation of a **standardised** ~~systematic~~ process of identification, quantification and evaluation of any risks to **a SoHO** ~~the~~ donor**s**, **a SoHO** ~~or the~~ recipient**s or the offspring from medically assisted reproduction** arising from the chain of activities performed for the SoHO preparation **and taking into account the technical guidelines published by EDQM for the performance of such risk assessments, as referred to in Articles 56(4)(a) and 59(4)(a)**;

(ba) an evaluation of the potential benefits for SoHO recipients weighed against the risks identified in the assessment referred to in point (2)(b)(v).

(c) in cases where the indicated risk is ~~other~~ **greater** than negligible, **or the expected clinical effectiveness is unknown,** a **proposed plan** ~~proposal~~ for clinical outcome monitoring ~~to demonstrate safety, quality and efficacy~~ **for providing evidence, where necessary,** of the SoHO preparation, in line with the results of the **benefit-**risk assessment **and pursuant to Article 22(4a)**;

(d) an indication of the data which should be regarded as proprietary accompanied by verifiable justification, where appropriate.

3. ~~In the **proposed clinical outcome monitoring plan** proposal referred to in paragraph 2, point (c), the applicant shall **take into account the guidance from their SoHO competent authority as referred to in Article 21(1)**. propose a clinical outcome monitoring plan as follows:~~ **If the application for SoHO preparation authorisation includes recording the results of the clinical outcome monitoring in an existing clinical registry, in accordance with Article 22a(4)~~as referred to paragraph 2 point (e)~~, the applicant shall request approval for the use of such registry to their SoHO competent authorities.**

~~(a) in cases of low risk, clinical follow-up of a defined number of patients;~~

~~(b) in cases of moderate risk, in addition to point (a), a clinical investigation study of a statistically significant number of patients assessing pre-defined clinical endpoints;~~

~~(c) in cases of high risk, in addition to point (a), a clinical investigation study of a statistically significant number of patients assessing pre-defined clinical endpoints with a comparison to standard therapy.~~

4. SoHO entities shall **prepare and distribute the SoHO preparation in question solely for the performance, and within the limitations of** ~~perform~~ the clinical outcome monitoring **after approval of the clinical outcome monitoring plan by the SoHO competent authority,** ~~**plan as approved** once a conditional authorisation has been granted~~ pursuant to Article 21(2), point (c), and submit the results **and their analysis** to their **SoHO** competent authorities **according to the timeline set in the approval**. ~~In conducting the clinical investigation study as referred to in paragraph 3, points (b) and (c), for the SoHO preparation concerned, the applicant may use an existing clinical registry to record its results provided that their competent authorities have verified that the registry has data quality management procedures in place that ensure accuracy and completeness of data~~.

5. SoHO entities shall not make any **significant** change **within** ~~**the** to the chain of~~ **steps of the processing applied or in the** activities performed for **an authorized** SoHO preparation **subject to the authorisation**, without the prior written **authorisation** ~~approval~~ of their **SoHO** competent authorities.

SoHO entities shall also ~~**provide**~~ **inform, without** ~~**unduer**~~ **delay,** ~~**to** inform~~ their **SoHO** competent authorities **of any** changes **that might affect the authorisation, including the changes related to** ~~in the SoHO preparation authorisation **responsible's**holder's~~ details **of the SoHO entity previously authorised for the SoHO preparation**.

6. The **SoHO entity authorised for the** SoHO preparation ~~authorisation **responsible** holder~~ shall be based ~~in the Union~~ **in the Member State where the application is submitted**. ~~In cases where other SoHO entities carry out one or more of the processing steps for the SoHO preparation, the SoHO entity that holds the SoHO preparation authorisation shall be responsible for the release and shall supervise it, even if the release physically takes place at the site of the other SoHO entities~~.

CHAPTER VI (SoHO Donor Protection): Definitions 8, 9a, 13, 13a, 14, 23, 59, 64, 65; Articles 52, 53, 54, 55, 56

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CHAPTER I

GENERAL PROVISIONS

Article 3

Definitions

(8) 'SoHO donor' means any**:**

(a) living person who has presented themselves to a SoHO entity **or been presented by a person granting consent on th*ei*r behalf, in accordance with national legislation,** with a view to making a donation of SoHO**s, for the purpose of application to a person other than themselves, and other than situations of within couple use as defined in point (63)~~, for the purpose of application to a person other than themselves, and other than situations of within couple use as defined in point (63); or~~**, ~~whetherthat donation is successful or not~~**;**

(b) deceased person who has been referred to a SoHO entity, and ~~for~~from whom consent has been granted or from whom SoHO collection is permitted, in accordance with national legislation;

(9a) 'consent', in the context of this Regulation, means the permission given by:

(a) a living SoHO donor or a SoHO recipient for an action affecting them to proceed, or

(b) any person granting consent on their behalf, or the authorisation granted by the national law, for such an action to proceed in the case of living SoHO donors or SoHO recipients who have no capacity to consent, or

(c) any person granting consent, or the authorisation granted by national law, for such an action to proceed in the case of deceased SoHO donors in accordance with national legislation.

~~(13) '**SoHO** donor recruitment' means any activity aimed at encouraging persons to become SoHO donors;~~

(13a) 'SoHO donor registration' means recording information ~~regarding a prospective~~ on SoHO donors, including the results of the donor health evaluation and, ~~the biological~~ tests performed, ~~including~~and transferring such information to other registries, when applicable ~~for the purposes of matching that registered prospective SoHO donor to a prospective SoHO recipient.~~[3]

(14) 'collection' means a process by which SoHOs are ~~removed, procured, excreted, secreted or~~ obtained **from a SoHO donor~~person~~** ~~by any other manner~~, including any preparatory steps **~~SoHO donor treatment~~**, such as ~~hormone~~ treatment~~,~~ needed to facilitate the process, **at or under the supervision of a SoHO entity ~~at or under the supervision of a SoHO entity~~**;

(23) 'autologous use**~~application~~**' means ~~collection~~**application~~use~~** of **a** SoHO **collected** from ~~one individual~~ **a person** ~~for subsequent application~~ to the same ~~individual~~ **person**~~, with or without further SoHO activities between collection and application~~;

~~[(59) 'EDQM SoHO monograph' means a specification of the critical quality parameters of a particular SoHO preparation defined by the European Directorate for the Quality of Medicines and HealthCare of the Council of Europe;]~~

(64) 'compensation' means making good of any **~~quantifiable~~** losses associated with donation;

(65) 'allogeneic use**~~application~~**' means ~~collection~~**application~~use~~** of **a** SoHO **collected** from **a person~~SoHO donor~~ other than the SoHO recipient**~~one individual for subsequent application to another individual~~;

[3] Changes highlighted in comparison to definition 13 as presented in 10846/23

CHAPTER VI

SoHO DONOR PROTECTION

Article 52

Objectives regarding SoHO donor protection

1. ~~**SoHO competent authorities and**~~ SoHO entities shall ensure ~~high levels of safety~~**respect for the dignity and integrity** of SoHO donors.

2. ~~**SoHO competent authorities and**~~ SoHO entities shall **ensure high levels of safety and** protect the health of living **SoHO** donors **from risks related to the donation. They shall do so by identifying and minimising such risks** before, during and after the **SoHO collection**~~donation~~.

2a. SoHO competent authorities shall verify the compliance of the provisions laid down in this chapter as well as the national provisions on consent and voluntary and unpaid donation.

Article 53

Standards concerning SoHO donor protection

1. In case of collection of SoHO**s** from ~~allogeneic~~**living** donors, regardless of whether or not the **SoHO** donor is ~~genetically~~ related to the intended recipient, SoHO entities shall:

   (a) meet all applicable consent or authorisation requirements in force in the Member State concerned;

   (b) provide **SoHO** donors or**, where applicable,** ~~their relatives or~~ any persons granting ~~authorisation~~**consent** on their behalf, in accordance with national legislation, with**:**

      (i) the information referred to in Article 55 and in a way that is adequate in view of their capacity to understand it;

ii) the contact details of the SoHO entity responsible for the collection from which they can request further information, if needed;

~~(c) provide donors or their relatives or any persons granting authorisation on their behalf, in accordance with national legislation, with the contact details of the responsible SoHO entity from which they can request further information, if needed;~~[4]

(d) safeguard the rights of the **SoHO** donor to physical and mental integrity, to privacy and to the protection of the personal data**, including health data,** concerning them in accordance with Regulation (EU) 2016/679;

(e) ensure that donation is voluntary and unpaid, pursuant to Article 54;

(f) verify the eligibility of the **SoHO** donor on the basis of a donor health evaluation that aims to **identify and** minimise any risk that the ~~donation~~**SoHO collection** might pose to the **SoHO** donor's health;

(g) document the results of the **SoHO** donor health evaluation ~~referred to in point (f)~~;

(h) communicate and clearly explain the results of the **SoHO** donor health evaluation to the **SoHO** donor or**, where applicable,** ~~his/her relatives or~~ any persons granting ~~authorisation~~**consent** on ~~his/her~~**their** behalf, in accordance with national legislation;

(i) identify and minimise any risks to the health of the **SoHO** donor during the ~~donation~~**collection** procedure, including exposure to reagents or solutions that might be ~~toxic~~**deleteriousharmful to health**;

(j) verify, by means of a registry, **as referred to in paragraph 3,** that **SoHO** donors are not donating more frequently than indicated as safe in technical guidelines as referred to in Article 56**(4)** and ~~demonstrate~~**make sure, by monitoring relevant health indicators to evaluate,** that their health is not compromised;

(k) develop and implement a plan for monitoring the **SoHO** donor's health after the donation in cases where the SoHO donations imply a significant risk to a **SoHO** donor as referred to in paragraph **4**~~3~~;

[4] Elements of point c are reflected in point (b)(ii)

(l) in the case of an ~~allogeneic and~~ unrelated donation, refrain from revealing the **SoHO** donor's identity to the **SoHO** recipient **or to the offspring**, apart from ~~exceptional~~ circumstances where such information exchange is permitted in the Member State**s concerned** ~~and follows the expressed wishes of both parties~~.

2. In the course of the **living SoHO** donor health evaluations referred to in paragraph 1, point (f), SoHO entities shall conduct interviews with the **SoHO** donors and gather information concerning the **SoHO** donors' present and recent state of health and their health histories to assure the safety of the donation process for those donors. SoHO entities may perform ~~laboratory~~ **additional** tests as part of the **SoHO** donor health evaluations. They shall perform such tests in cases where evaluations indicate that ~~laboratory~~ **such** tests are necessary to establish the eligibility of those **SoHO** donors from the perspective of their own protection. The **responsible** physician, ~~as~~ referred to in Article ~~51~~**49b**, shall approve the procedure and criteria for **SoHO** donor health evaluations.

3. SoHO entities that collect SoHOs from donors that are subjected to a surgical procedure in order to donate, that are treated with ~~hormones~~**prescribed medication** to facilitate donation, or that donate on a frequent and repeated basis **with a potential risk to the SoHO donor**, shall register such **SoHO** donors and the results of their donor health evaluations **and relevant health indicators** in a cross-entity registry that allows interconnection with other such registries, **as referred to in paragraph 1, point (j).** ~~as referred~~ **according** to **the standards issued by their SoHO competent authorities** in **this regard** ~~paragraph 1, point (j). SoHO entities that manage such registries shall ensure interconnectivity between them~~. **SoHO entities that manage such registries shall ensure interconnectivity between them, in accordance with national legislation.**

4. The SoHO entities referred to in paragraph 3 shall ensure that the plan for monitoring **the SoHO** donor health after **living** donation, as referred to in paragraph 1, point (k), is proportionate to the risks associated with the donation. They shall include in the plan the time period during which the monitoring shall continue.

~~5. In case of collection of SoHOs for autologous use or in the context of individuals or couples from whom SoHOs are collected as part of their own current or future medically assisted reproduction treatment, the treating physician~~**SoHO entities** ~~shall ensure that any risks associated with the collection are explained to the individuals and are outweighed by the potential benefit for those individuals.~~ **In such cases, the paragraphs 1(a), (b), (d), (f), (g) (h) and (i) shall apply.**

5a. In case of collection of SoHOs from deceased SoHO donors, in accordance with national legislation, the paragraphs 1(a), (b), (d), (e) and (l) shall apply, as well as 1(h), for those cases in which the results of the health evaluation may affect persons related to the SoHO donor.

6. The Commission is empowered to adopt delegated acts in accordance with Article 77 in order to be able to supplement this Regulation in cases where additional standards are needed in order to ensure the protection of donors.

7. Where, in the case of risk to the safety of **SoHO** donors, imperative grounds of urgency so require, the procedure provided for in Article 78 shall apply to delegated acts adopted pursuant to this Article.

Article 54

Standards concerning voluntary and unpaid nature of SoHO donations

1. SoHO entities shall not provide financial incentives or inducements to **SoHO** donors or ~~their relatives or~~ any persons granting ~~authorisation~~**consent** on their behalf**, in accordance with national legislation**~~, in accordance with national legislation~~.

2. Member States may allow for the ~~compensation or~~ reimbursement **of SoHO donors for** ~~from~~**of actual expenses incurred in connection with SoHO donation or for** the **compensation of** SoHO ~~entities to~~ donors for losses related to their participation in **SoHO** donations through fixed rate allowances. In such case, Member States shall establish the conditions for such **reimbursement or** allowance~~s~~ in national legislation, including the setting of an upper limit that ensures ~~that allowances are financially neutral and~~**financial neutrality** consistent with the standards laid down in this Article. ~~They~~**Member States** may delegate the setting of conditions for such **reimbursement or** allowances to independent bodies that are established in accordance with national legislation.

2a. The conditions applied by each Member State shall be made available ~~to the public~~ on the EU SoHO P~~p~~latform and be updated without undue delay if modified.

2b. Member States shall take all necessary measures to ensure that any promotion and publicity activities in support of the donation of SoHO does not include the compensation or reimbursement as an element of such activities.

3. SoHO entities may **reimburse or** compensate ~~or reimburse~~**SoHO** donors as provided for by their ~~competent authorities~~**Member States,** pursuant to paragraph 2.

~~3a. In order to ensure that voluntary unpaid SoHO donations do not, as such, lead to a profit from the human body, and for compliance with the Charter in this respect,~~ Member States shall take appropriate measures to ensure transparency in the fees for technical services required for making SoHO~~s and derived products~~ available~~, and in the pricing strategy applied to such products~~.

Article 55

Standards concerning information to be provided prior to consent ~~or authorisation~~

1. SoHO entities shall provide prospective SoHO donors~~, their relatives~~ or**, if applicable,** any persons granting ~~authorisation~~**consent** on their behalf, ~~in accordance with national legislation,~~with all appropriate information relating to the donation ~~and collection~~ process**,** in accordance with national legislation~~, including a general description of the potential uses and benefits of the donation~~.

2. SoHO entities shall provide the information referred to in paragraph 1 before the consent ~~is given or authorisation~~**to ~~donation~~ donate** is granted ~~for the donation~~. SoHO entities shall provide the information in an accurate and clear manner, using terms that are easily understood by the prospective **SoHO** donors~~,~~ or**, if applicable,** ~~the~~**any** persons ~~to~~ **granting** consent ~~or authorise the donation. It shall not mislead the prospective donors or persons granting authorisation~~ on their behalf~~,~~**. The information shall not be misleading,** in particular, as to the benefits of the donation to future recipients of the SoHO concerned~~.~~ **~~This provision shall also apply to persons from whom SoHO are to be collected for autologous use or as part of a current or future medically assisted reproduction treatment in the context of individuals or couples.~~**

3. In case of living **SoHO** donors **or, if applicable, persons granting consent on their behalf**, SoHO entities shall provide information regarding:

(a) the purpose and nature of the donation;

(aa) the intended use of the donated SoHO, specifically covering proven benefits for the future SoHO recipients and for patients treated with products manufactured from SoHO ~~any possible research or commercial uses, in particular for manufacturing products~~and regulated by other Union legislation, as provided for in Article 2.3, to which specific consent shall be granted~~the SoHO donor or any persons acting on their behalf shall consent;~~[5]

(b) the consequences and risks of the donation;

(ba) the obligation for consent, ~~as applicable in the Member State~~in accordance with national legislation, in order for SoHO~~s~~ collection to be carried out.

(c) the right to ~~withdraw~~**revoke** consent and any restrictions on ~~the~~**that** right **after the collection**~~to withdraw consent following donation;~~

~~(d) the intended use of the donated SoHO, in particular covering proven benefits for the future recipients and any possible research or commercial uses to which the donor should consent;~~

~~[5] This section captures elements of the deleted point (d)~~

(e) the **purpose of the** ~~analytical~~ tests that will be performed in course of the donor health evaluation**, in accordance with Article 53(2)**;

(f) the right of the ~~donor~~**SoHO donor or, if applicable, the person granting consent on their behalf** to receive the confirmed results of the ~~analytical~~ tests **when relevant for their health,** ~~when relevant for their health~~ **in accordance with national legislation**;

(g) the recording and protection of ~~donor~~**SoHO donor's** personal ~~and~~**data, including** health data**,** and medical confidentiality, including any potential sharing of data in the interest of **the SoHO** donor health monitoring and of public health, as necessary and proportionate**, in accordance with Article 76**;

(ga) the possibility that the SoHO donor identity may be revealed to offspring born from their SoHO donation in cases where national legislation grants this right to such offspring;

(h) ~~the~~**other** applicable safeguards ~~intended~~ to protect the **SoHO donor.**

~~(i) the obligation for consent and authorisation, as applicable in the Member State, in order for SoHOs collection to be carried out.~~

3a. In case of deceased SoHO donors, SoHO entities shall provide any persons granting consent to donation, according to the national law, with the information referred to in paragraphs 3(a), (aa), (ba), (c), (e), and (g), as well as 3(f) for those cases in which the results of the health evaluation may affect persons related to the SoHO donor ~~and their personal data;~~**.**

Article 56

Implementation of the standards concerning SoHO donor protection

1. When the Commission deems it necessary to provide binding rules on the implementation of a particular standard or element of a standard referred to in Articles 53, 54 or 55, in order to ensure convergent and high levels of **SoHO** donor ~~safety~~**protection**, the Commission may adopt implementing acts describing particular procedures to be followed and applied to meet such standard, or element thereof.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).

2. On duly justified imperative grounds of urgency relating to a risk to **SoHO** donor health, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 79(3).

3. ~~In order to apply the standards concerning donor protection or elements thereof, referred to in Articles 53, 54 and 55, SoHO entities shall follow the procedures laid down in any~~**The** implementing ~~act~~**acts** adopted in accordance with paragraphs 1 and 2 of this Article **shall also apply to SoHO entities when they apply the standards or elements concerning SoHO donors protection as refered to in Articles 53, 54 and 55**.

4. For those standards concerning **SoHO** donor protection or elements thereof for which no implementing act has been adopted, in order to apply such standards or elements thereof, SoHO entities shall ~~follow:~~ **take into account, in this order of priority:**

(a) the most recent technical guidelines, as indicated on the EU SoHO Platform ~~referred to in Chapter XI~~, as follows:

(i) published by the ECDC concerning the prevention of communicable disease transmission ~~through SoHO donation~~;

(ii) published by the EDQM concerning **SoHO** donor protection other than from transmission of communicable disease**s** ~~through donation~~;

(b) ~~other guidelines accepted by competent authorities, as achieving an equivalent level of donor safety as set by the~~**national or international** ~~technical~~ **other** guidelines**, as** referred to in **article 29(7a)** point (~~a~~**b**);

(c) ~~where the guidelines referred to in points (a) or (b) do not address a particular~~**other** technical method**s**, **applied in specific circumstances, as referred to in article 29 (7a) point (c)** ~~other technical methods in line with relevant international guidelines and~~**the** ~~scientific evidence in peer-reviewed scientific publications, where available~~.

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5. In those cases referred to in paragraph 4, point (a), for the purpose of Article 30 in conjunction with Article 29, SoHO entities shall ~~be able to~~ demonstrate to their **SoHO** competent authorities, for each of the standards or elements thereof, which and to what extent they follow the **technical** guidelines referred to in paragraph 4, point (a).

6. In those cases referred to in paragraph 4, point (b), for the purpose of Article 30 in conjunction with Article 29, SoHO entities shall demonstrate to their **SoHO** competent authorities, for each of the standards or elements thereof, ~~the equivalence~~**~~, in terms of SoHO donor protection,~~** ~~of the other guidelines applied~~ ~~in terms of the level of safety~~, ~~quality and efficacy~~ **which and to what extent they follow** ~~to the level set by~~ the technical guidelines referred to in paragraph 4, point (**b**~~a~~).

7. In those cases referred to in paragraph 4, point (c), for the purpose of Article 30 in conjunction with Article 29, SoHO entities shall perform a risk assessment to demonstrate that the technical methods applied achieve a high level of **protection of SoHO** donor**s** ~~safety~~, and record the practice followed to establish the technical methods. They shall make the assessment and record available for review by their **SoHO** competent authorities during inspection or on specific request of the **SoHO** competent authorities.

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CHAPTER X

UNION ACTIVITIES

Article 69

Union training and exchange of SoHO competent authorities' personnel

1. The Commission shall**, in cooperation with SoHO National Authorities,** organise Union training **on the implementation of this Regulation.** ~~in cooperation with the Member States concerned.~~

   ~~In the Union training organised, the Commission shall cover at least, the following topics, as appropriate:~~

   ~~(a) the implementation of this Regulation;~~

   ~~(b) procedures relevant for the SoHO supervisory activities of the competent authorities;~~

   ~~(c) the functionality and use of the EU SoHO Platform;~~

   ~~(d) other knowledge and skills relevant to facilitate SoHO supervisory activities.~~

2. The Commission may provide Union training to personnel of **SoHO** competent authorities of EEA Member States**,** ~~and~~ of countries that are applicants or candidates for Union membership and to personnel of bodies to whom specific responsibilities for SoHO **supervisory** activities have been delegated. It may organise aspects of the training in collaboration with international organisations and regulators working in the field of SoHOs.

3. **SoHO** ~~C~~**c**ompetent authorities shall ensure that the knowledge **and materials** acquired through the Union training activities referred to in paragraph 1 of this Article ~~is~~ **are** disseminated as necessary and appropriately used in the personnel training activities referred to in Article ~~16~~**9**.

4. The Commission may support, in cooperation with the **SoHO National Authorities** ~~Member States~~, the organisation of programmes for the exchange of **SoHO** competent authorities' personnel between two or more Member States and for the temporary secondment of personnel from one Member State to the other as part of personnel training.

5. The Commission shall maintain a list of the **SoHO** competent authority personnel that have successfully completed the Union training referred to in paragraph 1, with a view to facilitating joint activities, in particular those referred to in Articles 23, 31, and 70**1**~~.~~ The Commission shall make this list available to the **SoHO National Authorities** ~~Member States~~.

6. ~~The Commission is empowered to adopt delegated acts in accordance with Article 77 in order to be able to supplement this Regulation by laying down rules on the organisation of the training activities referred to in paragraph 1 and of the programmes referred to in paragraph 4.~~

~~Article 69a~~

~~Information exchange~~

~~The Commission shall hold regular meetings with the SoHO National Authorities designated by the Member States, delegations of experts designated by the Member States and other relevant parties to exchange information on the experience acquired.~~

Article 70

Commission verifications~~controls in Member States~~

1. The Commission shall perform **verifications to confirm whether** ~~controls, including audits, in the~~ Member States **effectively apply** ~~to verify the effective application of~~ the requirements relating to:

   (a) **SoHO** competent authorities and delegated bodies provided for in Chapter II;

   (b) the SoHO supervisory activities ~~provided for in Chapter III as~~ carried out by **SoHO** competent authorities and delegated bodies;

(c) the notification and reporting requirements of this Regulation.

2. The Commission shall organise the ~~controls~~ **verifications** referred to in paragraph 1 in cooperation with the **SoHO National Authorities** ~~Member States~~, and shall carry them out in a manner that avoids unnecessary administrative burden.

3. When performing the ~~controls~~ **verifications** referred to in paragraph 1, the Commission experts shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c), on ~~inspection, vigilance and any other~~ SoHO supervisory activities ~~as needed.~~

4. ~~Experts from the Member States may assist~~ **T**~~t~~he Commission experts**,** in carrying out the ~~controls~~ **verifications** referred to in paragraph 1, **may be supported by experts from the SoHO competent authorities**~~. The Commission shall~~ select**ed**~~the experts from the Member States~~, whenever possible**,** from the list referred to in Article 69(5)~~,and~~**. Experts from the SoHO competent authorities** shall **be** give**n** the~~m~~ same rights of access as the Commission experts.

5. Following each **verification**~~control~~, the Commission shall:

(a) prepare a draft report on the findings and, where appropriate, include recommendations **addressing** ~~on how best to address~~ the shortcomings **identified**;

(b) send a copy of the draft report referred to in point (a) to the concerned **SoHO National Authority**~~Member State~~ for its comments;

(c) take the comments ~~of the Member State~~ referred to in point (b) into account in preparing the final report; and

(d) make publicly available **a summary of** the final report **on the EU SoHO P**~~p~~**latform** ~~referred to in point (c) and the comments of the Member State referred to in point (b).~~

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Article 71

Cooperation with the EDQM

The Commission shall establish and maintain cooperation with the EDQM**, in the form of a cooperation agreement,** in relation to the guidelines published by the EDQM.

Article 72

Assistance by the Union

1. To facilitate the fulfilment of the requirements provided for in this Regulation, the Commission shall support implementation by:

   (a) providing secretariat and technical, scientific and logistic support to the SCB and its working groups;

   (b) funding Commission **verifications**~~controls~~ in Member States, including the costs of Member State experts assisting the Commission ~~in such controls~~;

   (c) providing funding from the relevant Union programme**s** in support of public health to:

      (i) support collaborative work between **SoHO** competent authorities and organisations representing groups of SoHO entities and SoHO professionals with the aim to facilitate effective and efficient implementation of this Regulation, including for training activities **referred to in article 69(1) and programmes for the exchange of SoHO competent authorities' personnel referred to in article 69(4)**;

      (ii) co-finance a cooperation agreement with the EDQM to support the development and updating of technical guidelines ~~supporting~~ **in order to support** the ~~coherent~~ **consistent** implementation of this Regulation.

   (ca) establishing, managing and maintaining the EU SoHO Platform;

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2. With regard to the support referred to in paragraph 1, point (a), the Commission shall, in particular, organise the meetings of the SCB and its working groups, **~~the meetings with SoHO National Authorities,~~** the travel of members ~~of the SCB~~, reimbursement and special allowances for ~~scientific~~ experts that participate in those meetings~~, and ensure the appropriate follow-up~~.

3. Upon request from Member States, technical support may be provided, through the Technical Support Instrument established by Regulation (EU) 2021/240 of the European Parliament and of the Council[6], for the reform of national or regional SoHO supply supervision, provided those reforms aim to achieve compliance with this Regulation.

4. In order to perform the activities referred to in paragraph 1 to the mutual benefit of the Commission and of the beneficiaries, relating to preparation, management, monitoring **and verifications**~~, audit, and control~~, as well as to support expenditure, the Commission shall have recourse to the technical and administrative assistance it might need.

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[6] Regulation (EU) 2021/240 of the European Parliament and of the Council of 10 February 2021 establishing a Technical Support Instrument (OJ L 57, 18.2.2021, p. 1).

CHAPTER XI (EU SoHO Platform): Recitals 41, 42, 43 ; Articles 3(31), 73, 74

Recitals

(41) In order to limit administrative burden on **SoHO** competent authorities and the Commission, the latter should establish an online platform (the 'EU SoHO Platform') to facilitate timely submission of data and reports**. The EU SoHO Platform will contribute to** ~~as well as~~ improve~~d~~ transparency of ~~national~~ reporting and **SoHO** supervisory activities **and to the exchange of information between relevant parties.**

(42) The processing of personal data under this Regulation should be subject to strict guarantees of confidentiality and should comply with the rules on the protection of personal data**, including health data,** laid down in Regulation (EU) 2016/679 of the European Parliament and of the Council and in Regulation (EU) 2018/1725 of the European Parliament and of the Council.

(43) As the EU SoHO Platform requires the processing of personal data, **including health data,** it will be designed respecting the principles of data protection. Any processing of personal data, **including health data,** should be limited to achieving the objectives and **the fulfilment of** obligations of this Regulation. Access to the EU SoHO Platform, **by SoHO entities, SoHO competent authorities, Member States or the Commission**, should be limited to the extent necessary to **perform SoHO related** ~~carry out supervisory~~activities **laid down**~~provided for~~ in this Regulation.

CHAPTER I

GENERAL PROVISIONS

Article 3

Definitions

~~(31) 'EU SoHO Platform' means the digital platform established by the Commission~~**, referred to in Chapter XI** ~~to exchange information concerning SoHO activities;~~

CHAPTER XI

EU SoHO PLATFORM

Article 73

Establishment, management and maintenance of the EU SoHO Platform

1. The Commission shall establish, manage and maintain ~~the~~ a **digital platform** ~~EU SoHO Platform~~ to facilitate effective and efficient exchange of information concerning SoHO activities in the Union, as provided for in this Regulation **("EU SoHO Platform").**

2. ~~The Commission shall make a summary of data of public interest and make it accessible to the public on the EU SoHO Platform in aggregated and anonymised formats. The EU SoHO Platform shall provide a channel for restricted exchange of information and data between competent authorities, and between SoHO entities and their respective competent authorities.~~

3. The processing of personal data**, including health data,** by the **SoHO entities, the SoHO competent authorities, the** Member States and the Commission through the EU SoHO Platform ~~and any one of its components~~ shall only be carried out **in cases where it is necessary for the performance of the tasks, the achievement of the objectives and the fulfilment of obligations as laid down in this Regulation. The processing of personal data shall be carried out in accordance with the applicable Union data protection legislation for the purpose of performing SoHOs related activities in accordance with this Regulation and in compliance with the applicable data protection legislation**~~for the purpose of performing SoHOs related activities in accordance with this Regulation and in compliance with the applicable data protection legislation~~.

4. The Commission, **after having consulted the SCB,** shall adopt delegated acts in accordance with Article 77 supplementing this Regulation by laying down technical specifications regarding the ~~establishment~~, management and maintenance of the EU SoHO Platform.

5. The Commission shall provide instructions**, materials and training on the correct use of the EU SoHO Platform** for SoHO ~~entities and~~ competent authorities **via their SoHO National Authority. The Commission, where appropriate and in cooperation with their SoHO National Authority, shall provide instructions and training for SoHO entities** on the correct use of the EU SoHO Platform. **Those training materials shall be availabe on EU SoHo Platform.**

Article 74

General functionalities of the EU SoHO Platform

1. The EU SoHO Platform shall enable SoHO entities, **SoHO** competent authorities, Member States and the Commission to process information, data and documents concerning SoHO~~s~~, **and SoHO activities**, including the submission, retrieval, storage, management, handling, exchange, analysis, publication and deletion of such data and documents as provided for in this Regulation.

2. The EU SoHO **P**platform shall ~~also~~ provide **a channel for restricted** ~~a secure environment for the~~ exchange of information **and data, in particular:**

(a) between **Member States' SoHO National Authorities;**

(b) between two SoHO competent authorities within the Member State or between a SoHO competent authority and its SoHO National Authority;

(c) between SoHO National competent authorities and the Commission, in particular in relation to **activity data concerning SoHO activities of SoHO entities, the summaries of notifications and investigation reports of confirmed SAR or SAE,** ~~SAO~~ **SoHO** ~~and~~ rapid alerts **and SoHO supply alerts;**

(d) between SoHO National Authorities and the SCB; and

(e) between SoHO National Authorities and the ECDC ~~for SoHO rapid~~ alerts related to communicable diseases~~, according to article 36(3).~~

(f) ~~T~~the EU SoHO Pplatform shall also provide a secure communication channel for the exchange of information between SoHO entities and their respective SoHO competent authorities, when the SoHO competent authorities choose to use the EU SoHO Platform for such exchanges.

2a. The EU SoHO Platform shall ~~It shall also~~ provide public access to information regarding**:**

(a) the registration and authorisation status of SoHO entities **and their identification code** and **the SoHO establishment identification code;**

(b) authorised SoHO preparations ~~authorised~~;

(c) annual SoHO Activity Report and annual SoHO vigilance report, in aggregated and anonymised formats, after their approval by SoHO National Authorities;

(d) relevant best practices agreed and documented by the SCB;

(e) technical guidelines for quality management published by the EDQM;

(f) technical guidelines concerning the prevention of communicable disease published by the ECDC and concerning SoHO donor, SoHO recipient and offspring protection other than from transmission of communicable diseases published by the EDQM;

(~~g~~f) the name, the institution of origin and the declaration of interest of each SCB member and alternate;

(h~~g~~) the SoHO compendium;

~~(ih) the conditions established in national legislation for reimbursement or allowances, including the setting of an upper limit to SoHO donors for losses related to their participation in SoHO donations.~~

~~The EU SoHO Platform~~ ~~shall~~ **~~also~~** ~~indicate the applicable guidelines to be followed to meet the technical standards laid down in Articles 56 and 59.~~

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3. The Commission shall adopt implementing acts laying down technical specifications for the EU SoHO Platform, including its functions, the roles and responsibilities of each of the parties listed in paragraph 1, the retention periods for personal data and the technical and organisational measures to ensure the safety and security of personal data processed, **including health data**.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).

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