

Federal Commission for Sexual Health's (FCSH) recommendation on dispensing HIV tests for self-administration ("HIV self-tests") to the public

The Federal Commission for Sexual Health (FCSH) is an extra-parliamentary commission appointed by the Federal Council. Its task is to advise the Federal Council, the Federal Department of Home Affairs (FDHA) and the Federal Office of Public Health (FOPH) on strategic issues relating to efforts against HIV/AIDS and on the implementation of the National Programme for HIV and other Sexually Transmitted Infections (NPHS). The FCSH has monitored and analysed the latest developments in the field of HIV testing and, on this basis, has drawn up and issued the Recommendation by the Federal Commission for Sexual Health (FCSH) on the provision of HIV tests for self-testing (HIV self-tests) to the public. The Federal Office of Public Health agrees with this recommendation, and has asked Swissmedic, the Swiss authority responsible for the authorisation and supervision of medicinal products and medical devices, to approve the provision to the public of legally compliant HIV tests for self-testing in the interest of public health.

POINT OF DEPARTURE

After a diagnosis, patients infected with HIV are swiftly referred for antiretroviral treatment. Timely and effective treatment can prevent those affected from developing AIDS. In addition, effective treatment prevents infected individuals from transmitting HIV, which is why it is vitally important to diagnose infections as quickly as possible. Aside from preventing new infections, the goal to end the AIDS epidemic by 2030 as declared by the United Nations General Assembly [1] necessitates in particular that, to the extent possible, all individuals infected with HIV know their serostatus. However, not all those affected are aware that they have been infected. Based on estimates, a maximum of one fifth of these people in Switzerland believe that they are HIV negative [2].

THE CURRENT PROHIBITION AGAINST DISPENSING HIV TESTS FOR SELF-ADMINISTRATION TO THE PUBLIC

Up until now, HIV tests in Switzerland may be dispensed and applied only in professional settings. Dispensing them to the public is prohibited (Art. 17, para. 3 of the Medical Devices Ordinance, MedDO, SR 812.213). In a March 2013 statement [3], the FCSH recommended upholding this prohibition for the time being. It argued that the HIV tests for self-administration available at the time (hereinafter "HIV self-tests") did not ade-

quately satisfy the public interest at safeguarding a quality-assured HIV diagnosis. Furthermore, the FCSH pointed out that the European authorities had yet to make a decision regarding the administration of HIV self-tests.

RELEVANT DEVELOPMENTS

Since then, the FCSH has continued to monitor and analyse the relevant developments regarding the dispensation of HIV self-tests to the public. Its new assessment of the situation is as follows:

HIV self-tests can have a positive impact on public health [8]

Based on currently available scientific findings, dispensing HIV self-tests to the public has a favourable benefit/risk profile for public health.

A systematic literature review identified randomised controlled trials which compared the use of HIV self-tests with the use of conventional testing methods [4]. The meta-analysis of three of these trials, two of them on heterosexual men and one on men having sex with men (MSM), demonstrated that the probability of taking the test doubled in the "self-testing" groups (risk ratio = 2.12; 95 % CI: 1.51–2.98).

None of the five trials identified in the literature review revealed any negative effects in connection with the use of HIV self-tests, and the increase in risk behaviour related to sexually transmitted infections appears to be minimal.

Trials (randomised controlled trials and observational trials) were analysed in a further systematic literature review to determine whether an increase in testing could be established in MSM in connection with the availability of HIV self-tests [5]. The combined outcomes of these trials illustrate that HIV self-testing boosts the testing frequency over a period of six months (mean difference = 0.88; 95 % CI: 0.52–1.24). The share of persons who used HIV self-tests and underwent testing for the first time was 18.7 % (95 % CI: 9.9–32.4).

A systematic scientific review of qualitative trials and reports on experiences with HIV self-testing in several countries likewise revealed that previously unreachable target groups can be reached and that existing test offers can be expanded [6]. Based on the investigation, HIV self-tests are used primarily by stigmatised population groups, because they are readily available and confidential. HIV self-testing lowers the risk of stigmatization associated with visiting a test facility. HIV self-tests provide people with more control over their personal testing behaviour. The analysis concludes that HIV self-testing should be offered as an addition to existing testing options in order to raise the testing rate and bolster the autonomy of individuals undergoing the tests.

WHO and ECDC recommend self-testing for HIV

The World Health Organization (WHO) recommends self-testing for HIV by means of kits approved by international or national authorities for dispensing to the public as an additional test option. According to the WHO, there is evidence of a high rate of acceptance for these tests, which can reach individuals who may not otherwise undergo testing. The rate and frequency of testing can be boosted with HIV self-testing, without an increase in risk behaviour or any other adverse effects [7]. The testing system is also apt to improve access to prevention, care and treatment, particularly if the offering is integrated into existing testing services for target groups [8]. The European Centre for Disease Prevention and Control (ECDC) likewise advocates self-testing for HIV and calls on Member States to integrate and promote it as an innovative approach in their test strategies [9].

Market-compliant HIV self-testing in Europe

Since 2015, self-testing for HIV by medical lay persons has become marketable in several European countries. These products fulfil the highest quality requirements in terms of sensitivity and specificity.¹ They bear the CE marking, which indicates that, according to the “basic requirements” set forth in the Di-

¹ The sensitivity of a test is expressed as the percentage of persons whose infection was identified correctly, that is, correct positive results. The specificity of a test is expressed as the percentage of persons in whom the absence of an infection was determined correctly, that is, correct negative results.

rective 98/79/EC of the European Parliament and the Council of 27 October 1998 on in-vitro diagnostic medical devices, they are not only safe but are also a powerful medical technology in the context of the intended purpose specified by the manufacturer. These tests enable interested individuals in less than thirty minutes and with a high degree of reliability to independently detect an HIV infection that dates back more than three months.

CONCLUSION: THE FCSH RECOMMENDS DISPENSING HIV SELF-TESTS TO THE PUBLIC

Against this backdrop, the FCSH views the existing prohibition against dispensing HIV tests to the public as outdated and no longer in the interest of public health. The prohibition prevents

- *the central testing scheme of Switzerland – which is based on a personal HIV/STI risk assessment [10] as well as professional personal specialist counselling and testing in the context of the concepts and guidelines of voluntary counselling and testing (VCT) and provider-initiated counselling and testing (PICT) [11] – from being supplemented with a procedure which can contribute to making it easier for individuals to undergo testing for HIV;*
- *interested consumers from obtaining transparent and comprehensive information about the possibilities, limits and risks of the use of high-quality HIV self-tests;*
- *the effective counteraction of the risks associated with the use of low-quality yet nevertheless available HIV self-tests.*

The FCSH therefore recommends that the dispensation of qualitatively impeccable HIV self-tests to the public be permitted in the interest of public health and that access to these tests be designed with as low a threshold as possible.

Several points need to be considered in this context.

Interpretation and consequences of a negative test result

Correctly interpreting a negative test result and drawing the right conclusions from it is a challenge for individuals. The FCSH deems it essential that appropriate procedures be deployed to ensure that HIV self-test users don't incorrectly interpret a negative (non-reactive) test result, thereby drawing false and potentially harmful conclusions for their behaviour [12].

Connection to professional counselling on HIV and other sexually transmitted infections

HIV self-tests do not establish an automatic link to the professional care system. However, based on applicable law, all dispensing bodies are required to provide pertinent accompanying information about the product and its use [13]. The FCSH deems it important that HIV self-test users have access to adequate counselling at any time (including nights and weekends). This should be made possible through pertinent advice provided at the time of dispensation or in the product information leaflet.

Analyses on the use and effect of HIV self-tests

There currently exist some research and knowledge gaps with regard to users' access to professional counselling as well as concerning the effects of HIV self-tests on public health. The FCSH therefore recommends that the dispensation of HIV self-tests to the public be accompanied by appropriate measures.

Literature and sources:

1. United Nations (2016). United Nations General Assembly Resolution A/RES/70/266, June 8 2016. Political Declaration on HIV and AIDS: On the Fast Track to Accelerating the Fight against HIV and to Ending the AIDS Epidemic by 2030 (http://www.unaids.org/sites/default/files/media_asset/2016-political-declaration-HIV-AIDS_en.pdf).
2. Kohler Ph, Schmidt A J, Cavassini M, Furrer H, Calmy A, Battegay M, Bernasconi E, Ledergerber B, Vernazza P (2015). The HIV care cascade in Switzerland: reaching the UNAIDS/WHO targets for patients diagnosed with HIV. *AIDS* 2015, 29: 2509–2515 (http://www.shcs.ch/user-files/file/news/Kohler_The_HIV_care_cascade_in_Switzerland_2015_AIDS.pdf).
3. Eidgenössische Kommission für Sexuelle Gesundheit (EKSG) (2013). Stellungnahme zu „HIV-Hometests“ (<https://www.bag.admin.ch/dam/bag/de/dokumente/mt/p-und-p/eksg/stellungnahme-eksg-zu-hometests.pdf.download.pdf/stellungnahme-eksg-zu-hometests.pdf>).
4. Johnson CC, Kennedy C, Fonner V, et al. Examining the effects of HIV self-testing compared to standard HIV testing services: a systematic review and meta-analysis. *Journal of the International AIDS Society* 2017;20(1):21594 (<https://dx.doi.org/10.7448/IAS.20.1.21594>).
5. Zhang C, Li X, Brecht ML, et al. Can self-testing increase HIV testing among men who have sex with men: A systematic review and meta-analysis. *PLoS ONE [Electronic Resource]* 2017;12(11):e0188890 (<https://dx.doi.org/10.1371/journal.pone.0188890>).
6. Qin, Yilua et al. (2018). Experiences using and organizing HIV self-testing. In: *AIDS: January 28, 2018 – Volume 32 – Issue 3 – p 371–381* (https://journals.lww.com/aidsonline/Abstract/2018/01280/Experiences_using_and_organizing_HIV_self_testing.11.aspx).
7. World Health Organization (WHO) (2017). Statement on HIV testing services. WHO recommends two new HIV testing services approaches (<http://www.who.int/hiv/topics/vct/hts-new-opportunities/en/index2.html>).
8. World Health Organization (WHO) (2016). Guidelines on HIV self-testing and partner notification: supplement to consolidated guidelines on HIV testing services (<http://apps.who.int/iris/bitstream/10665/251655/1/9789241549868-eng.pdf?ua=1>).
9. European Centre for Disease Prevention and Control (ECDC) (2017). HIV testing. Monitoring implementation of the Dublin Declaration on Partnership to fight HIV/AIDS in Europe and Central Asia: 2017 progress report (<https://ecdc.europa.eu/sites/portal/files/documents/HIV%20testing.pdf>).
10. Website of the Federal Office of Public Health (ed.). LOVE-LIFE-Kampagne: <https://www.lovelife.ch/de/>; Safer Sex-Check: <https://www.lovelife.ch/de/safer-sex-check/>; Risiko-Check: <https://www.lovelife.ch/de/hiv-co/risiko-check/>.
11. Website of the Federal Office of Public Health (ed.). Freiwillige Beratung und Testung (VCT und PICT). (<https://www.bag.admin.ch/bag/de/home/themen/strategien-politik/nationale-gesundheitsstrategien/nationales-programm-hiv-und-andere-sexuell-uebertragbare-infektionen/freiwillige-beratung-und-testung.html>).
12. Vernazza, P (2005). HIV-Testberatung: ein kurzes Vademecum für die Praxis. In: *Schweizerische Ärztezeitung* 2005;86: Nr 28, pp. 1737 f. (<https://saez.ch/de/resource/jf/journal/file/view/article/saez/de/saez.2005.11352/2005-28-901.pdf>).
13. Das Schweizer Parlament (ed.). Fragestunde. Frage 18.5180 «HIV-Heimtests. Bereiten wir eine professionelle Abgabe dieser Produkte durch Gesundheitsfachkräfte vor!». Antwort des Bundesrates vom 12.03.2018 (<https://www.parlament.ch/fr/ratsbetrieb/suche-curia-vista/geschaefft?AffairId=20185180>).