Krajowe Centrum
Bankowania Tkanek i Komórek

Wytyczne EDQM
– dlaczego są ważne
a będą jeszcze ważniejsze

Izabela Uhrynowska-Tyszkiewicz

Projekt → ***Rozporządzenie***

Parlamentu Europejskiego i Rady

w sprawie norm jakości i bezpieczeństwa

substancji pochodzenia ludzkiego przeznaczonych do zastosowania u ludzi

oraz

uchylające dyrektywy 2002/98/WE i 2004/23/WE

European Commission

Projekt SoHOR Komisja Europejska

14.07.2022

European Parliament

Parlament Europejski

12.09.2023 r.

- Poprawki do projektu

Council of the European Union

Rada (Unii Europejskiej)

26.10.2023 r.

- Poprawki do projektu

z 2 wersji poprawek

European Parliament
2019-2024

TEXTS ADOPTED

P9_TA(2023)0299

Standards of quality and safety for substances of human origin intended for human application

Amendments adopted by the European Parliament on 12 September 2023 on the proposal for a regulation of the European Parliament and of the Council 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 (COM(2022)0338 – C9-0226/2022 – 2022/0216(COD))[1]

(Ordinary legislative procedure: first reading)

https://www.europarl.europa.eu/doceo/document/TA-9-2023-0299_EN.pdf

Council of the European Union

Brussels, 20 October 2023
(OR. en)

13802/23

LIMITE

SAN 564
CODEC 1775
IA 268

PUBLIC

Interinstitutional File:
2022/0216(COD)

NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
No. Cion doc.:	11396/22 + ADD 1 - ADD 6
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 *- Mandate for negotiations with the European Parliament*

https://data.consilium.europa.eu/doc/document/ST-13802-2023-INIT/en/pdf

1 wersja

European Parliament

SoHOR 2024

Council of the European Union

→ przyjęcie i publikacja

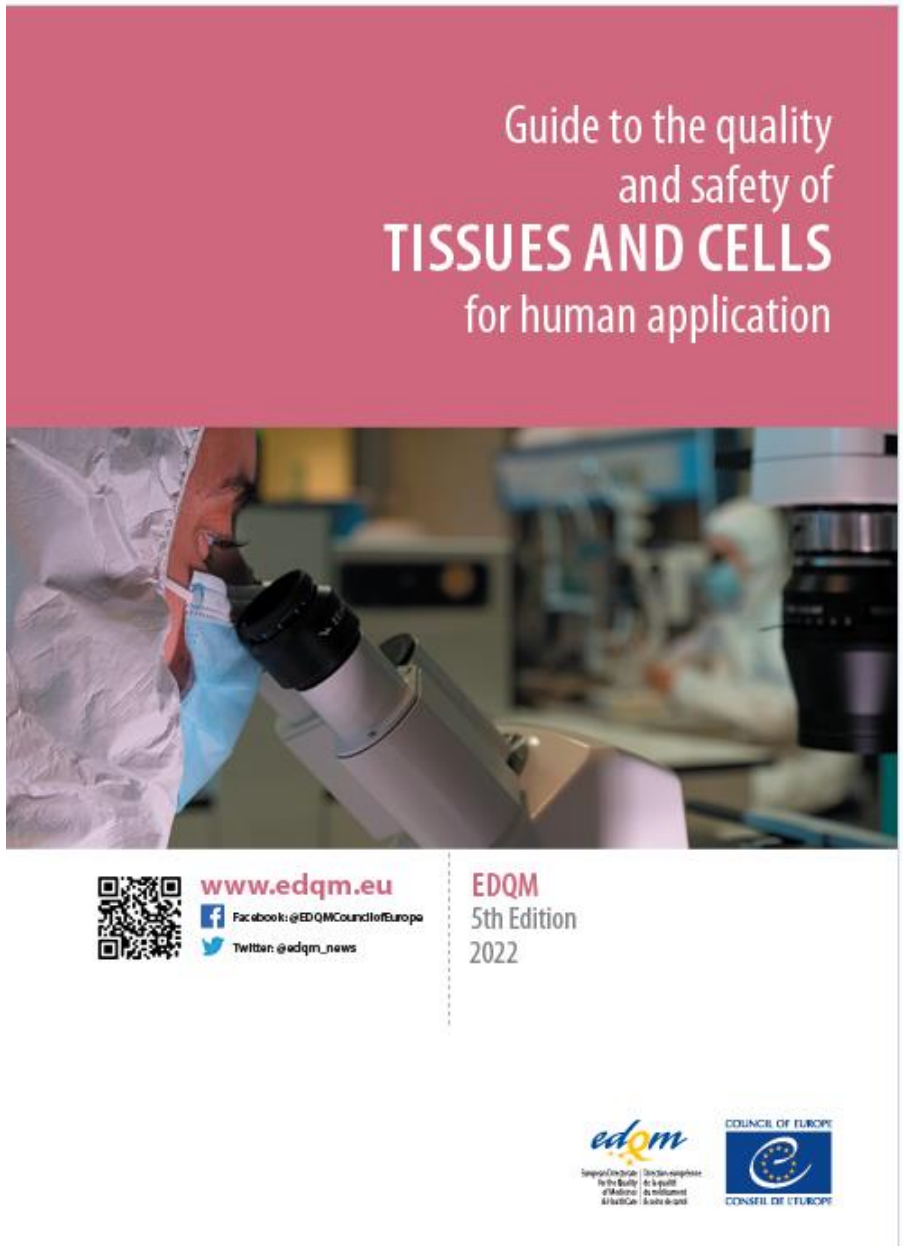
→ okres przejściowy 2-3 lata

SoHOR będzie obowiązywać WPROST w MS

Rozporządzenie Parlamentu Europejskiego i Rady w sprawie norm jakości i bezpieczeństwa substancji pochodzenia ludzkiego przeznaczonych do zastosowania u ludzi oraz uchylające dyrektywy 2002/98/WE i 2004/23/WE

→ w PL NOWE AKTY PRAWNE doszczegóławiające

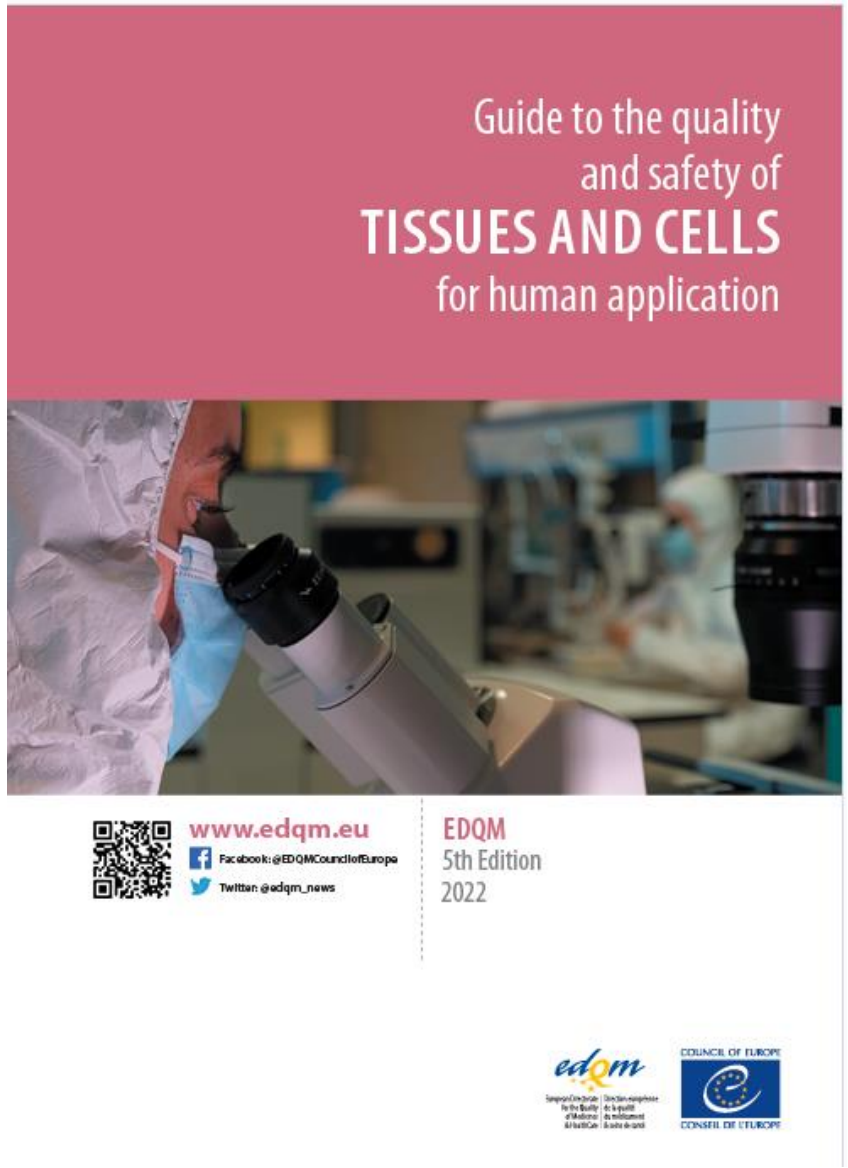
rozpoczęły się prace nad 6. edycją Guide'u



→ ang. *Guide to the quality and safety of tissues and cells for human application*

→ pl. *Przewodnik dotyczący jakości i bezpieczeństwa tkanek i komórek do zastosowania u ludzi*

Wytyczne EDQM



European Committee (Partial Agreement) on Organ Transplantation (CD-P-TO)

EDQM
5th Edition
2022

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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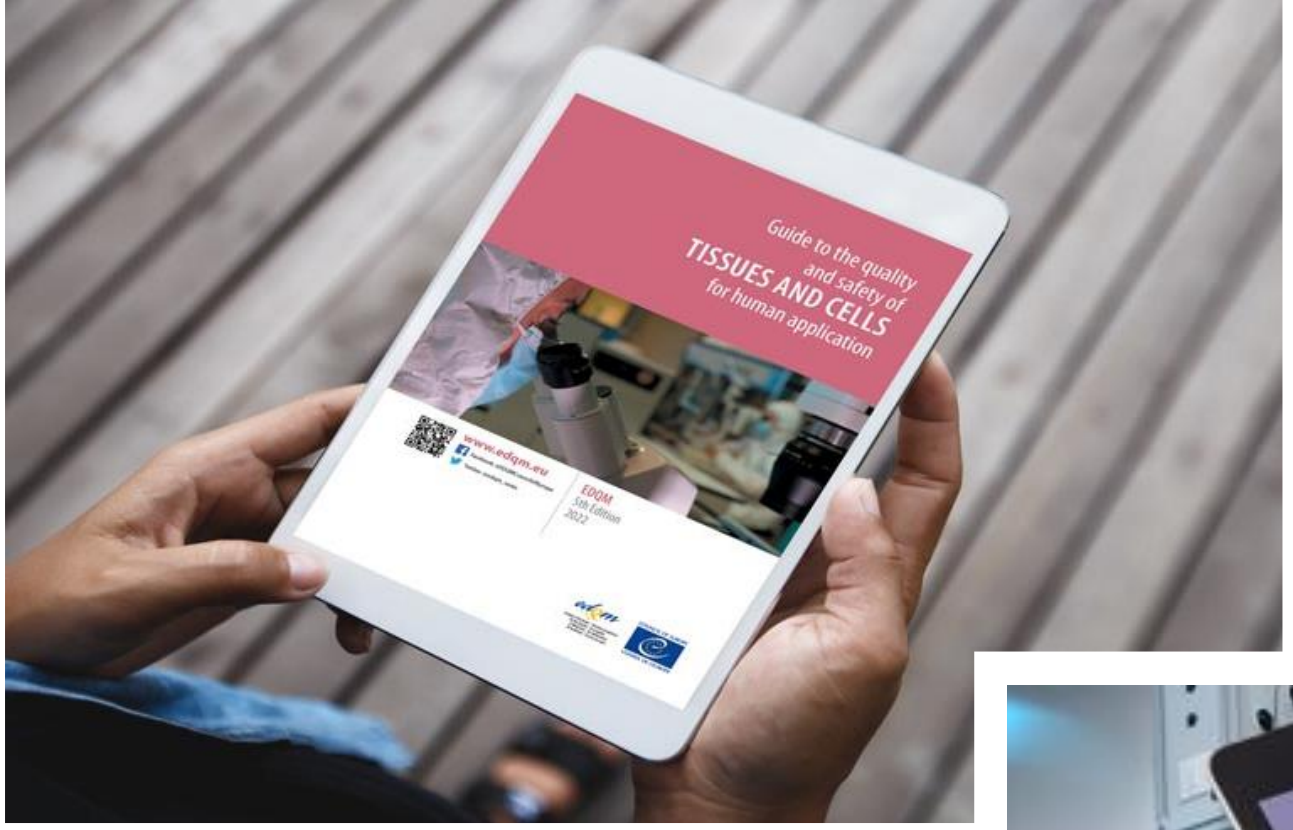
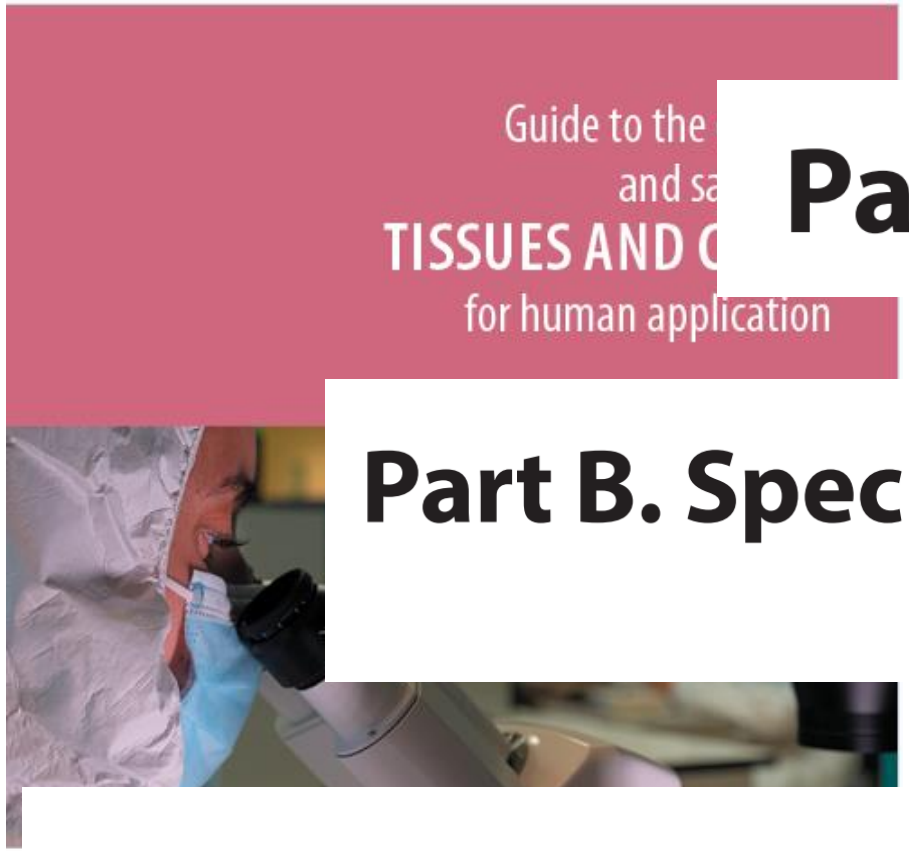


[Guide to the quality and safety of organs for transplantation - European Directorate for the Quality of Medicines & HealthCare (edqm.eu)]

[Guide to the quality and safety of tissues and cells for human application - European Directorate for the Quality of Medicines & HealthCare (edqm.eu)]



Part A. General requirements

Part B. Specific requirements for substances of human origin

Part C. Good Practice Guidelines for tissue establishments

Part D. Tissue and cell monographs

24.1. Haematopoietic progenitor cells from bone marrow – HPC(M)

Tissue/cell product	Haematopoietic progenitor cells from bone marrow – HPC(M)
Definition	HPC are found in small numbers in bone marrow. The infused HPC(M) can originate from the recipient (autologous) or from another individual (allogeneic). They can be used as fresh unmanipulated product or can be further processed (e.g. buffy-coat preparation, cell selection, cryopreservation).
Established clinical indications	• Restoration of haematopoiesis after chemo- and/or radiation therapy (autologous and allogeneic transplantation). • Establishment of donor chimerism (allogeneic transplantation).
Critical properties	• Cellularity/viability *a.* for autologous transplantation: – nucleated cell dose: >1.0-2.0 × 10^8/kg recipient body weight, – viable CD34⁺ cell dose: ≥ 2.0 × 10^6/kg recipient body weight; *b.* for allogeneic transplantation: – nucleated cell dose: ≥ 2.0-3.5 × 10^8/kg recipient body weight, – viable CD34⁺ cell dose: ≥ 2.0-3.5 × 10^6/kg recipient body weight. • Absence of microbial contamination (the presence of microbial contamination may not preclude release but may indicate the need for antibiotic treatment in the recipient). • In case of ABO incompatibility, red cell volume should limited to 0.2 to 0.4 mL/kg or 10-30 mL • In cases of cryopreserved HPC(M), DMSO volume should be less than 1 mL/kg recipient body weight.
Quality control requirements	• Nucleated cell count • Enumeration of viable CD34⁺ cells • Microbiological testing • ABO Rh blood group for allogeneic products • Measurement of residual ABO-incompatible red cell volume
Storage and transport	• Fresh HPC(M) can be stored and transported up to 72 hours at room temperature (15-25 °C) or refrigerated (2-8 °C) as requested by the transplant centre. • Cryopreserved HPC(M) are stored and transported at temperatures equal to or below – 140 °C. • Cryopreserved HPC(M) can be stored for up to 10 years or longer. • Thawed HPC(M) are stored and transported refrigerated (2-8 °C).
Special labelling and accompanying information	• To be placed in a container, which must be appropriately labelled with a uniquely identifying code. When applicable, this code must also be included in the accompanying documentation. • In the EU, when grafts are distributed for human application, they must be labelled with the Single European Code (SEC) as applicable. • Specific information not coded in the SEC that must be included in accompanying documentation: – donor name (autologous or related donors) or donor ID (unrelated donors) – recipient name (if permitted), recipient ID (if applicable) – nucleated cell count and viable CD34⁺ cell enumeration – ABO Rh blood group – volume – identity of the collection facility and/or donor registry – identity of processing and distribution facility – instructions for appropriate thawing, if applicable.
Special warnings (if needed)	• Do not irradiate. • Properly identify intended recipient and product. • For use by intended recipient only. • For autologous use only, if applicable. • Do not use leukoreduction filters. • Use immediately after thawing. • If presence of microbial contamination, consider antibiotic treatment in the recipient.

24.2. Haematopoietic progenitor cells from peripheral blood apheresis – HPC(A)

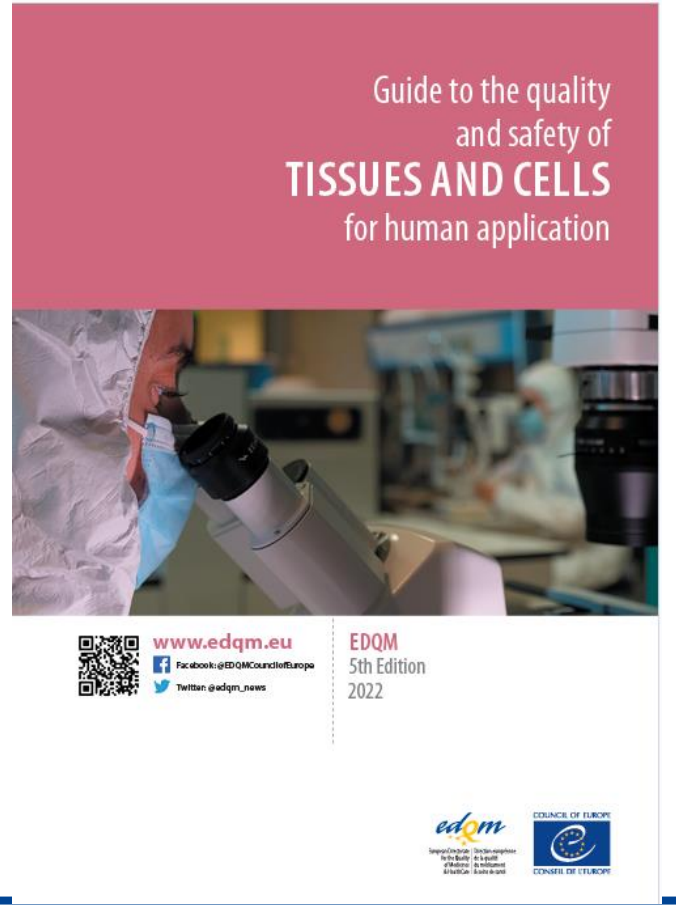
Tissue/cell product	Haematopoietic progenitor cells from peripheral blood apheresis – HPC(A)

24.3. Mononuclear cells from unstimulated peripheral blood apheresis – MNC(A)

Tissue/cell product	Mononuclear cells from unstimulated peripheral blood apheresis – MNC(A)

25.1. Haematopoietic progenitor cells from umbilical cord blood – HPC(CB)

Tissue/cell product	Haematopoietic progenitor cells from umbilical cord blood – HPC(CB)
Definition	HPC are found in umbilical cord blood (UCB). UCB banks collect, transport, process and store UCB and, after validation of the UCB, transfer the data to a stem cell registry. Upon request, UCB units are distributed cryopreserved as whole blood or buffy-coat enriched.



L 102/48 EN Official Journal of the European Union 7.4.2004

DIRECTIVE 2004/23/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 31 March 2004
on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

+ EU akty wykonawcze
(m.in. dyrektywy techniczne)

U S T A W A

z dnia 1 lipca 2005 r.

o pobieraniu, przechowywaniu i przeszczepianiu komórek, tkanek i narządów

Opracowano na podstawie: t.j. Dz. U. z 2023 r. poz. 1185.

Art. 29

2. System zapewnienia jakości obejmuje w szczególności następujące dokumenty:

1) standardowe procedury operacyjne;

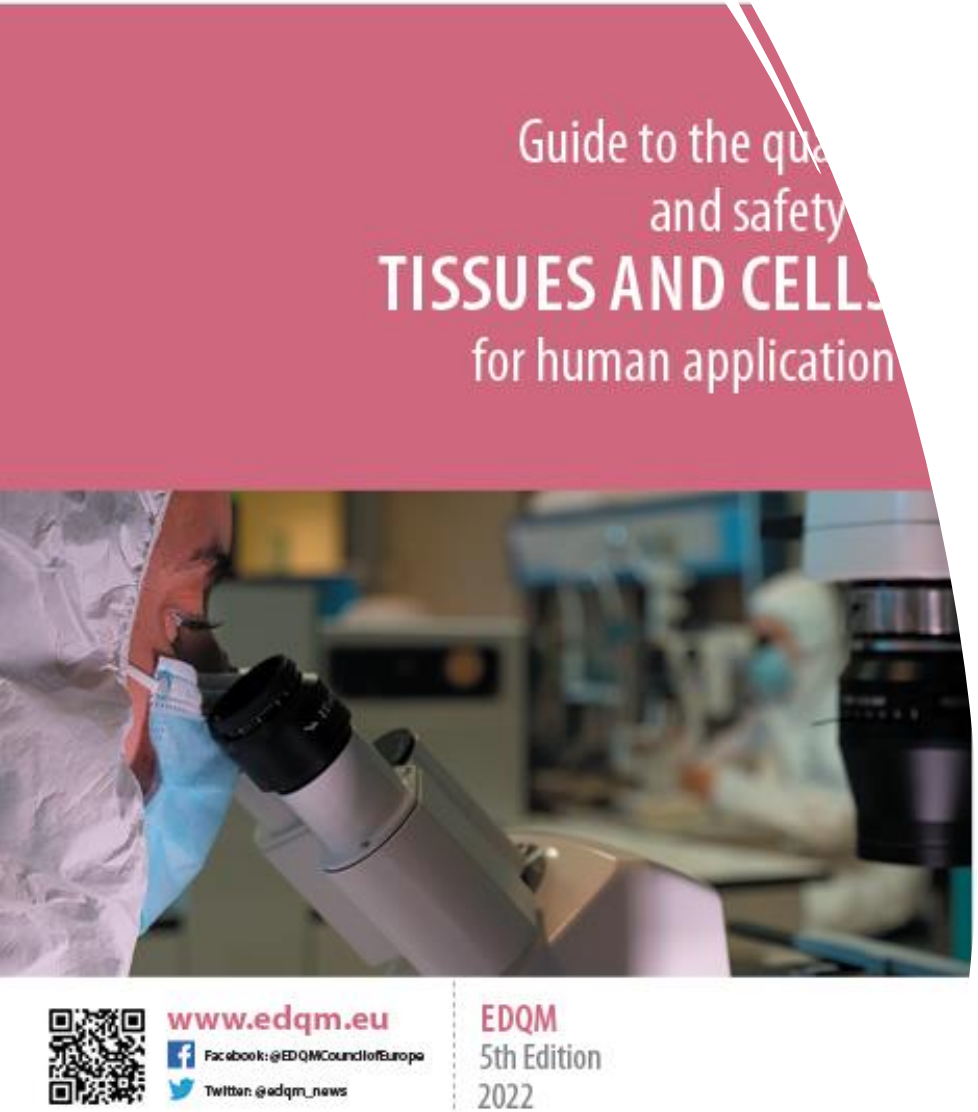
2) wytyczne;

3) instrukcje postępowania;

4) formularze sprawozdawcze;

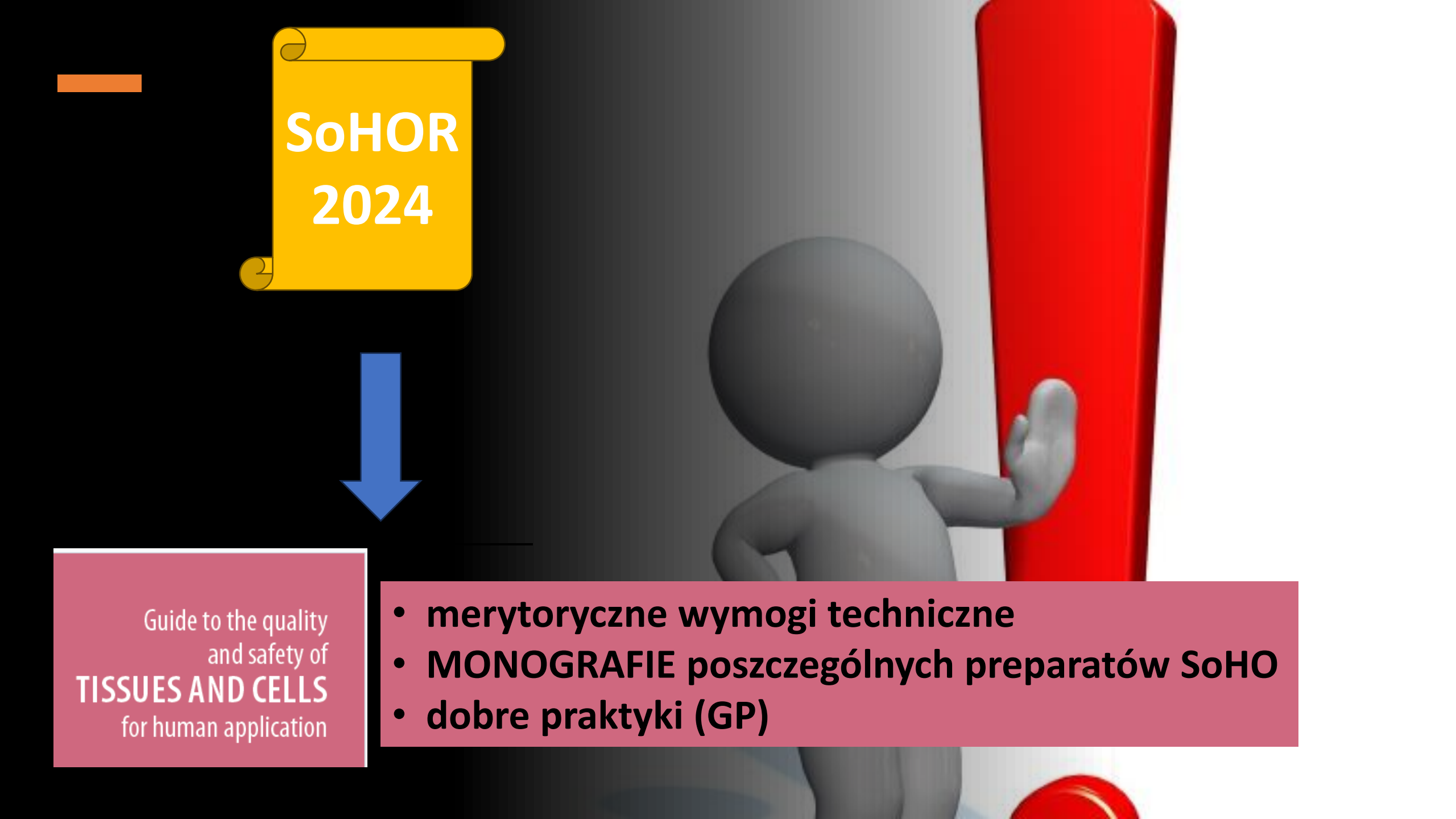
5) karty dawców;

6) informacje w sprawie miejsca przeznaczenia tkanek lub komórek.



Wytyczne EDQM – dlaczego są ważne a będą jeszcze ważniejsze

SoHOR 2024



Guide to the quality and safety of **TISSUES AND CELLS** for human application

- **merytoryczne wymogi techniczne**
- **MONOGRAFIE poszczególnych preparatów SoHO**
- **dobre praktyki (GP)**

Guide to the quality
and safety of
TISSUES AND CELLS
for human application

- **merytoryczne wymogi techniczne**
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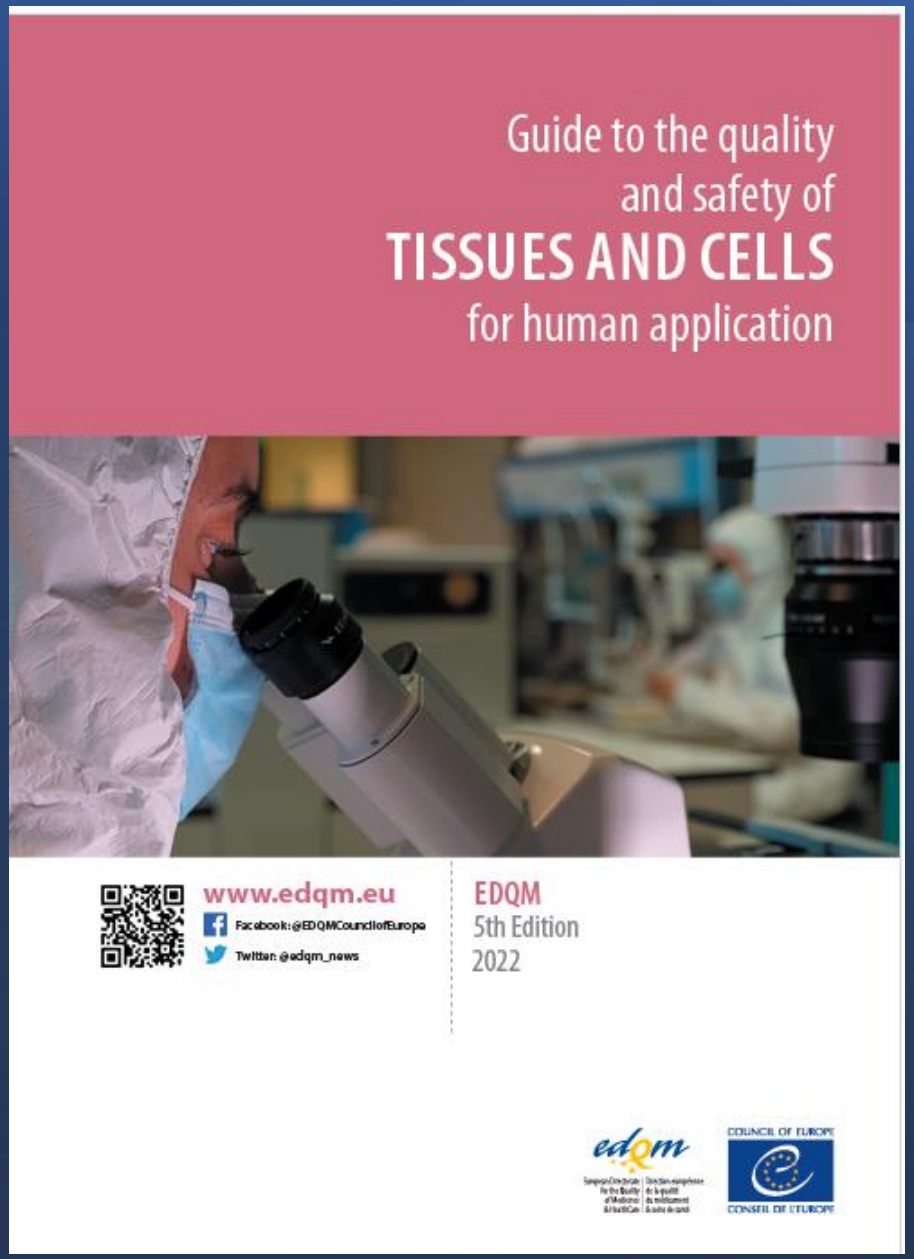
- **dobre praktyki (GP)**

SoHO entities

inspectors



1. zachęcam do zapoznania się z 5. edycją Guide'u **i już teraz zgłoszenie do mnie uwag**
2. wzięcie udziału w publicznych konsultacjach ogłaszanych przez EDQM

The end

pytania →izabela.tyszkiewicz@kcbtik.pl