



Temos

Trust • effective medicine • optimized services

Temos International Healthcare Accreditation - TIHA -

Terms and Conditions Quality in Community Pharmacy Services

Version 2.0 January 2020

Temos International GmbH
Friedrich-Ebert-Str. 75
51429 Bergisch Gladbach
Germany
Phone +49 2204 42648 0
Fax +49 2204 42648 10
Email info@temos-international.com
Web www.temos-international.com

© Temos International GmbH

The reproduction, transmission or use of this document or its content is not permitted without express written authority of Temos International GmbH.

Content

- 1. Purpose of Temos International Healthcare Accreditation (TIHA) in Community Pharmacies..... 3
- 2. TIHA Participation Policy..... 3
- 3. Entitlements to TIHA Applying Organizations and Participants 4
- 4. Responsibilities of TIHA Applying Organizations and Participants..... 5
- 5. TIHA Awards, Certificates, and Seals 7
- 6. Re-accreditation 8
- 7. Scientific publications 8
- 8. Warranty, Liability and Dispute Resolution 8
- 9. Confidentiality 9
- 10. Place of Performance and Application Law10

1. Purpose of Temos International Healthcare Accreditation (TIHA) in Community Pharmacies

The purpose of the Temos accreditation is to neutrally assess, evaluate and validate the quality of services, if the organization's practices are in accordance with Good Pharmacy Practice (GPP), to identify potential for improvements and to optimize quality of services in the Applying Organization with the overall aim to assure continuum of care for patients. For the participation in the Temos International Healthcare Accreditation (TIHA) the Applying Organization has to comply with the Accreditation Participation Requirements as stated in the standards' document and agrees to the terms and conditions set out below.

2. TIHA Participation Policy

TIHA participation is granted on the following basis:

- a. The participation is based on an ongoing three-year cycle. The Applying Organization acknowledges that Temos International allocates resources based upon Applying Organizations committing to the TIHA program for three years.

- b. The Applying Organization must pay the fees set out in the quotation and respective invoices. Upon acceptance of the quotation offered by Temos and order placement, the Applying Organization will receive an invoice for the pre-payment of fees which is 50 % of the (re-)accreditation fee (in Euro). Payment shall be made within 30 days after receipt of the invoice. The accreditation fee is based on the size of the organization and the number of assessors and days required conducting the on-site inspection.

A second invoice of 50 % plus travel and additional expenses (where applicable) will be sent to the Applying Organization within 14 days after the conclusion of the on-site inspection visit. Payment shall be made within 30 days after receipt of the invoice.

The accreditation report, and if the organization achieves (re-)accreditation, the Temos certificate is sent immediately to the Applying Organization as soon as the final payment has reached Temos accounts and the report has been approved by the Temos Board.

For the annual follow-ups and respective annual fees TIHA will advise of the date by which payment must be made; this will be at least six weeks before the payment is due.

- c. Temos International reserves the right to cancel or postpone scheduled onsite assessments due to non-payment of fees and in other circumstances it considers appropriate.

Unforeseen reasons might occur making a postponement or even a cancellation necessary and may include but are not limited to:

- Unexpected changes in the governance and/or organization's structure
- Evidence that the Applying Organization is not ready for the onsite assessment
- Natural disaster that totally or substantially disrupts operations
- The organization is involved in a major strike

- The organization is being moved to another building during the scheduled assessment visit
- Wars
- Terrorism
- (Changed) government regulations
- Civil disorders
- Other emergencies of a similar nature

Cancellation and request for postponement due to any reasons cited above have to be communicated in writing as soon as practically possible. The cancellation or postponement of onsite assessments is carried out on a case by case basis.

d. Postponement fee

In rare circumstances, Temos may, at its discretion, approve a request to postpone an on-site assessment not exceeding three months. In such cases, the organization may be charged a fee to defray costs, e.g. due to already booked flights, accommodation and other applicable arose costs. In case of a re-accreditation, the status in the database is set to “re-accreditation pending”. Within 3 months the process has to be continued and completed accordingly.

e. Cancellation fee

In case the Applying Organization cancels its application, the on-site assessment or its participation during the three-year cycle, pre-paid fees will not be refunded. Where there are unpaid fees in respect of the remainder of the accreditation period of three years, such fees will be payable in full by the Applying Organization.

f. An organization with outstanding fees of more than three months shall have their accreditation status revoked. The status on the Temos website will be updated to “accreditation revoked” until the outstanding fees are balanced. Afterward, the organization’s details will be removed from the Temos International “Accredited Partner Guide” website. The organization is not allowed to use or display any of the TIHA award logos and certificates (including seals of the cooperation partner Diplomatic Council) on their website or any other materials.

3. Entitlements to TIHA Applying Organizations and Participants

The TIHA Applying Organization and Participant are entitled to the following:

- a. Access to TIHA related materials including standards, guides, and publications, access to the electronic self-evaluation tool.
- b. Access to (technical) support and advice from Temos International on the TIHA program, the process and in case of any technical problems that occur during the preparation phase.
- c. Access to a technical review. The Applying Organization shall complete its self-evaluation tool and supporting evidence at least six weeks in advance of the (onsite) assessment. This review is done by the Temos assessors that are scheduled

for the onsite assessment and includes completeness of the submitted documents as well as traceability and intelligibility of the submitted documents. It does not include the assessment of the level of achievement demonstrated by the submitted documentation.

- d. Onsite visit of the Temos assessors as stated in the quotation and order.
- e. Receipt of an accreditation report summarizing the main findings, areas of best practice, areas where the TIHA standards were “partially met” or “not met” including opportunities for improvement (assessors’ recommendations) the need for improvement (assessors’ demands).
- f. Upon receipt of the award of accreditation, the right to display TIHA logo(s) as well as Diplomatic Council logo(s), quality seal(s) and certificate(s) in electronic and paper version, subject to Temos International usage policy.

4. Responsibilities of TIHA Applying Organizations and Participants

The TIHA Applying Organization and Participant agree to the following:

- a. To communicate in a proper and timely manner during the (re-)accreditation process.
- b. To provide accurate and truthful information at all times in the (re-)accreditation process.
- c. To provide all evidence, the filled-in self-evaluation tool and relevant accompanying documentation in English. For internally used documentation respective translations shall be assured for verification and validation.
- d. To agree and adhere to a mutually agreed path relating to the key dates of the TIHA process based on the Applying Organization’s desired onsite assessment dates as stated in the order and defined individually after the start of the (re-)accreditation process.
- e. To review the assessor allocations for the assessors’ team and to provide a rationale to Temos International in case of a veto for a proposed assessors’ team member.
- f. To support booking of flights, accommodation, and transportation for the Temos assessors’ team:
Within flight distances < 6 hours, economy class flights are to be booked. For flight distances > 6 hours business class flights are to be booked for the Temos assessors. The booking of the flights can be done by the Applying Organization in consultation with Temos Headquarters or directly by Temos Headquarters. For the latter, Temos will invoice the estimated costs in addition to the applying deposit.
 - In case of onsite assessments where the Applying Organization is booking the flights for the Temos assessors, to discuss and agree on suitable flights (to reduce travel time, the number of connecting flights and the like).

- In case of onsite assessments where Temos International is booking the flights for the Temos assessors, to review and confirm the flight options. Temos International will invoice the estimated flight costs as part of the pre-payment and will offset the costs against the paid amount in the final invoice.
 - To book accommodation including breakfast for all assessors for the duration of the onsite assessment plus travel days.
 - To reimburse additional expenses incurred by the assessors during the onsite assessment including travel, visa, transportation in the home and destination country as well as meals (full board). These costs will be added in Euro to the final invoice and a copy of the receipts will be provided to the Participant on request.
- g. To notify Temos International as soon as possible of their intention to cancel or postpone the accreditation and to explicitly outline to Temos International why they are requesting to cancel or postpone the accreditation. Accreditations shall only be canceled on request from the Applying Organization's CEO or equivalent. The rescheduling of an accreditation onsite visit where specific dates have been requested will be discussed and considered on an individual basis. The Applying Organization that requests postponement of a scheduled onsite assessment will be contacted by Temos International within 14 working days regarding their request. In case of a successful request for postponement, Temos International will contact the Applying Organization with the new onsite assessment dates.
- h. In case of cancellation or postponement of a scheduled onsite assessment, to pay any outstanding (annual) fees and to cover any incurred costs such as flight costs for the Temos assessors if Temos International has already booked flights based on the agreed onsite assessment days.
- i. To submit post-assessment progress reports including respective evidence within six months after the onsite assessment or as stated in the assessment report and to provide requested information and data during the annual follow-ups (AQ 1 and AQ 2).
- j. To provide written notification to Temos International of any major change within 30 days of that change. Information that must be reported to Temos includes the following:
- A change in organization name and/or ownership
 - Any change of governance
 - Any change of the contact information and/or contact persons
 - A significant increase or decrease in the volume of services
 - A significantly altered building
 - Any other important information that impacts the business operation and/or delivery of patient services
- k. The Applying Organization and Participant acknowledge that:
- Continuing accreditation status will be subject to the submission of progress reports (see 4.i.) and payment of relevant fees.

- Where the Applying Organization is not awarded accreditation following the accreditation assessment, the costs of any additional assessment must be met by the Applying Organization.
- I. Temos International has the right to terminate the Participant’s involvement and accreditation status by notice in writing to the organization in case of:
- The fees are more than 90 days in arrears of the stated payment date. In which case the organization will remain liable for any outstanding fee, regardless of when participation is canceled.
 - There is a change in the ownership or control of the organization that affects the organization’s ability or willingness to meet the requirements of TIHA.
 - There is a significant failure in the standard of services provided by the organization.
 - The organization fails to comply with the TIHA standards.

5. TIHA Awards, Certificates, and Seals

Temos International is committed to improving its services. After the (onsite) assessment each organization is asked to complete an online questionnaire (TIHA Customer Feedback) on their experience with the accreditation process.

- a. In case of successful passing the accreditation program, Temos International will provide the accreditation report, the certificate(s) and seal(s) as soon as:
- The TIHA Customer Feedback has been completed; and
 - The Temos International accounting has confirmed the receipt of all accreditation-related fees.

The final report summarizes the demands and recommendations and the time frame in which the respective points are to be realized and evidence is to be provided to Temos International. The Applying Organization provides evidence about the changes in the frame of a progress report. Where applicable and in case of the certificate was awarded “under reservation” a follow-up onsite visit might be necessary. The Applying Organization has to cover the costs (travel expenses, accommodation, and assessor’s fee) for the follow-up visit.

The progress report and further submitted material will be reviewed by Temos International staff. If there are any concerns about lack of progress or maintenance of the Temos Accreditation Standards the Temos Board will be informed and may request an independent review of the Applying Organization.

- b. In case of successful passing the accreditation program, Temos International will provide the accreditation report, the certificate(s) and seal(s) provided the following conditions are met:
- Subject to all relevant privacy legislation and regulations, Temos International may publicly disclose the accreditation status and details about the organization’s services and contacts.
 - Temos International reserves the right to publish a public correction of any incorrect material that the organization publishes related to its Temos accreditation.

- The Temos certificate(s) and seal(s) shall specify the particular accreditation program assessed and accredited.
 - Temos accreditation will only be granted to an organization that has all required licenses, authorities, and approvals, legally required to perform their designated activities. Accreditation may be suspended or canceled if any required license, authority or approval is suspended or canceled.
 - The Temos certificate(s) and seal(s) and any TIHA signage shall remain the sole property of Temos International. Temos International provides each organization with three certificates (size A4) at the time of initial accreditation and every year after the annual follow up invoicing. There is no charge for the certificates. Additional copies of certificates are available on request. The certificate(s), seal(s) and TIHA signage shall be held by the organization under the license of Temos International and may be recalled by Temos International for non-compliance with standards, non-payment of TIHA fees, termination of the accreditation program or for any reasonable cause as determined by Temos International.
- c. Accreditation certificates must be returned or destroyed if:
- A new certificate is issued due to the change of the organization's name, location, or a clerical error on the original certificate.
 - The organization's certificate is withdrawn or denied for any reason.

6. Re-accreditation

Nine months before the due date of the re-accreditation the organization is contacted by the Temos Headquarters or regional office and reminded on the due re-accreditation. In case of the organization wishes to apply for the re-certification, the respective process is started.

A three (3) months' period is the maximum delay for the renewal after the certificate is expired.

If there is more than a three (3) months' delay, the organization is considered as first accreditation and not as re-accreditation.

7. Scientific publications

Subject to all relevant privacy legislation and regulations and ensuring confidentiality and data protection Temos International GmbH is entitled to scientifically analyze and publish data which are raised within the scope of the assessments. Data which allows conclusion to its source according to the identity of the accredited institution may not be published without prior explicit approval of the institution, which shall not be denied unreasonably.

8. Warranty, Liability and Dispute Resolution

- a. Warranty and liability

Temos International warrants conducting the assessments in compliance with applicable scientific standards. The Applying Organization warrants to fulfill its duties of cooperation in proper form and not to fall below the accredited standard during the validity period of certificate. In case of shortfall, the Applying Organization is obliged to immediately inform Temos International GmbH in writing or per email about the respective changes.

For cases of malpractice, accidents, and any other incidents caused by the Applying Organization or its internal or external staff members/cooperating partners and where patients, relatives, employees or any other visitors suffer damage Temos International GmbH does not take any responsibility and excludes any liability. The organization must have respective protective measures and adequate insurances in place.

The liability of Temos International GmbH for malpractice, accidents and any other incidents caused by Temos International GmbH shall, except in cases of willful misconduct or gross negligence, be limited to an amount equal to the accreditation fee (including VAT).

The provisions of this point 8.a. shall not apply with respect to our liability for personal injury.

b. Complaints

Formal complaints to Temos International must be expressed in writing. They will be processed according to the Temos International complaints management system.

c. Appeal

It is expected that the Temos International quality assurance process ensures accuracy and consistency and that there is no need to demand an appeal from Applying Organization's side. However, if there is dissatisfaction with the accreditation decision, the Applying Organization has the right to appeal within 21 days of receipt of the assessment report including the final decision, clearly outlining the grounds for appeal and the reasons why they disagree with the decision.

All appeals must be addressed to the Chief Executive Officer (CEO). The revision request has to be accompanied by appropriate data, information and/or photos to support the request.

The Temos International CEO considers this request for revision together with the Temos Board and makes the final decision within one month.

9. Confidentiality

In the frame of the TIHA process, Temos international might get insight into and receive confidential information of the organization or develop confidential information about the organization.

According to the European regulation GDPR all Temos International employees, regional offices and assessors sign a confidentiality and privacy agreement with Temos International to ensure that personal data as part of their job as a Temos assessor,

employee or regional partner in connection with the preparation, performance, and post-processing of Temos assessments has to be protected and maintained in confidentiality. All Temos assessors sign a confidentiality agreement also with the Applying Organization to ensure that all information accessed remains confidential and secure.

Privacy legislation differs across jurisdictions and it is not possible to generalize the requirements to comply with all privacy statements. Temos International strongly encourages the Applying Organization to include wording in their staff and client consent forms, privacy policies and other relevant documentation notifying them that their information may be accessed by organizations, such as Temos International, for the purpose of accreditation activities.

Each party shall promptly advise the other in writing of any disclosure, misappropriation or misuse of confidential information by any person as soon as practicable after it becomes aware of such disclosure, misappropriation or misuse.

10. Place of Performance and Application Law

- a. The place of performance of any obligation of Temos International shall be its domicile.
- b. The content of this document shall be exclusively construed under the laws of the Federal Republic of Germany. The application of international treaties concerning the international sale of goods as well as the law of conflict of laws shall be excluded.
- c. Any and all disputes, controversies or questions which might arise between the organization and Temos International in connection with or out of this agreement, or its interpretation or compliance or non-compliance thereof, or the performance or non-performance of any obligation or right under the terms and provisions of this document, which cannot be settled amicably by the organization and Temos International, shall be exclusively and finally settled by a court of arbitration of Germany, according to its applicable rules of conciliation and arbitration. The place of jurisdiction shall be Germany. The language of arbitration shall be German.

01 January 2020