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VVD - Gebrauchs- und Fachinformation für PBSC allogen (UKE) in englischer Sprache

REVISIONSGRUND:

Ersetzt Version [002] vom 01.04.2018. Englische Übersetzung der GFI 9-58.520.1-0 [003] für die Abgabe von Stammzellprodukten in das nicht-deutschsprachige Ausland. Änderungs-Details siehe Revisionsgrund des Dokuments 9-58.520.1-0 [003].

DOKUMENTATIONSABLAGE:

Entfällt.

ERLÄUTERUNGEN

Diese Gebrauchs- und Fachinformation wird dem behandelnden Arzt gemeinsam mit einem präparatespezifischen Begleitdokument ausgehändigt.

General Product Information

Human allogeneic hematopoietic stem cells collected from peripheral blood (PBSC / HPC, apheresis)

1. Identification of pharmaceutical product

1.1 Designation: “PBSC allogen ACD (UKE)”

Subgroup 1: PBSC allogen ACD (UKE) (Allogeneic PBSC, fresh product)	PEI.G.04062.01.1
Subgroup 2: PBSC allogen DMSO (UKE) (Allogeneic PBSC, cryopreserved with DMSO)	PEI.G.04062.02.1
Subgroup 3: PBSC allogen (UKE) CD34-selektiert (Allogeneic PBSC, after CD34 selection)	PEI.G.04062.03.1
Subgroup 4: PBSC allogen (UKE) CD3/CD19-depletiert (Allogeneic PBSC, CD3/CD19 depleted)	PEI.G.04062.04.1

1.2 Substance group
Human allogeneic hematopoietic stem cell preparation, collected from peripheral blood (PBSC) / Haematopoietic progenitor cells (HPC, apheresis).

2. Areas of application
Hematological and immunological reconstitution of bone marrow after conditioning treatment

3. Application information
3.1 Contraindications
3.1.1 Absolute contraindications
Absolute contraindications for the application of stem cell products are not known.

3.1.2 Relative contraindications
- Pregnancy
- Lactation
- Intolerance or known hypersensitivity against one of the ingredients, e.g. A-CDA (citrate, citric acid, glucose).

  Only applicable for PBSC allogen DMSO (UKE): Intolerance or known hypersensitivity against dimethyl sulfoxide (DMSO).

  Only applicable for PBSC allogen (UKE) CD34-selektiert respectively PBSC allogen (UKE) CD3/CD19 depletiert: Intolerance or known hypersensitivity against mouse antibodies / other antibodies used in the selection process, iron dextran particles or other ingredients listed in the manufacturing protocol.

3.2 Precautions for application
- Before applying the allogeneic stem cell product specialized treatment / preparation according to the underlying disease and standards of the transplantation center is required.
- Stem cell preparations must not be irradiated.
- Stem cell preparations must be stored under controlled and monitored conditions at the specified temperature (check container labeling).
- Stem cell preparations are only applicable before the specified expiration date and for the indicated recipient (check container labeling and accompanying documentation).
- The correct assignment to the intended recipient (identification) as indicated by the manufacturer must be assured.
- Stem cell preparations must only be applied by qualified professionals (see guidelines of respective national institutions).
- Before application of the stem cell product, drug prophylaxis against allergic or hemolytic reactions is recommended.
- For the application a transfusion device with standard filter (pore size of 170 – 230 µm) for elimination of clots is recommended. The transfusion device must not include a leucocyte filter.

- Quick application of the stem cell product is preferable, although transfusion rate should be adapted to the underlying disease and clinical status of the patient.
- For pediatric recipients the recommended transfusion volume of 10-15 ml/kg body weight must be respected. Higher transfusion volumes may lead to volume overload and provoke cardiac distress, especially in patients with known cardiovascular disease.
- Appropriate monitoring of the patient's clinical status and vital parameters must be assured during and after the application of the stem cell product.
- In case of HLA-incompatibility, there is an increased risk of Graft-versus-Host-Disease (GvHD) or rejection of the donor cells.
- In case of major blood group incompatibility, reduction of hematocrit and prophylaxis with increased diuresis may be required.
- In case of minor blood group incompatibility, reduction of plasma content in the stem cell product may be required. Delayed hemolysis due to "passenger lymphocyte syndrome" may occur.
- After transplantation depending on the donor/recipient constellation, regular CMV screenings may be required.

Only applicable for cryopreserved stem cell preparations (PBSC allogen DMSO (UKE))

Thawing instructions must be followed (see point 8.)

- To minimize the damaging effect of DMSO for stem cells at room temperature the transfusion must be performed **immediately** after thawing.
- Maximum dose of 1 g (= 0.9 ml) DMSO per kg body weight must not be exceeded.
- Drug prophylaxis to avoid side effects of DMSO, especially release of histamine, is recommended (see point 6.3).

3.3 Interactions with other pharmaceuticals and main incompatibilities

- Blood transfusions, infusions und medication must not be administered in the same transfusion device as the stem cell preparation. In particular, there is a risk of hypotonic lysis of stem cells by hypotonic infusions and clot formation by infusions containing calcium.
- Adding drugs or solutions to the stem cell product is not permitted.
- Application of blood transfusions, antibiotics and liposomal antimycotics as well as medication that may affect stem cell function, are only permitted after sufficient time interval.

3.4 Application in specific patient groups

- Women of child-bearing age: Before starting the treatment for stem cell transplantation, pregnancy must be ruled out and, if necessary, contraceptive measures must be taken.
- Pregnancy and lactation: During pregnancy and lactation period special risks for the fetus or child must be considered, in particular by the ingredients of the stem cell preparation and due to the necessary preparation and the accompanying therapy. Individual risk assessment is necessary. Weaning should take place before starting the therapy (see point 3.1.2).
- Infants and young children: This patient group shows an increased risk of adverse reactions, volume overload as well as DMSO and citrate intoxication.
- Effect on the ability to drive and operate machines: Application of stem cell products usually takes place in a clinical setting.

3.5 Warning notices

- If full application of the stem cell product is not possible, there is an increased risk (depending on transfused cell count) of delay / failure of engraftment with delayed, partial or missing reconstitution of hematopoiesis. Additionally, there is an increased risk of graft rejection.
- Due to long time intervals until reconstitution of hematopoiesis, especially if T-cell depleted stem cell preparations are administered, there is a high risk of infections, in particular of severe fungal and viral infections.
- Malignant transformation of donor stem cells inside the body of the recipient is possible.

4. Notes for proper application

4.1 Dosage

The current recommended minimal dose of vital stem cells, calculated on the body weight of the recipient, as requirement for successful allogeneic stem cell transplantation is

≥ 4 x 10^6 $CD34^+$-cells per kg body weight

Only applicable for PBSC allogen (UKE) CD34-selektiert: In the case of haploidentical HLA-constellation between donor and recipient: target dose ≥ 10 x 10^6 vital CD34+CD45+ cells per kg body weight.

A significant overweight of the recipient (e.g. BMI > 35 kg/m^2) should be considered when calculating the minimal dose of vital stem cells. Individual dosage depends on the donor as well as the underlying disease of the recipient. HLA-compatibility and implementation of selection or depletion procedures might also influence the calculation. Minimal dosage of the corresponding therapy protocols must be respected. Product details are specified by the user in the individual request and must be verified by the manufacturer.

4.2 Method of application

	Method of application
PBSC allogen ACD (UKE)	Suspension for intravenous infusion
PBSC allogen DMSO (UKE)	Suspension for intravenous infusion after thawing
PBSC allogen (UKE) CD34-selektiert	Suspension for intravenous infusion
PBSC allogen (UKE) CD3/CD19-depletiert	Suspension for intravenous infusion

4.3 Frequency of application
According to indication
A single intravenous transfusion is the regular application method for stem cell preparations. In special clinical situations (e.g. patients diagnosed with osteopetrosis or after non-myeloablative pretreatment) multiple applications may improve treatment success.

4.4 Duration of application
According to indication
Quick application of the stem cell product is preferable to maintain stem cell vitality, although transfusion rate should be adapted to the underlying disease and clinical status of the patient.

4.5 Overdosage
There is no risk of CD34+-cell overdose. If the product contains a high cell count of nucleated cells, including high T-lymphocyte counts, there is an increased risk for developing acute or chronic Graft-versus-Host-Disease (GvHD) as well as more severe course of GvHD.

4.6 Underdosage
If minimal dose of CD34+-cells is not reached, there is an increased risk of delayed or missing engraftment. As a result, reconstitution of hematopoiesis might fail, be delayed or remain partial. There is a higher risk of graft rejection as well.

4.7 Emergency measures
If severe incompatibility reactions occur, continued application of the stem cell preparation should depend on the clinical state of the patient and already administered volume. Emergency measures according to the current rules of emergency therapy and severity of symptoms must be administered.

5. Side effects when used as directed

5.1 Immunological reactions
- Acute or chronic Graft-versus-Host-Disease (GvHD)
- Recipient-versus-Graft Reaction (e.g. rejection)
- Acute and delayed hemolytic reactions (e.g. “passenger lymphocyte syndrome“)
- Transfusion-associated acute lung insufficiency (TRALI)
- Febrile, non-hemolytic transfusion reaction caused by e.g. anti-leukocyte antibodies or cytokines.
- Allergic and anaphylactic incompatibility reaction e.g. urticaria, eyelid or glottic edema as well as anaphylactic shock if there is a hypersensitivity against plasma contents, anticoagulants or other auxiliary material of the stem cell preparation. Additionally, there is a risk of anaphylactic reaction in recipients with congenital IgA deficiency.
- Immunization against erythrocytic, leukocytic or thrombocytic antigens respectively plasma proteins or other ingredients of the stem cell preparation.
- Post-transfusional purpura.

5.2 Infectious complications
- When using drugs prepared from human blood or bone marrow, the transmission of infectious agents, even of a hitherto unknown nature, cannot be completely ruled out. This also applies to infectious

diseases like hepatitis B and C and, less frequently, to acquired immunodeficiency syndrome (AIDS). This risk is minimized by donor selection and testing of donations (see point 8.3).
- In the United Kingdom of Great Britain and Northern Ireland, individual cases have been reported, in which pathogens of variant Creutzfeldt-Jacob disease (so called prions) were also detected in recipients if the stem cell donor later contracted the disease. Variant Creutzfeldt-Jacob disease has not yet been observed in Germany.
- The risk of bacterial contamination of the stem cell preparation or toxin formation cannot be completely ruled out, especially with fresh, non-cryopreserved preparations.

5.3 Other complications
- Incompatibility reactions such as nausea, vomiting, diarrhea, headache, bradycardia, drop in blood pressure, tachycardia or increase in blood pressure in case of hypersensitivity against one of the ingredients (see point 7.4). Particularly in infants and young children and at high transfusion rate, intolerance reactions and reactions resulting from citrate or DMSO intoxication are possible.
- Volume overload in the case of high-volume stem cell preparations, if transfusion is administered too rapid or in close temporal relation to other circulatory infusions and transfusions.
- Hypothermia due to quick administration of the refrigerated stem cell preparation. The use of blood warming devices is not indicated.
- Microcirculatory disturbances due to platelets or cell aggregates.
- Complications due to hemolytic stem cell preparations as a result of osmotic or mechanical damage to erythrocytes during preparation adminstration or due to improper storage or other causes such as enzyme defects.

Reporting suspected side effects
Reporting suspected side effects is of great importance. It allows continuous monitoring of the benefit-risk ratio of the drug. Health care professionals in Germany are encouraged to report any suspected adverse event with the exception of GvHD (see point 5.1) to: Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel, Paul-Ehrlich-Institut, Paul-Ehrlich-Straße 51 - 59, 63225 Langen Telefon +49 6103-773116, Telefax: +49 6103-771268, Website: www.pei.de respectively www.pei.de/haemovigilanz-formulare, E-Mail: pharmakovigilanz2@pei.de. Please check national regulations for comparable institutions. In addition, according to the legal requirements and regulations, any suspicion of adverse event or reaction must be reported immediately to the pharmaceutical company or manufacturer.

Patients should be informed to contact their doctor or health care professional if they notice any side effects. This also applies to side effects that are not reported in this leaflet. By reporting side effects, more information about the safety of this medicine can be obtained and made available.

6. Pharmacological and toxicological properties

6.1 Preclinical data concerning safety
Are not available. Testing the toxicity of human stem cells in animal models is of little relevance and does not allow the determination of a toxic or lethal dose.

6.2 Medicinally active ingredients (active substances)
Medicinally active components of human stem cell preparations are morphologically and functionally intact stem and progenitor cells for reconstitution of hematopoiesis and immune system after myeloablative or non-ablative pretreatment. After cell division, stem cells are capable of retaining the character of a stem cell (self-replication) or differentiating into mature cells such as granulocytes, erythrocytes, platelets, monocytes/macrophages, osteoclasts and lymphocytes (asymmetric division). The cells considered to have the greatest hematopoietic potency express the CD-34 antigen as a surrogate marker which is used for quality determination (see Drug Content section 7.4.1).

After transplantation, stem cells are able to settle in sites of hematopoiesis (especially in bone marrow, initially also in spleen and liver tissue) and, given sufficient numbers of vital stem cells, ensure permanent reconstitution of erythropoiesis and lymphopoiesis. After 10 to 30 days the first mature blood cells (granulocytes, platelets, erythrocytes and lymphocytes) are detectable. It usually takes several weeks for complete erythropoiesis to be established and several months for lymphopoiesis to be reconstituted. The velocity of reconstitution depends on the number and type of stem cells / progenitor cells and, in particular, on recipient-related factors such as the underlying disease and, if applicable, concomitant diseases.

The immune reconstitution and T-lymphocytes (CD-3+ cells) of the stem cell preparation are also expected to provide an anti-tumor effect (Graft-versus-Tumor (GvT)) as an important therapeutic component in certain

malignancies. In parallel, however, the T-lymphocytes can lead to a severe immunological reaction against recipient organs (see point 5. GvHD).

6.3 Other ingredients

Residual cells and plasma
The residual content of erythrocytes can lead to the release of hemoglobin, especially in the case of AB0 major incompatibility, or after thawing of cryopreserved stem cell preparations, with toxic side effects, in particular to kidney function. A high residual level of CD3+ cells, as seen particularly in PBSC, can lead to severe GvHD. Granulocytes contained in the stem cell preparation can release a number of active reagents after thawing of cryopreserved preparations. The resulting cell- and tissue-toxic effects are usually neutralized by inhibitors contained in the remaining plasma. The residual plasma content may lead to allergic reactions in case of protein incompatibility and to a hemolytic reaction in case of AB0 minor incompatibility.

Stabilizer ACD-A (formulation according to Ph. Eur.)
The total amount of stabilizing agent is indicated on the container label or in the accompanying document to assess the risk of hypocalcemic reactions.

Human albumin
Hypersensitivity reactions or anaphylactic-allergic reactions were observed very rarely even after infusions of large amounts. There are no reports of virus transmission from human albumin prepared in accordance with the European Pharmacopoeia. The documentation obligation according to the Transfusion Act exists in the context of the use for the production of the stem cell preparations.

Sodium chloride solution 0.9%
Sodium chloride solution 0.9% usually has no effect on electrolyte, water and acid-base balance.

PBS / EDTA
For PBS / EDTA buffer (European Pharmacopoeia: phosphate buffer solution containing NaCl / disodium edetate), no particular effects or hazards are known in regard to genotoxicity, mutagenicity, carcinogenicity, teratogenicity and impairment of fertility.

Antibodies / Iron dextran particles
The formation of human antibodies against selection antibodies (usually murine antibodies) or intolerance reactions to residual amounts of these excipients are possible.

DMSO (only applicable for cryopreserved preparations)
Dimethyl sulfoxide is an antifreeze that penetrates the cell membrane and acts inside the cell. Adverse effects, especially at high doses and during rapid infusion, include headache, nausea, chills, dyspnea, bradycardia or tachycardia and hypertension. Therefore, the dose of 1 g (= 0.9 ml) DMSO per kg of body weight of the recipient should not be exceeded. Drug prophylaxis, especially with antihistamines, is recommended to reduce side effects (see point 3.2). In addition, the application can be spread throughout the day if multiple fractions of the graft need to be administered. Apart from a garlic-like halitosis, other severe side effects due to the DMSO content are not to be expected, if the instructions for thawing (and washing, if necessary) are followed rigorously. When washing stem cell preparations to reduce the DMSO content, the possibility of cell damage and loss needs to be considered.

7. Further notes

7.1 Information on durability
The various types of stem cell preparations are stable under the specified conditions (see point 7.2) until the expiry date indicated on the container labeling or in the accompanying documentation is reached. The pharmaceutical preparations must not be used after the expiry date. The preparations must be transfused immediately after opening the container / after thawing, the product must not be refrigerated again.

7.2 Information on storage and transport
The specified storage and transport conditions must be observed, documentation of the conditions is necessary. The cold chain must not be interrupted. In the case of cryopreserved preparations, there is a risk of damage, so special care must be taken when handling the frozen bags to avoid bacterial contamination or loss of the product.

The storage period of non-cryopreserved preparations should be kept as short as possible. During storage and transport, special care must be taken to assure that the quality and functionality of the stem cells are not compromised and that no unauthorized person has access to the product. The stem cell preparations must not be irradiated under any circumstances. The transport of stem cell preparations must be carried out in a suitable

and appropriately labeled container by a qualified courier who is instructed about the importance of the product and the required transport conditions.

	Durability, storage and transport
PBSC allogen ACD (UKE)	72 hours at 2-6° C
PBSC allogen DMSO (UKE)	2 years at below -140°C (storage LN2 gas phase)
PBSC allogen (UKE) CD34-selektiert	72 hours at 2-6° C
PBSC allogen (UKE) CD3/CD19-depletiert	72 hours at 2-6° C

7.3 Visual inspection
Immediately prior to transfusion, each stem cell preparation must be inspected visually (check for aggregate formation, integrity and correct allocation to the recipient). Use despite quality deficiencies must be medically justified and documented. The associated risks must be minimized and appropriate measures taken where necessary. The use of stem cell preparations is the responsibility of the treating physician.

7.4 Final composition of the drug
7.4.1 Active substance (by type and quantity)
Human hematopoietic stem cells from single donor apheresis
Target dose: ≥ 4 x 10^6 $CD34^+$-cells per kg body weight
Preparation-specific information on the active substance content: see container labeling and accompanying document!

7.4.2 Other ingredients

	Components per mL cell suspension
PBSC allogen ACD (UKE)	0.07-0.10 mL ACD-A stabilizer solution (PhEur) 0.93-0.90 mL donor plasma containing cells
PBSC allogen DMSO (UKE)	0.13-0.16 mL ACD-A stabilizer solution (PhEur) 0.78-0.75 mL donor plasma containing cells 0.09 mL DMSO
PBSC allogen (UKE) CD34-selektiert	1.00 mL glucose solution containing cells (5%) May contain residues of PBS/EDTA buffer
PBSC allogen (UKE) CD3/CD19-depletiert	1.00 mL glucose solution containing cells (5%) May contain residues of PBS/EDTA buffer

Additional information on other ingredients required for proper production: see container labeling and accompanying document

7.5 Dosage form and content, container
Suspension in plastic bag with CE certificate

	Package sizes
PBSC allogen ACD (UKE)	100-300 mL per bag, 1-2 bags per graft
PBSC allogen DMSO (UKE)	95-115 mL per bag, 1-2 bags per graft
PBSC allogen (UKE) CD34-selektiert	10-50 mL per bag, 1-2 bags per graft
PBSC allogen (UKE) CD3/CD19-depletiert	10-50 mL per bag, 1-2 bags per graft

7.6 Information on the pharmaceutical organization / holder of the authorization:
Universitätsklinikum Hamburg-Eppendorf
Institut für Transfusionsmedizin
Martinistraße 52
20246 Hamburg

7.7 Information on the manufacturer who has released the finished medicinal product for distribution:
Universitätsklinikum Hamburg-Eppendorf
Institut für Transfusionsmedizin
Martinistraße 52
20246 Hamburg

7.8 Authorization numbers
Subgroup 1: PBSC allogen ACD (UKE) PEI.G.04062.01.1
Subgroup 2: PBSC allogen DMSO (UKE) PEI.G.04062.02.1
Subgroup 3: PBSC allogen (UKE) CD34-selektiert PEI.G.04062.03.1
Subgroup 4: PBSC allogen (UKE) CD3/CD19-depletiert PEI.G.04062.04.1

7.9 Date of issue of the permit
14.11.2011

7.10 Drug status
Prescription

8. Further instructions

8.1 Thawing instructions

In general: Before thawing, the correct allocation (identification) and the quality, including the integrity of the stem cell preparation, must be checked. Thawing should be performed as close as possible to the patient to ensure immediate transfusion after thawing. Only suitable and qualified equipment (e.g. Plasmatherm) with a CE certificate and valid inspection certificate may be used for thawing. Thawing takes place at +37°C. As soon as crystals are no longer visible or palpable, the stem cell preparation should be administered immediately through a standard filter of pore size 170 to 230 µm. After transfusion, inspect the container and the filter system for clots, apply a sterile seal on the preparation container and the transfusion system and store the material for 24 hours at +2 to +10°C for any follow-up testing that may be required.

8.2 Washing instructions

In general: Washing of the stem cell product is not intended by the manufacturer.

8.3 Measures to reduce the risk of transmission of infectious agents
In order to minimize the risk of transmission of infectious agents, the donor was tested on the occasion of the suitability examination with negative results for

- Human Immunodeficiency Virus (anti-HIV-1/2-Ab, HIV-1 genome)
- Hepatitis B Virus (HBsAg, anti-HBc-Ab, HBV genome)
- Hepatitis C Virus (anti-HCV-Ab, HCV genome)
- Hepatitis E Virus (HEV genome)
- West Nile Virus (WNV genome), seasonally for stem cell donations collected from June 1 to December 31 of the respective year. Testing may be omitted, if the donor history excludes a stay in a WNV endemic area for at least two consecutive days within the 4 weeks prior to stem cell donation.
- Treponema pallidum (Ab test)

If requested by the transplant center, determination and declaration of:

- Epstein Barr Virus (anti-EBV Ab)
- Toxoplasmosis (anti-Toxoplasmosis Ab)
- Humane T-lymphotropic Virus (anti-HTLV1/2-Ab) (Testing is also performed if donor history includes long-term stay / origin in endemic countries)
- If applicable, parvovirus B19 (parvovirus B19 genome)

In the case of a repeatedly reactive result for anti-HBc antibodies in the screening, in accordance with the announcement of the Paul Ehrlich Institut (BAnz AT 18.03.2014 B6) the finding must be evaluated as non-specific by further testing or, in the case of specifically reactive anti-HBc findings, it must be ensured that virological criteria (HBV genome negative, anti-HBs titer ≥ 100 IU/L) indicate a healed HBV infection.

The donor was tested for Human Cytomegalovirus (anti-CMV IgG and IgM, CMV genome if applicable). In case of a positive IgM detection for Eppstein-Barr Virus and toxoplasmosis, an additional genome detection is performed.

For fresh stem cell preparations, the donor was retested for the above parameters at stem cell collection.

► Findings: See accompanying document! If the current findings are not yet available at the time of delivery of fresh stem cell preparations, they will be submitted immediately as soon as possible. In case of proven infectivity, the preparation is marked accordingly (Caution: Biological hazard!) and must be transported and stored separately.

8.4 Quality assurance

For the transplantation of stem cell preparations, quality assurance measures must be taken by the health care facilities in accordance with the legal requirements. These include, among others, detailed instructions for the

- Indication,
- Pre- and post-transplantation care,

- Measures in case of transplantation-associated complications,
- Choice of the type and quantity of stem cell preparation,
- Precautionary measures to maintain the integrity of the graft and the functionality of the stem cells,
- Follow-up examination of the patient to determine the success of the transplantation,
- Patient-related documentation and
- Reporting obligations.

The decision criteria for donor selection and, if necessary, for special preparation of the stem cell preparation as well as prophylactic measures during use and monitoring of use must be defined within the framework of patient-related quality assurance.

8.5 Special precautions for disposal

After use, the primary containers of the stem cell preparations must be sterilely sealed and stored for 24 hours at +2°C to +10°C for any follow-up testing that may be required. Unused preparations must be reported to the manufacturer and disposed of properly. They must not be used for recipients other than those specified by the manufacturer. Proper disposal of preparations that have been opened or are no longer usable, must be ensured in accordance with the specifications of the health care facility. Use for scientific purposes is possible only with the consent of the donor. The use and whereabouts of all stem cell preparations must be documented as part of a quality assurance system.

9. References

The preparation-specific information on the container labeling and the accompanying document must be observed.
Furthermore, the current "Guideline for the Preparation and Use of Hematopoietic Stem Cell Preparations" and, if applicable, supplementary publications and announcements of the German Medical Association and the Paul Ehrlich Institute must be taken into account.

10. Date of last revision

01.02.2022