

The document consists of three parts, your Personal Details, the Public declaration of interests and the Confidentiality undertaking. **All parts should be duly completed.**

SECTION 1: PERSONAL DETAILS

First Name: Huldrych
Last Name: Günthard
Organisation / Company: University Hospital Zurich / University of Zurich
Country: Switzerland
Committee: Human Medicines Expert Committee (HMEC)

I do hereby declare on my honour that, to the best of my knowledge, the only direct or indirect interests I have in the pharmaceutical industry are those listed below:

Please specify the interests that you currently have (at the time of completion of the form) or have had within the past 5 years.

SECTION 2: PUBLIC DECLARATION OF INTERESTS

2.1 Employment ⁱⁱ No Yes

ⁱⁱ Employment in a pharmaceutical company.

(Pharmaceutical company includes supply or service companies which contribute to the research, development, production and maintenance of a medicinal product)

2.2 Consultancy ⁱⁱⁱ No Yes

ⁱⁱⁱ Provision of advice or services to a pharmaceutical company (in a particular field such as the development of a product) regardless of contractual arrangements or any form of remuneration. (Pharmaceutical company includes supply or service companies which contribute to the research, development, production and maintenance of a medicinal product)

Note: Conference / Seminar attendance is not considered as consultancy but should be indicated under Financial Interests, if subject to a fee / honoraria.

Consultancy¹

Period:² Current Past

From Month: 01 From Year: 2016 To Month: 12 To Year: 2020

Name of Pharmaceutical Company:³ Gilead Sciences

Product Related⁴ General (non product related)⁵

Product Name: TAF/FTC, Elvitegravir, Bictegravir, Remdesivir, Lenacapavir

Therapeutic Indication: antiretroviral treatment (HIV treatment), SARS-CoV-2 Treatment

General Role / Area of Activity: Various advisory boards / consultations, on how all these drugs will and could potentially be used in HIV treated patients, potential for resistance development of HIV when these drugs are used.

How remdesivir will be used in SARS-CoV-2 treated patients. Potential for resistance.

Consultancy¹Period:² Current Past

From Month: 01 From Year: 2017 To Month: 12 To Year: 2017

Name of Pharmaceutical Company:³ Mepha Product Related⁴ General (non product related)⁵

Product Name:

Therapeutic Indication: antiretroviral treatment (HIV treatment)

General Role / Area of Activity: Advise on how generics would be perceived in HIV treatment

Consultancy¹Period:² Current Past

From Month: 01 From Year: 2017 To Month: 12 To Year: 2017

Name of Pharmaceutical Company:³ Sandoz Product Related⁴ General (non product related)⁵

Product Name:

Therapeutic Indication: antiretroviral treatment (HIV treatment)

General Role / Area of Activity: Advise on how generics would be perceived in HIV treatment

Consultancy¹Period:² Current Past

From Month: 01 From Year: 2019 To Month: 12 To Year: 2019

Name of Pharmaceutical Company:³ ViiV Product Related⁴ General (non product related)⁵

Product Name: Cabotegravir / Rilpivirene

Therapeutic Indication: long-acting injectable antiretroviral therapy (HIV)

General Role / Area of Activity: Discussion on how patients and physicians possibly would accept such a treatment, what would be the problems in routine clinical care with this new treatment

Consultancy¹

Period:² Current Past

From Month: 09 From Year: 2018 To Month: 10 To Year: 2018

Name of Pharmaceutical Company:³ Merck, Philadelphia

Product Related⁴ General (non product related)⁵

Product Name:

Therapeutic Indication:

General Role / Area of Activity: Merck Global Therapeutic Expert Forum: Discussions on how the field of antiretroviral therapy could / will evolve in the future. Potential indication for newer drugs such as islatravir or Doravirine. However, this was not a product specific meeting.

Consultancy¹

Period:² Current Past

From Month: 09 From Year: 2019 To Month: 10 To Year: 2019

Name of Pharmaceutical Company:³ Merck, Philadelphia

Product Related⁴ General (non product related)⁵

Product Name:

Therapeutic Indication:

General Role / Area of Activity: Merck Global Therapeutic Expert Forum: Discussions on how the field of antiretroviral therapy could / will evolve in the future. Potential indication for newer drugs such as islatravir or Doravirine. However, this was not a product specific meeting.

Consultancy¹

Period:² Current Past

From Month: 12 From Year: 2021 To Month: To Year:

Name of Pharmaceutical Company:³ Jansen Vaccine

Product Related⁴ General (non product related)⁵

Product Name: Johnson and Johnson Vaccine

Therapeutic Indication: Update from Company on Vaccine status (efficacy, safety)

General Role / Area of Activity: Infectious Disease Specialist. Discussion on the use of J&J in the landscape of currently available vaccines in Switzerland

2.3 Strategic Advisory Role ^{iv} No Yes

^{iv} Participation (with a right to vote on/influence the outputs) in a (Scientific) Advisory Board/Steering Committee with the role of providing advice/expressing opinions on the (future) strategy, direction or development activities of a pharmaceutical company, either in terms of general strategy or product related strategy, regardless of contractual arrangements or any form of remuneration. Pharmaceutical company includes supply or service companies which contribute to the research, development, production and maintenance of a medicinal product).

Note: Involvement in Data Safety Monitoring Committees is not included in this category. Such involvement should be recorded under section 2.6 Principal Investigator Involvement in clinical research should be listed under section 2.6 or 2.7 as appropriate.

2.4 Current Financial Interests ^v No Yes

^v Financial interests relate to:

CURRENT Holding of shares of a pharmaceutical company with the exclusion of independently managed investment funds/pension. Compensation, fees, honoraria, salaries **CURRENTLY** being paid directly to you by a pharmaceutical company, other than payment for expenses incurred with research work or re-imburement of reasonable expenses incurred in relation to conference/seminar attendance (i.e. accommodation and travel costs). (**CURRENT** is interpreted at time of completion of this form).

2.5 Patent ^{vi} No Yes

^{vi} Relates to a patent for a medicinal product/competitor product **CURRENTLY** owned by either the individual or the individual's Institution, and the individual is a beneficiary. (**CURRENT** is interpreted at time of completion of this form)

2.6 Principal Investigator ^{vii} No Yes

^{vii} Principal Investigator with the responsibility for the coordination of investigators at different centres participating in a multicentre trial or the leading investigator of a monocentre trial, or the coordinating (principal) investigator signing the clinical study report. This definition does not include a national coordinating investigator in a multinational trial. Involvement in Data Safety Monitoring Committee should be included in this section.

Principal Investigator¹

Period:² Current Past

Funding paid into an institutional account with shared power of disposition³: No Yes

From Month: 01 From Year: 2014 To Month: 12 To Year: 2018

Name of Pharmaceutical Company:⁴ MerckProduct Name⁵: External Data Safety Monitoring Board Member (eDSMB) for the new NNRTI drug: Doravirin

Therapeutic Indication: Antiretroviral treatment (HIV)

Principal Investigator¹Period:² Current PastFunding paid into an institutional account with shared power of disposition³: No Yes

From Month: From Year: 2018 To Month: To Year:

Name of Pharmaceutical Company:⁴ MerckProduct Name⁵: Islatravir (anti HIV drug that is being developed in phase II and III studies). I am a member of the eDSMB of different Phase II and phase III trials on this drug. In addition, a long active Nucleoside-Reverse Transcriptase Inhibitor (MK8507) is also being studied together with Islatravir in some of the studies.

Therapeutic Indication: antiretroviral treatment (HIV)

2.7 Investigator ^{viii} No Yes^{viii} Investigator involved in a clinical trial at a specific trial site who can be the responsible lead investigator of the trial at that specific site or a member of the clinical trial team who performs critical trial related procedures and makes important trial related decisions.**2.8 Grant / Funding to Institution** ^{ix} No Yes^{ix} Refers to a grant or other funding from a pharmaceutical company, **CURRENTLY** being received (as far as the individual is aware) by an institution (please indicate funding to the smallest institutional unit) or an organisation (e.g. patient organisation), irrespective of whether or not the individual is employed or is a volunteer, and the individual receives no personal gain.

Grant or other Funding¹

Funding paid into an institutional account with shared power of disposition²: No Yes

Name of Pharmaceutical Company ³	Subject Matter	≥ 500 TCHF	Add
Gilead Sciences	unrestricted research on "HIV cure" I am a co-investigator on this grant. This is a competitive research program by Gilead. I am a coinvestigator. The Principle Investigator is Prof. Alexandra Trkola, Institute of Medical Virology, University of Zurich	<input type="radio"/> No <input checked="" type="radio"/> Yes	X
Gilead Sciences	Unrestricted research grant for COVID-19. This is a global funding project for COVID-19 research. It is not product related.	<input checked="" type="radio"/> No <input type="radio"/> Yes	X

Further to the interests declared above, I do hereby declare on my honour that I do not have any other interests or facts that should be made known to Swissmedic, the Swiss Agency for Therapeutic Products and the public.

In case of any other facts or interests of related parties, please specify:

Should there be any change to the above due to the fact that I acquire additional interests, I shall promptly notify **Swissmedic** and complete a new Declaration of Interests detailing the changes. This declaration does not discharge me from my obligation to declare any potential conflicting interest(s) at the start of any Swissmedic Activity in which I participate.

SECTION 3: CONFIDENTIALITY UNDERTAKING

In view of the following definitions:

“**Swissmedic Activities**” encompass any meeting (including meeting preparation and follow-up, associated discussion or any other related activity) or work as a member of the Swissmedic Medicines Expert Committees.

“**Confidential Information**” means all information, facts, data and any other matters of which I acquire knowledge, either directly or indirectly, as a result of my Swissmedic Activities.

“**Confidential Documents**” mean all drafts, preparatory information, documents and any other material, together with any information contained therein, to which I have access, either directly or indirectly, as a result of my participation in Swissmedic Activities. Furthermore, any records or notes made by me relating to Confidential Information or Confidential Documents shall be treated as Confidential Documents.

I understand that I may be invited to participate either directly or indirectly in certain Swissmedic activities and hereby undertake:

- **to treat all Confidential Information and Confidential Documents under conditions of strict confidentiality.**
- **not to disclose (or authorise any other person to disclose) in any way to any third party¹ any Confidential Information or Confidential Document.**
- **not to use (or authorise any other person to use) any Confidential Information or Confidential Document other than for the purposes of my work in connection with Swissmedic activities.**
- **to dispose of Confidential Documents as confidential material as soon as I have no further use for them.**
- **to comply with the Code of the Swissmedic Medicines Expert Committees.**

This undertaking shall not be limited in time, but shall not apply to any document or information that I can reasonably prove was known to me before the date of this undertaking or which becomes public knowledge other than as a result of a breach of any of the above undertakings.

I confirm that I allow all my contracting partners of the pharmaceutical industry to announce in the Pharma-Kooperations-Kodex (PKK) any payments falling under the scope of the PKK.

I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically and published on the Swissmedic website.

¹ Third party does not include Swissmedic employees or other SMEC Members.

Full Name: Huldrych Günthard, MD

Date: 01.12.2021

Signature: