

Obligations of representatives of foreign sponsors

Background

A sponsor, according to the definition in Art. 2c ClinO, is a person or institution headquartered or represented in Switzerland that takes responsibility for organising a clinical trial in Switzerland. This means that persons or institutions headquartered in another country are acceptable as sponsors only if they have a designated representative in Switzerland. The ordinance does not regulate the specific obligations of such representatives. Given that the sponsor has three main obligations – legal procedural obligations in the approval procedure, responsibility for liability and coverage in relation to patients, and notification and reporting requirements in relation to the supervisory authorities – the tasks of the representative can be specified in greater detail as follows:

Communication with the authorities in the approval procedure

- Sponsors headquartered in another country must specify a representative in Switzerland in accordance with Art. 2c ClinO. This provision is primarily designed to ensure the availability of a contact for the Swiss authorities in accordance with Art. 11b para. 1 Administrative Procedure Act (APA). Under this provision, parties headquartered in another country are obliged to designate a **domicile for service** in order to ensure the legally valid issuing of rulings.
- Bearing in mind the procedure for obtaining from **Swissmedic** approval for clinical trials of therapeutic products (Art. 54 TPA) in which a foreign sponsor is a party as defined in Art. 6 APA (see also Art. 31 para. 1 ClinO), and on the basis of Art. 11b para. 1 APA, a natural or legal person must be designated as a representative with responsibility for fulfilling all the obligations in respect of communication between the foreign addressees and the authority in the manner of a domicile for service.¹
- The same applies to the procedure for obtaining approval for clinical trials of transplantation from the **Federal Office of Public Health** (Art. 36 Transplantation Act, Art. 54 para. 1 ClinO).

¹ The statements in the Explanatory Report on the Ordinances to the Human Research Act of 21 August 2013, p. 13, can be read primarily with this in mind.

- Where a foreign sponsor is the applicant in the procedure for obtaining approval from a **cantonal ethics committee** (see Art. 24 para. 3 ClinO), a representative should similarly be appointed in order to ensure that the approval decision can be delivered.²
- The approval authorities are responsible for specifying the detailed **requirements to be satisfied by the representative** in terms of procedural law. These authorities can decide on a case-by-case basis whether, in the interests of the efficient disposition of proceedings, the representative in Switzerland must be aware of the legal requirements for clinical trials, familiar with the specific trial in question or able to provide substantive information in response to verbal queries. Conversely, the competent approval authority can also accept that certain aspects of communication with a sponsor based abroad can be dealt with if that sponsor can always be contacted by the authority. For legally material correspondence such as (interim) rulings, however, the representative in Switzerland remains the authoritative domicile for service.

Liability and coverage

- The person or institution that organises the clinical trial is responsible for the liability and coverage described in Art. 19 - 20 HRA even if it is not headquartered in Switzerland. The law does not provide for any delegation of the above-mentioned obligations to a third party. This order is not fundamentally affected by Art. 2c ClinO: The wording of this provision does not mean that the representative must accept responsibility for the liability and coverage of the foreign sponsor.³ However, with the intent and purpose of the liability and coverage obligations in mind, it must be ensured at all times that injured participants are not disadvantaged by the fact that the sponsor is based in another country.
- During the approval procedure before an ethics committee, evidence must be provided to show that liability is covered by insurance or some other provision (Art. 25f ClinO). Under the relevant insurance oversight legislation, **coverage in the form of insurance** is in particular only acceptable if it is provided by an insurance company headquartered

² The direct delivery of rulings to an addressee in another country violates the sovereignty of the country concerned. Any ruling that is delivered without the consent of the foreign country will be rendered null and void (Supreme Court Ruling BGE 124 V 47 E. 3a; Res Nyffenegger, in: Auer/Müller/Schindler, commentary APA, Art. 11b margin note 4 and other refs.). Accordingly, the designation of a domicile for service also constitutes the minimum requirement for approval procedures before a cantonal authority and in which the foreign sponsor is a party.

³ Nor is there any corresponding provision in the 1st Section 4 ClinO ("Liability and coverage").

in Switzerland or by foreign insurance company with a branch office in Switzerland.⁴ This ensures that patients are able to assert both their right of direct claim (Art. 20 para. 3a HRA, Art. 14 para. 2 ClinO) and associated legal enforcement claims in Switzerland.

- If liability is not covered by insurance, but by the **provision of security of equivalent value** in accordance with Art. 13 para. 1b ClinO, the ethics committee must require the granting of a right of direct claim towards a person based in Switzerland (Art. 14 para. 4 ClinO). The Ordinance does not specify whether this is implemented by the "representative" according to Art. 2c ClinO or by a third party.
- If, exceptionally, liability does not need to be covered by insurance or equivalent securities (Art. 12b ClinO), injured persons must direct their claim for damages to the sponsor. Under international private law, injured persons resident in Switzerland can bring an action against a sponsor domiciled in another European country **in Switzerland**.⁵

Notification, reporting and cooperation requirements

- The notification, reporting and cooperation requirements specified in Art. 46 HRA and the relevant provisions of the ordinance (particularly Art. 37 ff. ClinO) are not directly affected by Art. 2c ClinO; ultimately the **foreign sponsor** is responsible for satisfying these requirements. The latter can forward the necessary notifications and reports directly to the competent executing authority without going through the representative within the meaning of Art. 2c ClinO.
- The foreign sponsor may mandate a third party (e.g. a **CRO**) to fulfill the notification, reporting and cooperation requirements assigned to it. The sponsor remains responsible for compliance with the notification, reporting and cooperation requirements if it has commissioned a third party to fulfill them.⁶
- The representative within the meaning of Art. 2c ClinO is not legally obliged to fulfill the notification and reporting requirements.
- However, the federal and cantonal authorities conduct all communications with the foreign sponsor – e.g. in relation to inspections (Art. 54 para. 5 TPA) or official measures

⁴ See in particular Art. 15 Act on the Oversight of Insurance Companies, (IOA, SR 961.01) and implementing provisions in the Oversight Ordinance (IOO, SR 961.011).

⁵ See Art. 5 of the Convention on Jurisdiction and the Recognition and Enforcement of Judgements in Civil and Commercial Matters, concluded in Lugano on 30 October 2007 (Lugano Convention, LugC, SR 0.275.12).

⁶ See section 5.2.1 ICH-GCP.

(Art. 48 HRA) – through its representative within the meaning of Art. 2c ClinO. In this connection, we refer to the statements relating to Part 1 (Communication with the authorities in the approval procedure).

Reference to the draft EU "Clinical Trials" Regulation (as at March 2014)

Under revised Art. 70 of this draft EU Regulation, a sponsor who is established outside the EU must ensure that a **"legal representative"** is established in the EU. This representative is responsible for ensuring "compliance with the sponsor's obligations pursuant to this Regulation, and shall be the addressee for all communications with the sponsor [...]". In other words, the new EU legislation requires sponsors outside Europe to appoint a representative responsible both for communication and all the other obligations of the sponsor.

Moreover, Art. 70 of the draft EU Regulation allows the member states to designate just one **"contact person on their territory"** who shall be the "addressee for all communications with the sponsor". The interpretation outlined above largely corresponds with the options listed in this draft as regards Parts 1 (Communication) and 3 (Reporting). As regards liability, the draft EU Regulation clearly states that the representation ruling does not affect the civil or criminal liability of the persons to whom the tasks are delegated (Art. 71).