

**Articles of Association of  
'Arzneimittel und Kooperation im Gesundheitswesen' (AKG e.V.)  
of 15 November 2007, last amended on 13 May 2014**

**§ 1**

**Name, Place of Domicile, Registration, Financial Year**

1. The name of the association is 'Arzneimittel und Kooperation im Gesundheitswesen e.V.' (AKG e. V.).
2. Its place of domicile is Berlin.
3. It is registered in the registry of associations at the Berlin-Charlottenburg local court.
4. The financial year is the calendar year

**§ 2**

**Aim and Functions**

1. The aim of the association is to sustainably strengthen trust in the integrity and credibility of the pharmaceutical industry, particularly in regard to marketing, by supporting and ensuring transparent, fair and trustworthy corporate conduct as a self-monitoring agency.  
The main focus is on information on prescription medicines and their possible applications, the content of and methods used in advertising for prescription medicines as well as cooperation by companies in the pharmaceutical industry with medical facilities, private practitioners and other associated members of the health professions.
2. The functions of the association are thus,
  - To define rules of conduct (Codex for the conduct of members of AKG e. V. ('Codex'),
  - To advise the member companies on these rules and on relevant laws in an appropriate manner,
  - To award an AKG Healthcare Compliance Certificate on the basis of the association's internal award regulations and a preparatory decision by the certification committee appointed for that purpose.
  - To monitor adherence to section 4 of the codex by means of a conciliation and arbitration board and to enforce it in formal procedures.
  - As an association for the promotion of commercial interests (§§ 8 paragraph 3 page 2 UWG, 3 paragraph 1 item 2 UKlaG), to admonish competition infringements against section 4 of the codex by companies that are not its members and to refer them to the courts if necessary.

3. The association is based on the willingness of its member companies to observe the code of conduct that they have recognised and the competition regulations laid down in the relevant laws at all times and in a responsible manner.

The aim of the association is to achieve fair competition that is ethically beyond reproach. Advice, mediation and conciliation aim to eliminate the need for compulsory measures.

### **§ 3 Altruism**

1. The association is altruistic. It pursues exclusive non-commercial aims in the sense of the section in the revenue code entitled 'tax-advantaged aims'. It does not pursue aims that are primarily for profit.
2. Association funds may only be used in accordance with the aims of the association as specified in these articles.
3. Members may not receive payments from association funds.
4. No member may receive a share of the association assets upon its withdrawal from the association or upon the association's dissolution.

### **§ 4**

#### **Start of Membership**

1. Any company in the pharmaceutical industry with its place of domicile in Germany may become a full member of the association if it recognises the aims of the association. This is also true for multiple companies within a group. Extraordinary (associate) membership is available to companies, organisations and individual persons who are not covered by the first sentence of this paragraph but who are interested in sustainably strengthening trust in the integrity and credibility of the pharmaceutical industry. This however applies only insofar as such entities or persons are not simultaneously the proprietor or co-proprietor of a company or under an employment contract with a company which is not a member of the association, but which would be a full member if it were to join the association.
2. Acquisition of membership requires a written application for membership. The board shall decide upon membership applications.

## § 5

### End of Membership

1. Membership ends
  - Upon withdrawal,
  - Upon expulsion,
  - Upon initiation of bankruptcy proceedings on the assets of the relevant member company,
  - Upon the permanent cessation of business activities by the relevant member company,
  - Upon a determination that the prerequisites for the acquisition of membership are no longer met.
2. Withdrawal must be declared to the board in writing. It may only become effective at the end of the calendar year and must be declared six months in advance. In the event that a complaint is outstanding with the conciliation and arbitration board the withdrawal only becomes effective once the complaint procedure has been concluded.
3. Expulsion of a member is decided by the board and requires a two-thirds majority. Prior to this decision the affected member company must be provided with all of the relevant facts and given the opportunity to make an official statement.

A member company can be expelled,

- If it is in arrears in the payment of the membership fee or its share of allocated costs despite two written reminders and corresponding payment deadlines or
- If it has repeatedly infringed the association's code of conduct in contravention of an express mandate by the conciliation and arbitration board or has repeatedly refused to fulfil a sanction mandated by the conciliation and arbitration board.

The member will be informed of the exclusion by registered letter. It becomes effective upon receipt.

The exclusion will be published on the Internet homepage and in the association's annual report and all pharmaceutical industry associations to which the company belongs will also be informed.

4. Members must immediately inform the board of the initiation of bankruptcy proceedings, the permanent termination of business activities or the removal of the prerequisites for membership. The board also decides upon termination of membership for these reasons. Paragraph 3 pages 1, 2, 4, 5 and 6 apply accordingly.

## § 6

### Fees, Shared Costs and Other Income

1. The membership fees are based on the member's domestic turnover in prescription medicines for the previous year and are staggered as follows:

Full members

Turnover in previous year:	Annual fee:
< € 1 Million:	€ 500.00
< € 1 Million to € 10 Million:	€ 1,000.00
€ 10 Million to € 20 Million:	€ 2,000.00
€ 20 Million to € 50 Million:	€ 4,000.00
€ 50 Million to € 100 Million:	€ 10,000.00
€ 100 Million to € 200 Million:	€ 15,000.00
> € 200 Million:	€ 20,000.00.

Extraordinary (associate) members

The membership fee shall be agreed upon a discretionary basis but shall amount to a minimum of € 1000.00 p.a. for companies and organisations within the meaning of § 4 Para. 1.

The general meeting can decide upon modifications to these contribution levels.

Turnover in the above sense means the effective, non-invoiced turnover from all sales and distribution channels (pharmacies, hospitals, direct sales etc.) during the calendar year prior to the current calendar year.

Other payments of obligatory fees should not be less than the minimum fee.

The member companies must promptly pay their fees in full in the second quarter of the current calendar year when requested to do so by the association office.

The companies must submit the turnover reports that are necessary for calculate the fees in writing to the association office by March 31<sup>st</sup> of the current calendar year. In the event that the office is not in possession of a current report, the first instalment is payable in an amount based on the last report. In the event of doubts as to the validity of the figures submitted, the board is entitled to have the figures verified by an independent auditor.

The annual fee must be paid in full, even if the membership is only begun in the course of the financial year.

2. The general meeting can also decide to allocate costs to the members if necessary.

3. In the event that a member fails to pay its membership fee or costs allocated to the members pursuant to a decision of the general meeting promptly upon demand, it will be sent a first reminder after 4 weeks. If the payment is still not made, another reminder will be sent after an additional 4 weeks with a deadline.
4. The association shall charge a one-off certification fee of up to € 2,500 for the award of the AKG Healthcare Compliance Certificate. Further details are specified in the regulations concerning the award of the AKG Healthcare Compliance Certificate (Award Regulations).

## **§ 7**

### **Rights and Obligations of the Members**

1. Full, fee-paying members are entitled to vote at the general meeting. Each full fee-paying member has one vote in the general meeting. Extraordinary (associate) members are entitled to speak at the general meeting, but not entitled to vote.
2. The members can utilize the services of the association as detailed in the aim and functions, in particular they can use the consultation service and/or invoke the conciliation and arbitration board.
3. The members are obliged:
  - To promote the aim and functions of the association through cooperative conduct. To respect the articles of the association, procedural regulations, code of conduct, decisions by the general meeting and the board in accordance with the articles of association as well as the decisions of the conciliation and arbitration board and to treat them accordingly.
  - To pay the fees and any allocated costs.
4. The rights of the members are held in abeyance as long as fees or costs remain unpaid.
5. Extraordinary (associate) members can be appointed to committees, on which they will have a seat and a vote.

## **§ 7a**

### **Data Protection**

The association collects, processes and uses personal data from its member companies to fulfil its aims and tasks in accordance with these articles.

Furthermore, the association stores and uses the names of the executive officers and/or board members of the member companies for communication purposes and to consult with the member's decision-makers and to deliver documents to the appropriate persons.

These data are also provided for these same purposes to the German Association of Pharmaceutical Industries (BPI e.V.), as membership in this association also entails a membership in it.

Other uses of these personal data, in particular their use or transfer for marketing purposes, is not permitted without the consent of the affected persons.

Additional personal data of the executive officers and/or board members of the member companies, such as telephone numbers, fax numbers and e-mail addresses will only be stored and used by the BPI e.V. with the consent of the affected persons.

The affected persons can support the association's work by consenting to the use of their contact data, thereby considerably easing the BPI e.V.'s efforts to contact the association members and to exchange views with them.

Personal data about member companies' registered employees will only be collected and processed by the association with the employees' consent.

To keep the data about member companies' registered employees held by the association current and error-free, and to test whether the consent provided by the employees is still current, the member companies commit themselves to annually inspect a corresponding list of the company employees registered with the association to determine whether they are still employed by the respective member company.

In accordance with § 34 of the Federal Data Protection Act (Bundesdatenschutzgesetz BDSG), anyone is allowed to demand information about their personal data being stored by others.

## **§ 8 Organs**

1. The organs of the association are the board, the general meeting, the advisory council, the managing director and the conciliation and arbitration board.
2. The members of the organs of the association must maintain silence with regard to the confidential, internal affairs of the association.

3. The liability of the association for culpable conduct of its organs in the sense of § 31 BGB (civil code) is limited to intent with respect to association members.

## **§ 9 Board**

1. The board comprises the chairman of the board, two deputies and a maximum of nine further members of the board. The managing director is automatically a member of the board. The general meeting will decide upon the final number of board members within the framework of this regulation.

The founding members will name the first board for the period until the first regular general meeting. Thereafter the board members will be elected by the general meeting for a term of three years.

2. Only persons who are primarily employed by a member company can become a board member.

The board's term in office should coincide with the calendar year, i.e. it shall begin on January 1st of a year. The board members elect the chairman of the board and the deputy chairmen from their ranks.

The board members remain in office until the term of office of the chosen successor begins. This is not valid for a member of the board for whom the prerequisite in § 9 No. 2 line 1 is no longer valid.

The board can replace members of the board who leave during their term of office for the remaining period of office by co-optation from the group of member companies.

3. The board represents the association in court and out of court. Any two members of the board are authorised to jointly represent the association.

Legal transactions by the board with a value of more than € 25,000 require the approval of the general meeting. This approval can also be given by the authorisation of a budget. The investment of liquid assets until their use in accordance with the budget does not require any special approval.

Furthermore, the board is responsible for all association affairs that are not conveyed by law or these articles to another organ. Decisions are made by a resolution of the board.

In particular the board is responsible for:

- Appointing and dismissing the managing director,
- Issuing instructions to the managing director,
- Establishment of an association office,

- Appointment of the members of the conciliation and arbitration board, i.e. the chairman of the board of the 1st instance (conciliator) and the chairman and other members of the 2nd instance (arbitration board),
  - Establishment of an advisory council,
  - Establishment of committees,
  - Establishment of a certification committee to prepare the award of the AKG Healthcare Compliance Certificate,
  - Preparation and calling of the general meeting including production of the agenda,
  - Submission of the main budget, the annual report and the annual financial statement to the general meeting,
  - Execution of instructing resolutions passed by the general meeting,
  - Proposing resolutions regarding the association's code of conduct to the general meeting,
  - Proposing resolutions regarding the rules of procedure of the conciliation and arbitration board to the general meeting,
  - Recommendations on the interpretation of the code of conduct,
  - Proposing resolutions concerning the guidelines for the award of the AKG Seal of Compliance (award guidelines) to the general meeting,
  - Proposing resolutions regarding the level of the certification fee to the general meeting,
  - Admission and expulsion of members and determinations of whether to discontinue membership.
4. Board meetings will be called in writing by the chairman of the board or by his deputy if he is unavailable. At least two week's notice must be provided for a meeting. This period can be reduced in urgent cases. The agenda should be included with the invitation.

The board has quorum if at least two thirds of its members are present. Unless otherwise stipulated, the board decides with a simple majority of the valid votes. In cases of a tie, the vote of the chairman shall be the decisive vote. Members of the board who are not present can take part in the decision-making process by having their vote submitted by members who are present.

Board decisions can also be taken in writing if all board members agree to do so.

The managing director is obliged to participate in the board meetings.

The decisions made by the board must be recorded in writing and signed by the chairman.

5. The board is responsible for requiring persons who are not organs of the association, but who gain knowledge of confidential, internal association information through their work for the association, to commit to maintaining confidentiality before they start their work.



### **§ 9 a Honorary Chairman**

A chairman whose term of office has expired and who has served the association in an exceptional way can be appointed honorary chairman for life by the general meeting on the recommendation of the board.

Honorary chairmen are entitled to attend the general meeting in an advisory capacity, to advise the board in matters relating to association membership and to fulfil duties entrusted to them by the chairman.

### **§ 10**

#### **General Meeting**

1. The member companies in the association form the general meeting. They exercise their rights via representatives who are authorised in writing to do so. These can only be persons who are employed full-time by the companies they represent on the date of the general meeting.
2. The general meeting is responsible for all matters that are conveyed by law or by these articles.

In particular it decides on

- The selection of board members
- Appointment of auditors
- Approval of the budget
- Approval of the annual report
- Auditing and determination of the annual financial statement
- Discharge of the board and the managing director
- Agreement of legal transactions with a value of more than € 25,000
- Determination of costs allocated to the members
- Modifications to membership fees
- Determination and modification of the certification fee
- Other modifications to these articles
- Determination of and modifications to the code of conduct in the sense of the aims and functions of the association as described in § 2 of these articles
- Determination of and modifications to the procedural code of the conciliation and arbitration board.  
Determination of and modifications of the guidelines for awarding the AKG Seal of Compliance (award guidelines).
- Dismissal of board members
- Appointment of a chairman as honorary chairman, upon the recommendation of the board
- Dissolution of the association

3. The ordinary general meeting takes place once every business year. It should take place in the first quarter if possible.

An extraordinary general meeting can be called at any time on special grounds upon a resolution of the board.

If at least one-third of the voting members request such a meeting in writing, it must take place within two months.

The general meeting is called in writing by the board, represented by the chairman or by one of his deputies if the chairman is not available. The invitation period for the ordinary general meeting is four weeks in advance and one week for an extraordinary general meeting.

The agenda must be included with the invitation.

If a member requests an addition to the agenda in writing to the board no later than one week before the ordinary general meeting, this request must be granted. The person chairing the general meeting will inform those present of the addition to the agenda at the beginning of the general meeting. The general meeting will decide on requests for additions to the agenda that are made during the general meeting itself.

To prepare for the eventuality that the number of votes needed to reach a quorum is not achieved, it is possible to include an invitation to a 'second' general meeting, which would be held immediately following the first general meeting, along with the invitation to the first general meeting. This invitation must include a notice that this 'second' general meeting is quorate regardless of the number of members present.

4. The chairman of the board, or his deputy in the event that he is not available, chairs the general meeting. If the deputy is not available, the meeting will be chaired by another member of the board.

The chair of the meeting determines the sequence of the votes and type of each vote. Votes are public as a matter of principle. A vote is carried out in writing and in secret if one third of the votes of the members present make a request to this effect.

Where no other provisions are made in these articles, resolutions of the general meeting are passed by a simple majority of the valid votes submitted.

Any resolutions regarding changes to these articles of association, the rules of procedure or the code of conduct requires a three-quarters majority of the votes of those present.

5. A 'first' general meeting is quorate if at least two thirds of the member votes are represented.

The 'second' general meeting is quorate regardless of the number of members present.

If a member is unable to participate in the general meeting then it can transfer its vote to another member. The managing director of the association must be informed in writing of this before the meeting.

6. The board members and the managing director are fundamentally obligated to take part in the general meeting. The members of the advisory council are entitled to participate in the general meeting. They have the right to speak. They do not have the right to make proposals or to vote.

7. The board can also make proposals to the general meeting using a written process unless the votes of ten members are opposed and request it be taken up orally in the plenary.

The managing director processes such a written vote. At least two weeks must pass between the receipt of the relevant documents by the member companies and the end of the voting process. Votes received once the given deadline has passed are invalid. A notary oversees the counting of the votes at the association office.

The managing director will immediately inform the members and the board of the result of the vote.

8. Minutes must be taken of the decisions taken in the general meeting and they must be signed by the chair of the meeting.

## **§ 11**

### **Auditor**

The general meeting will appoint two auditors for the duration of three years. They may not be members of the board or with a committee appointed by the board and who may not be employees of the association. They are responsible for auditing the accounts of the association and to report the result to the ordinary general meeting.

## **§ 12**

### **Managing Director**

1. The managing director will lead the operations of the association within the framework of the tasks and powers transferred to him by the board. He is a special representative in the sense of § 30 BGB. He is responsible for managing operations related to the continuous administration of the association, including

the conclusion of legal transactions with a financial volume of not more than €10,000 per transaction.

2. The managing director also has the following duties
  - Advising member companies on code-compliant competitive conduct in collaboration with medical facilities, private practitioners and other associated professionals (e.g. through seminars and training)
  - Providing administrative support to the certification committee
  - Carrying out the association's internal procedures for awarding the AKG Healthcare Compliance Certificate, as instructed by the board
  - Providing administration support to the conciliation and arbitration board as instructed by the arbitrator or the chair of the conciliation board
  - Admonishing association members in the event that they violate section 4 of the code, in coordination with the chair of the first instance (conciliator) and representing the association in its role as an admonishing association in competition law in the sense of §§ 8 paragraph 3 P. 2 UWG, 3 paragraph 1 item 2 UKlaG to companies who are not part of the association and in court if necessary.
3. The managing director will make use of the staffed office provided by the board for him to carry out his duties.

### **§ 13 Committees**

The board can establish committees for specialist advice and to prepare opinions and decisions.

It determines their number and tasks and decides on staffing based on suggestions by the members.

The term of office of the committees is three years. This period should correspond to the term of office of the board.

### **§ 14 Advisory Council**

1. The board will form an advisory council. Its term of office shall be three years.
2. The duties of the advisory council are:
  - To exchange views at biannual meetings chaired by the chairman of board on current opportunities to further promote the integrity of the pharmaceutical industry's cooperation with medical facilities, private practitioners and other members of the health professions, to maintain the effectiveness of the work of the conciliation and arbitration board, to make its results transparent for all

interested parties at all times and to increase the public's trust in the competence of self-monitoring efforts.

- To advise the board accordingly.
3. In principle, the advisory council should be made up of representatives of the pharmaceutical industry, physicians, other members of the health profession, patients, healthcare payers (insurers) and policymakers. It is the responsibility of the board to recruit members of the advisory council.
  4. The board supports the advisory council by informing it of the resolutions that it passes. At regular intervals the managing director will inform the council about the complaints handled by the conciliation and arbitration board.
  5. The advisory council receives administrative support from the German Association of Pharmaceutical Industries (BPI e.V.), which has recommended that its members become members of the association.

## **§ 15 Advice**

An important element in the work of the association is providing advice to its members regarding behaviour in accordance with the code of conduct.

This shall include, among other things, seminars on common, recurring conflict situations in prescription medicine competition, namely cooperation with medical institutions, private practitioners and other members of the health professions.

Based upon current case law and internal industry legal opinions and practice, information shall be provided on about the current state of law and the resulting available courses of action.

The managing director shall make himself available toward this end.

## **§ 16 Conciliator and Arbitration Board**

1. The conciliation and arbitration board comprises a chairman of the 1<sup>st</sup> instance (conciliator) and a decision-making body of the 2<sup>nd</sup> instance (arbitration board) comprised of the chairman and two committee members.

Both chairs must be qualified as judges and may not be connected in any personal way to a company or association in the pharmaceutical industry.

The other members of the arbitration board are one representative of a member company and one representative of the physicians or the other health professions.

The conciliators and the members of the arbitration board may not be given orders on how to fulfil the duties of their offices and are independent in their decisions. They enjoy the privileges of a judge under § 839 paragraphs 2 and 3 BGB. They can be refused on suspicion of prejudice.

2. The conciliator and the chairman of the arbitration board are appointed by the association board for a term of three years. They may be reappointed after this term expires.

The other members of the arbitration board are also appointed by the board for three years based on suggestions from member companies on the one hand and physicians' or other relevant professional organisations on the other hand. They may also be reappointed.

3. In the event that the conciliator or a member of the arbitration board is not available for de facto or legal reasons, the association board will appoint a substitute who must also fulfil the personal prerequisites in §16 Para. 1 lines 2 and 3 above.

Determination of the need for a substitute is the responsibility of the chairman of the arbitration board in the case of the conciliator and the responsibility of the members of the arbitration board and the conciliator in the case of the chairman of the arbitration board.

Early removal of the conciliator or the members of the arbitration board by the association board is only possible in the event that the person in question is permanently unable, for de facto or legal reasons, to perform their duties.

4. The conciliation and arbitration board is responsible for ensuring that the stipulations in the 4<sup>th</sup> section of the code of conduct are adhered to by the members, using a formal process if necessary.

The conciliation board becomes active based upon a complaint of violation of the 4<sup>th</sup> section of the code, communicated to the association and submitted to the conciliation board by the managing director. This kind of complaint can be made by another member company, the board of the association or by a third party, independent of a possible civil claim to injunctive relief.

5. In accordance with the aim of the association to prevent dishonest competition conduct based on the 4<sup>th</sup> section of the code of conduct, an attempt will first be made at conciliation.

The conciliator will first communicate orally with the representatives of the party about which the complaint is made and with the affected member based on his judgement of the state of facts and the legal situation.

If he considers the complaint to be unfounded, then he will recommend its withdrawal.

If he considers the complaint to be founded, he will urge the affected member to remove the violation through a voluntary declaration with the threat of a fine and/or to refrain from committing similar violations in future.

If the process is then concluded, it will not have monetary consequences (with the exception of necessary expenses for witnesses or experts).

If the process is not ended in the above manner, then a formal conciliation verdict will be given. If this verdict goes against the affected member it may, depending on the situation of the case, also include further sanctions such as a fine, publication of the name of the member or public admonishment; procedural costs will also ensue.

6. It is possible to file an appeal against the conciliation verdict, which will then be considered by the arbitration board. The arbitration board is not bound to the findings of the conciliator and may also carry out its own investigation into the facts of the case.

Insofar as the arbitration board considers the appeal to be justified, then the conciliator's verdict is overturned and replaced by the board's decision.

If it considers the appeal to be unjustified, then it will reject it.

If the arbitration board is also convinced in its investigation of the facts of the case and the legal situation that the conciliator's verdicts does not include a sanction against the member that it considers proper then it can also issue such a sanction.

This is also valid if the affected member has made the appeal itself. Thus, there is no prohibition that the situation will not be worsened by the appeal.

7. The details of the entire procedure from the conciliation and arbitration board to the generation and allocation of the process costs are regulated by the code of procedure as decided by the general meeting.

## **§ 17**

### **Activity Reports**

1. Within the framework of his administrative support of the conciliation and arbitration board (§ 12 item 2), it is the responsibility of the managing director
  - To inform the board, the members of the association and the advisory council on the complaints handled by the conciliation and arbitration board at regular intervals,

- To publish anonymised cases in which the conciliation and arbitration board has found a violation against the regulations on the association's Internet homepage,
  - To present, in the first quarter of a calendar year, a printed, anonymous report on all decisions made by the conciliation and arbitration board in the previous financial year.
2. The individual publication of names as decreed by the conciliation and arbitration board must be separate from the activity reports described above.

### **§ 18 Admonishing Association**

A further important element in the work of the association is, as a legal association for the promotion of commercial or self-employed professional interests in the sense of §§ 8 paragraph 3 item 2 UWG / 3 paragraph 1 item 2 UKlaG, to pursue legal violations (HWG, AMG, UWG, GWB, StGB and others) by non-members who are not subject to the code of conduct and the conciliation and arbitration board through admonishments and legal action aimed at abatement or injunction, if necessary.

This task is also the responsibility of the managing director.

### **§ 19 External Experts**

In individual questions the board, the general meeting, the managing director, the conciliator or the arbitrator can obtain the consulting services of an external expert (members of the health profession, marketing experts etc.).

### **§ 20 Dissolution**

1. The association can only be dissolved by the resolution of a general meeting called solely for that purpose. This requires a majority of three quarters of all votes of the members.
2. Unless the general meeting resolves otherwise, the chairman and his deputy are jointly authorised liquidators.
3. If the association is dissolved its assets are transferred to the German Association of Pharmaceutical Industries (Bundesverband der Pharmazeutischen Industrie e.V.), which must use the assets exclusively and directly for non-profit purposes.



**§ 21**  
**Gender Clause**

These articles use the masculine form for all officers and other persons. This is not meant to express any preference for males or discrimination against females. The chosen form serves purely to better clarify the text and thus make its content more easily comprehensible. The general meeting adopting these articles expressly acknowledges that a woman could also hold each of the above positions.

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We confirm that the foregoing articles are accurate and complete pursuant to § 71 (1) Sentence 4 BGB in accordance with the amendment of 5 April 2011 adopted by resolution of the general meeting

