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## Change history

Version	Valid and binding as of	Description, comments (by author)	Author's initials
<b>2.0</b>	<b>15.10.2020</b>	<b>Updating of articles of law relating to the implementation of H MV4</b>	<b>ze</b>
<b>1.0</b>	<b>29.07.2014</b>	<b>Content transferred from document: B2_1_09d_RL_Gesetzliche_Expertenpflichten_und_allgemeine_Vertrag sbedingungen.docx (abb / hbj / 22.01.07)</b>	<b>anj</b>

## 1 Definitions, terms and abbreviations

APA	Federal Act of 20 December 1968 on Administrative Procedure (SR 172.021)
F CPA	Federal Act of 4 December 1947 on Federal Civil Procedure (SR 273)
Personnel Ordinance	Ordinance of 4 May 2018 on the Personnel of the Swiss Agency for Therapeutic Products (Swissmedic Personnel Ordinance, SR 812.215.4)
SCC	Swiss Criminal Code of 21 December 1937 (SR 311.0)
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, SR 812.21)

## 2 Objective

The following statutory duties of experts and general terms and conditions are applicable to the procurement of external expert opinions in individual cases.

## 3 Scope

The Working Instructions are applicable to all external experts who provide expertise to Swissmedic.

## 4 Legal foundations

APA	Art. 10 (Abstention) Art. 12 point e (Use of expert opinions) Art. 19 (Supplementary provisions)
F CPA	Art. 37 (Admission of the evidence by the judge) Art. 39 – 41 (Evidence) Art. 43 – 61 (Further provisions) Art. 59 (Duties)
Personnel Ordinance	Art. 1 para. 1 and 3 (Scope) Art. 45 (Professional, commercial and official secrecy) Art. 48 (Recusal)
SCC	Art. 307 (Perjury, perjury by an expert witness, false translation) Art. 309 (Administrative cases and proceedings before international courts) Art. 320 (Breach of official secrecy) Art. 322 <sup>quater</sup> (Acceptance of bribes) Art. 322 <sup>sexies</sup> (Acceptance of an advantage)
TPA	Art. 68 para. 5 (Appointment of advisory committees and experts)

## 5 Duties of an expert

By affixing his signature, the appointee confirms that he has noted the statutory duties of experts specified in the following and will observe them in the performance of his tasks for the client:

### 5.1 Duty to maintain secrecy

#### 5.1.1 Personnel Ordinance

##### Art. 1 Scope

<sup>1</sup> This Ordinance is applicable to employees of the Swiss Agency for Therapeutic Products (Swissmedic).

<sup>2</sup> The provisions of the 8th Division of this Ordinance apply analogously to persons appointed by Swissmedic and to experts in particular.

##### Art. 45 Professional, commercial and official secrecy

<sup>1</sup> Employees are bound to maintain secrecy concerning professional and business matters which, by their nature or as required by particular or special statutory regulations, must be kept secret. This duty persists beyond the end of the employment relationship.

<sup>2</sup> Employees may only give evidence concerning such matters as witnesses, a party or court-approved experts if the Agency Council (for members of the Management Board) or the Director (for other employees) has authorised them to do so. Authorisation is not necessary if the evidence concerns facts that require employees to make a notification according to Article 302 of Criminal Procedure Code or Article 75a para. 1 or 2 TPA.

<sup>3</sup> Authorisation may only be refused if this is required by overriding public or private interests.

These duties to maintain secrecy already exist prior to conclusion of the contract and persist after the contractual relationship has ended. In this context the appointee takes note of the following provisions of criminal law:

### 5.1.2 Criminal Code

#### **Art. 320 Breach of official secrecy**

1. Any person who discloses a secret of which he gained knowledge in his function as a member of an authority or as a public official, or of which he became aware in his official or administrative capacity, will be punished with imprisonment for up to three years or a fine.  
A breach of official secrecy continues to be punishable after the official or administrative function has ended.
2. The offender is not punishable if he has disclosed the secret with the written approval of his superior authority.

### 5.2 Duty of recusal

#### 5.2.1 Personnel Ordinance

#### **Art. 48 Duty of recusal**

- <sup>1</sup> Employees who have to take or prepare a decision recuse themselves if:
- a. they have a direct personal interest in the matter;
  - b. their spouse or registered partner has a senior or supervisory function in a party that is directly affected by the decision;
  - c. they were involved in the matter in question on behalf of a party directly affected by the decision;
  - d. they could be biased in the matter for other reasons.
- <sup>2</sup> Persons with a duty of recusal must disclose their vested interests on their own initiative. In such cases they refer the matter to their direct superior.

The appointee informs the client about vested interests that could affect his suitability as an expert in a specific case by completing the *Public Declaration of Interests* form enclosed with this contract. If the appointee has accepted an expert opinion assignment, he informs the client immediately during the ongoing contractual relationship about all matters that could be detrimental to an independent expert opinion or could create an appearance of bias.

In this context the appointee takes note of the following provisions of criminal law:

### 5.2.2 Criminal Code

#### **Art. 322<sup>quater</sup> Acceptance of bribes**

Anyone who, as a member of a judicial or other authority, a public official, an officially appointed expert, translator or interpreter or an arbitrator, asks for, obtains the promise of or accepts in connection with their official activity an undue advantage for himself or a third party in return for an act or omission that is in breach of his duty or at his discretion, will be punished with imprisonment for up to five years or a fine.

#### **Art. 322<sup>sexies</sup> Acceptance of an advantage**

Anyone who, as a member of a judicial or other authority, a public official, an officially appointed expert, translator or interpreter or an arbitrator, asks for, obtains the promise of or accepts in connection with their official activity an undue advantage for himself or a third party will be punished with imprisonment for up to three years or a fine.

## 5.3 Impartiality

### 5.3.1 Federal civil procedure

#### Art. 59 Duties

- <sup>1</sup> The expert must perform his work to the best of his knowledge and belief and maintain the strictest impartiality. His attention must be drawn to this duty when he is appointed.
- <sup>2</sup> Improper fulfilment of an assignment that has been accepted is subject to a disciplinary fine according to Article 33 para. 1 of the Federal Act of 17 June 2005 on the Federal Supreme Court.

In this context the appointee takes note of the following provisions of criminal law:

### 5.3.2 Criminal Code

#### Art. 307 Perjury, perjury by an expert witness, false translation

- <sup>1</sup> Any person who appears in judicial proceedings as a witness, expert witness, translator or interpreter and gives false evidence or provides a false report, a false expert opinion or a false translation will be punished with imprisonment for up to five years or a fine.
- <sup>2</sup> If the statement, report, expert opinion or translation is made on oath or affirmation, the penalty is imprisonment for up to five years or a fine of no fewer than 180 penalty units.
- <sup>3</sup> If the false statement relates to matters that are irrelevant to the judicial decision, the penalty is a fine of up to 180 penalty units.

#### Art. 309 Administrative cases and proceedings before international courts

Articles 306–308 also apply to:

- a. administrative court proceedings, arbitration proceedings and proceedings before public authorities and public officials who are entitled to examine witnesses;
- b. proceedings before international courts where Switzerland recognises their mandatory jurisdiction.

## 6 Rights of parties

During the hearing, the parties in administrative proceedings are entitled in particular

- to know the identity of the expert
- to receive a copy of the expert opinion and
- to request that the expert be asked additional questions.

## 7 Contract components

The general terms and conditions of the appointee do not form part of the present assignment.

## 8 Remuneration

The appointee's fee is:

CHF 200 per hour of work done<sup>1</sup>

If the appointee is subject to valued added tax, this will be paid additionally. The fee will be paid after the expert opinion has been delivered and the appointee has submitted the respective invoice, within

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<sup>1</sup> The fee is a gross fee. Statutory pension and unemployment insurance contributions will be paid by Swissmedic. Experts will not be enrolled in the PUBLICA pension fund. Swissmedic does not pay contributions to the occupational pension scheme.

30 days of receipt of the invoice and after Swissmedic has been informed of the paying agent and payment status (self-employed or employed activity).

## **9 Final provisions**

The place of jurisdiction is Bern.

Should provisions of the contract be invalid or unenforceable, the validity of the other provisions remains intact. In this case, invalid or unenforceable provisions should be replaced by enforceable provisions the economic effects of which are as close as legally possible to those of the unenforceable provisions.