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# Announcement

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## Action plan to combat illegal fresh cell therapies

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**At the end of 2014 the Federal Office of Public Health (FOPH) and Swissmedic, in partnership with the cantons, initiated an action plan to combat non-authorised fresh cell therapies. The outcome at the end of the campaign: Swissmedic issued rulings against manufacturers and suppliers of non-authorised animal tissue preparations in four cases. Three of these cases are still pending with the Federal Administrative Court. Objections were lodged against 14 websites because of misleading claims.**

So-called fresh cell therapies involve injecting cells from young calves or lambs – usually living cells – into patients. These cells are generally injected into the buttocks and are advertised as having anti-ageing properties or being capable of strengthening the immune system. As yet, there has no scientific proof whatsoever to back up these claims.

Questions about "fresh cell tourism" were first raised via the Federal Department of Foreign Affairs (FDFA) in mid-June 2011. The Chinese noticed an increasing number of visa applications for medical treatment in Switzerland. In many cases, however, the purpose of these stays in Swiss clinics was not completely clear. The term "fresh cell therapy" was freely used to cover widely differing types of treatment, preparation and procedure. Not infrequent mention was made of "sheep placenta injections" for rejuvenation purposes. However, neither the FOPH nor Swissmedic had ever authorised such preparations or treatments.

Since an incident involving these obsolete and high-risk treatments could not be ruled out and would risk damaging Switzerland's reputation as a centre for medicine, a government task force was formed in 2012 to tackle this issue at the initiative of the State Secretariat for Economic Affairs (SECO). At the start of 2014, Swissmedic and

the FOPH proposed an action plan that involved working with the cantons to establish the extent and background of such treatments as offered in various Swiss clinics[i]. Cantonal directors of both health and finance were involved in the campaign, as were Cantonal Pharmacists and Cantonal Medical Officers. They all welcomed the initiative by the FOPH and Swissmedic. Moreover, the Swiss clinics were to be informed about the legal framework applicable to such treatments, while action was to be taken under therapeutic products legislation to combat the use of any non-authorised medicinal products.

In summer 2014, four cantons reported a total of 37 institutions that were potentially offering fresh cells or comparable treatments – VD (27), VS (6), GE (2) and AR (2) – and that required further investigation as part of the campaign. The cantons invited the institutions to declare their own activities by completing a detailed questionnaire. The questionnaires were assessed by Swissmedic and the FOPH and compared against the offerings presented on the websites of these institutions.

Seven institutions ceased their medical activities completely either before or during the campaign, while no evidence of relevant activities was established for nine institutions. In the remaining 21 cases, Swissmedic conducted in-depth investigations by asking the institutions to provide a more specific response. These investigations were backed up by inspections. In one case, the Federal Food Safety and Veterinary Office (FSVO) was also consulted.

Fortunately, the investigations revealed that none of the institutions offered treatments that involved preparations covered by the original term "fresh cell therapy", i.e. they did not prepare, import or inject into patients preparations derived from living animal cells or tissues.

However, Swissmedic did submit objections to 14 institutions concerning the offerings presented on their websites and asked them to correct the information and remove references to fresh cell treatments.

In five cases institutions were found to be preparing and/or administering fresh cell preparations (FCP) to their patients, i.e. extracts prepared from animal tissue. Two of these institutions prepared the FCP themselves as patient-specific preparations. One institution had patient-specific preparations produced by one of the two manufacturers for administration to its clients. This institution ceased further procurement of such preparations as a result of the investigation. Another institution had the preparation manufactured under contract by pharmaceutical manufacturers and then administered it as a patient-specific preparation. Swissmedic issued three official decisions against these institutions with the aim of stopping the manufacture and administration of these preparations, claiming that they had failed to comply with the compulsory authorisation requirement. Appeals against these rulings have been lodged with the Federal Administrative Court (FAC). The decisions of the FAC are

still pending.

In the fifth case, the investigations revealed that the orally administered preparation was not being manufactured, used or advertised as a medicinal product and was therefore not covered by the Therapeutic Products Act. Ultimately, Swissmedic issued a legally binding decision to the effect that the product in question is not a medicinal product and cannot therefore be advertised or used as one. The dossier was then referred to the relevant cantonal agencies so they could establish whether the preparation could be distributed under foodstuffs legislation.

In two cases, the clinics stated that they occasionally imported non-authorised FCPs into Switzerland from abroad and then used these in the course of their treatments. Corresponding new applications to import non-authorised medicinal products were subsequently rejected wherever they lay within Swissmedic's remit. In at least five cases, the campaign also indicated that healthcare professionals were probably using medicinal products that had been properly authorised by Swissmedic outside the authorised conditions (off-label use). Since the cantons are responsible for monitoring medical practice and the dispensing or use of medicinal products, they are also responsible for initiating further action.

Independently of the campaign, Swissmedic is continuing its parallel investigations of violations of the Therapeutic Products Act in various criminal proceedings. These proceedings are ongoing.

Overall, the campaign raised awareness of the current legal framework within the sector and individual professional associations. It also generated positive feedback and considerable interest from foreign authorities and media. In addition to numerous Swiss media outlets, the leading Chinese TV stations and news agencies in particular carried extensive coverage of the Swiss authorities’ campaign. The explanation for the significant decline in visa applications from China for medical treatments in Switzerland over the past two years – from an average of 1,000 applications a year in 2013 to approx. 300 in 2015 – must remain a matter of conjecture.

The campaign by the FOPH and Swissmedic against illegal treatments with fresh cells and non-authorised fresh cell preparations has now ended and is making the transition into ongoing monitoring of such treatment offerings by the federal government and the cantons. Cantonal-level monitoring of the lawful use of medicinal products by healthcare professionals will play an important role.

[i] Action to combat illegal fresh cell therapy and non-authorised fresh cell preparations Swissmedic Journal 03/2015 and FOPH Bulletin no. 15 of 8 April 2015