

| TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES |
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| LAWS AND REGULATIONS ON TELEMEDICINE |
| 1. Is telemedicine allowed in your country? If so, how is it defined? |
| <p>Telemedicine is permitted in France. Article L 6316-1 of the French Public Health Code (the FPHC) was introduced by Act No 2009-879 of 21 July 2009, on hospital reform and patients, health and territories, known as HPST, and its application Decree No 2010-1229 of 19 October 2010, relating to telemedicine. It defines telemedicine as '[...] a form of remote medical practice using information and communication technologies. It brings together a medical professional with one or more health professionals, either with each other or with the patient and, where appropriate, other professionals providing care to the patient.'</p> <p>Under French law, telemedicine is composed of five categories of acts: (1) teleconsultation (a patient consulting a medical professional on a remote basis); (2) tele-expertise (a medical professional asking the advice of another medical professional on a remote basis); (3) remote medical monitoring (a medical professional interprets data collected from the patient's residence on a remote basis); (4) remote medical assistance (a medical act performed with the help of another medical professional on a remote basis); and (5) the medical response provided in the context of medical regulation (emergencies assistance on a remote basis to deal with inbound requests) (Art R 6316-1 of the FPHC).</p> <p>More specifically, telemedicine is described as making it possible to establish a diagnosis, to ensure, for a patient at risk, a follow-up with a preventive aim or a post-therapeutic follow-up, to request a specialised opinion, to prepare a therapeutic decision, to prescribe products, to prescribe or carry out services or acts, or to carry out a monitoring of the state of the patients.</p> <p>Telemedicine is part of a wider category called 'telehealth', which contains a second category of activities called 'telecare'. Telecare was introduced in the French legal system by Act No 2019-774 of 24 July 2019, regarding the organisation and transformation of the health system. It is defined as a form of remote care practice using information and communication technologies and putting a patient in contact with one or more pharmacists or medical auxiliaries in the exercise of their competencies.</p> <p>'Telehealth' is defined by the French Ministry of Health as 'all activities [care, consultation...] carried out between health professionals and their patients thanks to digital technology'.</p> |
| 2. Please provide a high-level overview of the legal framework regarding telemedicine in your country. |
| <p>Telemedicine is mainly and specifically regulated by the FPHC, as well as by various guidelines and recommendations issued by health authorities. The FPHC and the telemedicine-related guidelines set criteria of eligibility of healthcare professionals to practice telemedicine, the conditions to be followed during telemedicine consultations, the technical (security, interoperability and ethics) rules to be followed, the way the patient should be informed if not trained when needed to access telemedicine, the way health data may be processed, conditions governing the management of the patient's medical record, how healthcare professionals may interact in the scope of telemedicine, as well as criteria for reimbursing certain telemedicine consultations under national health insurance.</p> <p>Pursuant to article R 6313-3 of the FPHC, each telemedicine consultation (or telecare activity) shall be performed under conditions which guarantee:</p> |

- 1a). The authentication of the health professionals involved in the procedure or activity;
 - b). The identification of the patient;
 - c). Access by health professionals to the patient's health data required in order to undertake the procedure or activity;
- 2). When required, the training or preparation of the patient for the use of the telemedicine or telecare device.

As of the end of December 2022, the costs of teleconsultation and tele-expertise consultations is reimbursed under national health insurance. The same system is also used to reimburse medical telemonitoring fees, confirmed by Decree No 2022-1767 of 30 December 2022, which came into force as of 1 January 2023.

Telemedicine is further subject to the broader regulatory framework governing medical practice in France. This includes, inter alia, the FPHC's provisions, the physicians' code of ethics, Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR), as well as the French Act No78-17 of 6 January 1978 as modified, on Data Processing, Data Files and Individual Liberties (the French Data Protection Act or FDPA).

3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.

As of 4 December 2022, there are no specific licensing bodies for telemedicine in France. However, the following government, regulatory or professional bodies are involved in the regulation of telemedicine:

- The French Digital Health Agency (*Agence du Numérique en Santé* or ANS) issues recommendations and has created an auto-declaration list of telemedicine providers during the Covid-19 pandemic.
- The High Authority for Health (*Haute Autorité de Santé* or HAS), an independent authority aimed at supporting public decision-making for optimising the collective financial coverage of reimbursable health products or services and upholding the solidarity-based and equitable financing of the French healthcare system in a sustainable manner. The HAS has issued guidelines on tele-expertise and teleconsultations (eg, Memo on Teleconsultation and Teleexpertise of May 2019 and the Good Teleconsultation practices Charter dated 1 April 2022).
- The Professional Order of Physicians (*Ordre des Médecins*) is a professional, administrative and disciplinary body for the defence and regulation of the medical profession. Among its other responsibilities, the Order receives physicians' registration, issues requirements and recommendations regarding medicine and telemedicine, or issues sanctions.
- The French data protection authority (CNIL) is an independent authority which controls compliance with applicable data protection rules, possibly issuing sanctions and providing data protection guidelines in the context of telemedicine among other areas (eg, <https://www.cnil.fr/fr/telemedecine-comment-protger-les-donnees-des-patients>).

Note that under the 2023 Health Insurance Financing Act, teleconsultation platforms will be required to be approved and certified in their compliance with the applicable security, interoperability and ethics frame of reference. Their approval shall be granted by the Ministry of Health, while their certification shall be delivered by the public body managing the enforcement of the above-mentioned frame of reference or some other accredited certification bodies.

4. Was telemedicine authorized during the Covid-19 pandemic?

Telemedicine in France was authorised during the Covid-19 pandemic. Measures were even taken to widen the scope of telemedicine during this period, with a series of specific measures such as:

- Up to 30 September 2022, teleconsultations have been completely reimbursed for all patients by the national health insurance system.
- Tele-expertise has been extended to suspected or diagnosed Covid-19 patients, with no limit on the number of procedures per year, allowing in particular for the reimbursement (Decree No 2021-13 of 8 January 2021).
- Amendment 8 to the national agreement for self-employed doctors, concluded on 11 March 2020, between the National Union of Health Insurance Funds (*Union nationale des caisses d'assurance maladie*) and self-employed doctors, extended the scope of teleconsultation consultations covered by national health insurance, by derogating from coordinated patient pathway or territorial organisation requirements.
- Amendment 9 to the same national agreement, dated 31 July 2021, consolidated the patient pathway by giving teleconsultations and tele-expertise a new frame of reference, issued in February 2022.

5. Is there any possibility of the regulatory landscape being changed in the post-pandemic scenario? Or has there been already a change in the regulation in the post-pandemic scenario?

In addition to teleconsultation and tele-expertise having been given a new frame of reference, new provisions have been introduced into more specific telemedicine legal regimes such as those for the remote monitoring of diabetic and heart failure patients (Order of 23 December 2020, NOR: SSAH2035801A) to continue exemptions implemented during the health crisis and therefore broaden the number of patients benefiting from telemedicine for a given duration.

The 2023 Health Insurance Financing Act brings an important change as it will now require teleconsultation platforms with salaried physicians to be approved and certified (see responses to questions 3 and 14).

6. What types of teleservices are allowed? (e.g. second opinion, teleconsultation, telediagnosis, telesurgery, among others)

As far as telemedicine is concerned, the FPHC expressly allows for: (1) teleconsultation; (2) tele-expertise (including second opinion); (3) remote medical monitoring; (4) remote medical assistance; and (5) the medical response provided in the context of medical regulation. This list is limited. Therefore, other practices, such as telesurgery, are not currently authorised in France.

7. Who can use telemedicine services? Please indicate if whether only doctor-doctor or also patient-doctor remote medical services are allowed.

Article L 6316-1 of the FPHC allows both doctor-doctor and patient-doctor telemedicine services. Any doctor can use teleconsultation, regardless of their specialty, practice area and geographical location, either in a town or health establishment (ie, town practice, multi-professional health centre, health centre, nursing home, hospital, clinic, etc). It can be carried out anywhere in mainland France and in the overseas departments and regions (DROM) as well as in Mayotte. Any patient, whether suffering from an acute or a chronic disease, can *a priori* be offered a patient-doctor telemedicine service. However, providing this service is at the sole decision of the doctor who shall assess the relevance of remote medical care rather than face-to-face care according to the context. As regards tele-expertise (between two healthcare professionals), the patient does not have to be known to the doctor who is asked to perform the procedure. The patient must simply be informed of the conditions under which the tele-expertise will be carried out and must have given consent prior to the procedure. Remote monitoring can be set up for any patient whose care requires a period of medical follow-up: it is particularly suitable for people at risk of hospitalisation or the complications of their illness (eg, chronic pathologies, discharge from hospital, etc).

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| <p>8. Please outline the funding model for telemedicine. Is it available in your jurisdiction public health system? Is telemedicine under mandatory insurance coverage? Please indicate what legislation applies.</p> |
| <p>An important step in the development of telemedicine in France took place in 2018, when tele-expertise and teleconsultation were covered by the national health insurance system pursuant to the 2018 Health Insurance Financing Act No 2017-1836 of 30 December 2017. This Act added teleconsultation and tele-expertise procedures to the law of reimbursement by the national health insurance scheme. These telemedicine acts are covered under the scheme if a number of conditions are met, pertaining, among other topics, to patient pathway characteristics, age or duration (eg, maternity, emergency, long-term illnesses, etc).</p> <p>As mentioned above, patients were completely reimbursed for teleconsultations under an exemption measure implemented during the Covid-19 pandemic until 30 September 2022. Since 1 October 2022, the amount of reimbursement for teleconsultations has been cut to 70 per cent, similar to that for face-to-face consultations and subject to meeting certain requirements. Exemptions are made, linked to a patient's condition (eg, long-term illness, maternity, etc).</p> <p>Tele-expertise is billed directly to the national health insurance fund. It is totally covered under the compulsory health insurance system. The patient can find a record of their procedure under the 'Teleexpertise' heading of their health insurance bill (<i>décompte</i>).</p> <p>As of 4 December 2022, remote monitoring and other types of telemedicine were not reimbursable under the health insurance system on a general basis. However, under Decree No 2022-1676 of 30 December 2022, which came into force as of 1 January 2023, remote monitoring is now within the scope of national health insurance reimbursement.</p> <p>Note that pursuant to the 2023 Health Insurance Financing Act (see above), the reimbursed of medical acts performed via teleconsultation platforms with several salaried physicians will be subject to prior Ministry of Health approval.</p> |
| <p>9. Please indicate whether any insurance requirements applicable to telemedicine services providers.</p> |
| <p>To date, there are no compulsory insurance requirements which specifically apply to telemedicine service providers in France beyond insurance policies to be more generally subscribed by companies and other legal entities (including civil or professional or products insurance policies). This may change in time with the adoption of coming frames of reference and codes of conduct applying to teleconsultation platforms. Healthcare professionals or establishments have their own professional or civil insurance policy requirements.</p> |
| <p>REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS</p> |
| <p>10. Who can practice telemedicine in your country? Please indicate whether other healthcare professionals are authorized to provide remote health services under the applicable rules (e.g. nurses, psychologists, nutritionists, alternative health therapies providers, etc.)</p> |
| <p>According to article L 6316-1 of the FPHC, telemedicine requires the involvement of at least one medical professional, (eg, a physician, odontologist or midwife), who will undertake the telemedicine. The medical professional may be in contact with one or several health professionals or a patient or a professional taking care of the patient. Teleconsultation may be undertaken by any medical professional, including those other than the patient's attending physician (<i>médecin traitant</i>) and as a first consultation.</p> <p>Each medical profession in France is regulated or supervised by its specific professional association (or Order) which defines its standards, supervises professional ethics, and issues good practice in the services to be delivered. Medical professionals must comply with the requirements detailed in Article L 4111-1 of the FHPC:</p> |

- hold a diploma, certificate or other title recognised in France;
- have French nationality, Andorran citizenship or be a national of an EU Member State or a State that is a party to the Agreement on the European Economic Area, or Morocco or Tunisia;
- be enrolled with the Order of Physicians, the Order of Odontologist or the Order of Midwives.

The nationality criteria may be waived for professionals holding a certain degree of diploma, certificate or title as mentioned above.

Those who are not physicians, odontologists or midwives (eg, pharmacists, nurses, psychologists, nutritionists or other alternative health therapies providers) are not considered to be 'medical professionals' in France and therefore cannot undertake initiate telemedicine consultations but may participate in the presence of a medical professional.

11. Are there any specific education requirements or trainings that healthcare professionals need to meet or attend to provide telemedicine services?

No, as of 4 December 2022. Healthcare professionals do not need to meet or attend specific educational requirements or trainings other than those required to be qualified and continue to practice as such. In this respect, healthcare professionals must meet both initial and ongoing training requirements.

That being said, pursuant to Article R 6316-5 of the FHPC:

'Organisations and liberal health professionals who organise a telemedicine [or telecare] activity shall ensure that the health professionals and psychologists participating in telemedicine [or telecare] activities have the training and technical skills required to use the corresponding devices.'

In other words, liberal health professionals, who organise a telemedicine, must ensure that those who participate in have the training and skills required to use the telemedicine equipment and are able to deliver their services to the patient as if it's in-person.

Decree No 2022-1419 of 10 November 2022 (which is specific to students enrolled in hearing and speech therapy courses and higher education and research institutions) and an Order of 10 November 2022, both published in the *Official Journal of the French Republic* on 11 November 2022, now include e-health (including telemedicine) in their compulsory educational pathway. This landmark reform becomes compulsory as of September 2024 but may start being implemented 12 months earlier. This is based on an already adopted official frame of reference (*Référentiel*) on education/e-health of healthcare professionals, which includes a whole section on telemedicine and interactions between healthcare professionals and patients or care givers.

12. Is there any registration requirement applicable to physicians that provide telemedicine services?

There is no specific registration requirement applicable to physicians who provide telemedicine services. Generally speaking, physicians must be registered with the Order of Physicians and pay professional fees to be able to practice medicine, including telemedicine.

13. Please indicate whether special licenses or authorizations are mandatory for institutional healthcare providers engaged in telemedicine services.

There are no special mandatory licenses or authorisations for institutional healthcare providers engaged in telemedicine services. Telemedicine acts shall always be practiced through authorised healthcare professionals as mentioned above.

REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES

14. Are there specific requirements applicable to the telemedicine platform?

Under Article L 1470-5 of the FPHC, in order to guarantee the exchange, sharing, security and confidentiality of personal health data, digital health services, including telemedicine platforms, intended for use by, among other users, healthcare and medico-social establishments and professionals, must comply with the applicable interoperability and security frame of reference. This applies to the processing of such data, its storage and transmission by electronic means. This frame of reference shall be drawn up after consulting representatives of the health professions, approved health system user associations, health establishments, establishments and services in the medico-social and social sectors, and public and private operators involved in developing and publishing information systems and digital health services and tools. They have been approved by an order of the Minister of Health. The interoperability requirements mentioned above are based on open standards with a view to facilitating the extraction, sharing and processing of health data as part of the coordination of care pathways, the improvement of the quality of care and the efficiency of the health system; or, for the purposes of clinical research, whenever the use of these standards is deemed relevant and possible by the competent authorities.

Compliance of digital health services providers with this frame of reference shall be evaluated and certified under Article L 1470-6 of the FPHC.

Ethics will be added to the above frame of reference by the 2023 Health Insurance Financing Act.

In May 2019, the HAS also issued recommendations on teleconsultation and tele-expertise, stating that telemedicine platforms must comply with: (1) rules on IS security and confidentiality, in particular the EU Regulation on the protection of personal data (GDPR) and the French general policy on the security of health information systems (PGSSI-S) throughout the telemedicine process (data exchanged before, during and after telemedicine activity, as well as for archiving data); (2) traceability of exchanges (Art R 6316-4 of the FPHC); (3) quality of audio and/or video streams; (4) operation of the equipment; (5) equipment disinfection procedures; (6) availability of any additional medical equipment; and (6) procedures to be applied in case of technical problems.

The HAS also recommends: (1) the use of a communicating information system, which allows for the transfer of reports of telemedicine procedures onto the patient's shared medical record, in compliance with the interoperability framework for health information systems (CI-SIS); and (2) the enforcement of security measures including protecting access to the premises, securing the computer (automatic lock, password), managing authorisations, tracking access, and managing incidents.

In August 2021, the ANS published a frame of reference regarding the Health Information System or SIS (*System d'Information de Santé*) interoperability framework which established the functional specifications (<https://esante.gouv.fr/volet-tlm-telemedecine>).

The CNIL recommends implementing: (1) a strong authentication system to recognise users and give them the necessary access – among other measures, the CNIL recommends the use of passwords, smart cards, etc, provided there is a double authentication system in place; (2) a system for managing user authorisation for using the telemedicine system so as to limit access to data; (3) a system for managing traces and incidents; and (4) sending medical reports via a secure messaging system.

Moreover, French law imposes an 'HDS certification' on any provider hosting health data (HDS stands for *Hébergeur de données de santé*, ie, a certified hosting services provider). The hosting of personal health data is strictly regulated, including by Articles L 1111-8, R. 1111-8-8 and R. 1111-9 of the FPHC.

During the Covid-19 pandemic, a self-declaration form was set up for platforms offering telemedicine solutions. The Ministry of Health has listed the solutions available in telehealth, as well as the functionalities offered and the level of security guaranteed. This list was drawn up following a self-declaration by the solution publishers to assist professionals in their choice of a digital tools and may be completed on the basis of proposals from the publishers. As of 4 December 2022, the extension of this mechanism is not in force and telemedicine platforms, in themselves, do not need to be self-declared.

However, the 2023 Health Insurance Financing Act includes a new Title VIII in the FPHC about teleconsultation platforms under which:

- Teleconsultation platforms shall be approved, and based on this approval they may request for the reimbursement of medical acts performed by their salaried physicians;
- Teleconsultation platforms may only be approved if:
 1. They operate in the form of a commercial company and their purpose, on an exclusive or non-exclusive basis, is to offer medical teleconsultations;
 2. They are not under the control of a natural or legal person carrying out the activity of supplier, distributor or manufacturer of medicinal products, medical devices or in vitro diagnostic medical devices, with the exception of devices allowing the performance of a teleconsultation act;
 3. Their digital tools and services comply with the rules relating to the protection of personal data;
 4. Their digital tools and services comply with the rules relating to the protection of personal data, within the meaning of Regulation (EU) No 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (GDPR) as well as the applicable frame of reference mentioned in Article L 1470-5 of the FPHC (the procedures for verifying compliance with the interoperability standards defined under the conditions of Article L 1470-6 of the FPHC).

Teleconsultation platforms with several salaried physicians shall have a medical board, to be filled with representatives of patients. The board is responsible for supervising the activity, the adoption of quality and security of care improvement plans and physicians' consistent continued training. They shall have an action plan for ensuring compliance with the platform's regulatory obligations, monitoring indicators, a report on the enforcement of which shall be submitted to the National Order of Physicians and the Ministry of Health on an annual basis.

The list of digital services platforms being certified for their compliance to the above-mentioned security, interoperability (and now ethics) frame of reference shall be made public.

When not complying with the applicable frame of reference, or not holding a certificate of compliance, a teleconsultation platform provider (more generally a digital services provider) may be sanctioned by fines, the amount of which, depending on the seriousness of the breach, is up to one per cent of the provider's turnover excluding VAT made in France by the platform provider during the previous year, up to a maximum of €1m.

Last, the 2023 Health Insurance Financing Act announces the adoption of specific codes of conduct with which teleconsultation platforms with several salaried physicians must comply.

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| <p>15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?</p> |
| <p>Subject to our other comments (including the responses to questions 14 and 21), there are no other legal requirements regarding electronic equipment and internet speed for telemedicine services. However, further to HAS recommendations, telemedicine platforms, in accordance with the general policy on the security of health information systems (PGSSI-S), must ensure the quality of the audio and/or video streams throughout the process - data exchanged upstream, during and after the telemedicine act, as well as for data archiving, which implies in particular a good internet connection.</p> |
| <p>16. Does the legislation provide for specific rules concerning patients' medical records?</p> |
| <p>The medical professional, pharmacist or paramedic involved in telehealth shall enter the following information into the patient's file and, where applicable, the shared medical file and where appropriate the medical record defined in Article R 6316-4 of the FPHC: (1) report on the performance of the telemedicine act or telehealth activity; (2) the acts and prescriptions carried out in the context of the telemedicine act or the telecare activity; (3) their identity and possibly the identities of other professionals participating in the telemedicine act or telecare activity; (4) the date and time of the telemedicine act or telecare activity; and (5) where applicable, the technical incidents that occurred during the telemedicine or telecare activity.</p> |
| <p>17. Are there geographic location requirements applicable to the provision of telemedicine services?</p> |
| <p>No territorial condition is required for tele-expertise or telemonitoring. But there are geographic location requirements for teleconsultation.</p> <p>More particularly, the territoriality of response to a patient's request for care, through the use of teleconsultation, is a general condition for health insurance coverage. It applies to both teleconsultations organised on the referral of the attending physician or those proposed by the 'coordinated territorial organisations'.</p> <p>In practice, the teleconsulting physician must be located near the patient's home. However, the proximity is not clearly defined under French law and is assessed on a case-by-case basis depending on the number of patients for a given physician in each region. This proximity makes it possible to ensure regular monitoring of a patient's state of health and to organise a face-to-face consultation if, at the end of the teleconsultation, this proves necessary.</p> <p>Teleconsultation shall alternate with in-person consultation on a regular basis.</p> <p>However, in order to improve access to care for all, there are exceptions to this condition. The territoriality requirement does not apply to patients residing in the most sparse areas in terms of medical care supply, that is, in the so-called 'priority intervention zones' (known as ZIPs or <i>zone d'intervention prioritaire</i>). This is provided that: (1) to tele-consult a general practitioner, the patient does not have an attending physician (<i>médecin traitant</i>) and there is no coordinated territorial organisation in the patient's area of residence; and (2) to tele-consult a specialist practitioner, there is no coordinated territorial organisation in the patient's area of residence.</p> |
| <p>18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?</p> |
| <p>Under article R 6316-2 of the FPHC, the appropriateness of using telemedicine or telecare is first assessed by the medical professional, pharmacist or paramedic. Once this assessment has been confirmed, telemedicine procedures must be carried out with the free and informed consent of the patient, in accordance with the provisions of articles L 1111-2 to L 1111-4 of the FPHC, which more generally apply to medical acts. Such consent may be withdrawn by the patient.</p> |

Please note the difference between 'consent' as intended in the context of telemedicine (or a medical act in general) and 'consent' under the GDPR. The first 'consent' acts as a safeguard, while the second is a legal basis in the context of personal data processing.

19. Is there any other important requirement that should be highlighted?

No, with the exception that other more detailed specifications apply in relation to the topics mentioned in this survey for France.

DATA PRIVACY ASPECTS

20. Are there data privacy issues should be considered for the exploitation of such market? If your answer is positive, please provide a short description.

Yes, data privacy issues should be considered for the exploitation of the telemedicine market.

Within the scope of telemedicine, health data is protected by medical secrecy and may only be shared among the healthcare team subject to patient consent. Beyond this principle, the healthcare professional or establishment using telemedicine shall in principle be deemed a data controller unless the context requires otherwise. GDPR, the French DPA No 78-17 of 6 January 1978 as modified, and related guidelines, as well as case law, shall be complied with in full. Among others, this implies that:

- when data processing resulting from a telemedicine activity is likely to result in a high risk to the rights and freedoms of natural persons, prior to the processing the controller shall carry out an impact analysis of the envisaged processing operations on persona data protection (DPIA);
- a data processing register must be established or completed with references to the telemedicine activity-related data processing;
- data processing agreements must be signed with data processors, including certified personal data hosting services providers, etc.

21. Does the applicable regulation provide for criteria and requirements for the security systems to protect the patient's information?

No, French law on telemedicine does not, in itself, entail any specific criteria or requirements for security systems to protect patient information. However, some more general requirements apply to the security of Health Information Systems (or SIS). See above comments regarding the obligation for telemedicine platforms to be approved and comply with a specified security and interoperability (and now ethics) frame of reference according to Article L1470-5 of the FPHC.

Under Article R6316-6 of the FPHC, health organisations and professionals using information and communication technologies for telemedicine or telecare activities, as far as they are concerned, must ensure that the use of these technologies complies with the required interoperability and security frame of reference.

Under Article L 1470-2 of the FPHC, health organisations and professionals using digital health services must identify themselves through a specific procedure following a frame of reference published by an Order of 28 March 2022. This electronic identification is based on means, material or immaterial, which guarantees an appropriate level of security and the protection of personal data processed by the digital health service concerned. The same identification requirement applies to patients using the service, as patients have their own frame of reference, also dated 28 March 2022. The above-mentioned health organisations and professionals must also be registered in the health repository managed by the public organisation controlling the enforcement of the above frame of reference (Art L 1470-4 of the FPHC). A health organisation or professional may be sanctioned for using a digital services provider not properly certified for its compliance with the applicable security, interoperability (and now ethics) frame of reference.

The HAS's 2019 recommendations about teleconsultation and tele-expertise provide that telemedicine platforms shall comply with the rules on computer security and confidentiality, in particular the GDPR and the general policy on the security of health information systems (PGSSI-S) throughout the telemedicine process (ie, data exchanged before, during and after teleconsultation, as well as for archiving data). The CNIL also recommends the use of a strong authentication system enabling the recognition of users and providing them with necessary access or to manage user authorisations or traces and incidents, and to send medical reports via a secure messaging system.

In addition, all public or private organisations that host or operate health information systems or carry out backups on behalf of a health establishment or a third party must be HDS certified.

See also the response to Question 14, above.

22. Does the applicable regulation provide for requirements for the transfer of information abroad?

When interpreted as a transfer from one professional to another one located within or outside the medical team, the rules are that the circulation of telemedicine medical data is possible within the medical team constituted around the patient, to which the patient may object. Patient consent shall be required for a transmission outside of the medical team (Art L 1110-4 of the FPHC).

When taken in the sense of an international transfer of data, the GDPR has expanded the possibilities of using pre-existing transfer instruments and introduced new transfer tools.

Depending on the situation, transfers outside the European Economic Area may for example take place based on the following tools:

An adequacy decision

The effect of such a decision is that personal data may be transferred from the EU to a third country without any further safeguard being necessary in addition to GDPR core requirements. In other words, transfers are then considered to be intra-EU transmissions of data. The following countries benefit from an adequacy decision: Andorra, Argentina, Canada (commercial organisations), Faroe Islands, Guernsey, Israel, the Isle of Man, Japan, Jersey, New Zealand, Switzerland, Argentina, South Korea, the United Kingdom under the GDPR and the LED, and Uruguay.

Until 16 July 2020, the United States were considered as providing an adequacy protection of personal data when US organisations were committing to comply with the so-called Privacy Shield mechanism as established by common agreement between the EU and the US in 2016. However, the Privacy Shield was invalidated by the European Court of Justice on 16 July 2020, and is therefore no longer available (judgment C-311/18).

The European Commission and the US Government have started negotiations on a successor arrangement to the EU-US Privacy Shield to comply with the judgement of the Court. An informal agreement was formed in March 2022 and negotiations continue. On 7 October 2022, the US took the next step in achieving a new EU adequacy decision in their favour: President Biden signed an Executive Order which laid out the steps the US will take to implement its commitments under the GDPR.

Regarding Switzerland, the European Commission had planned to review this adequacy decision but this review has been postponed. To date, we do not have any further information

about the revision of the 2000 adequacy decision in favour of Switzerland and it may therefore be deemed as still available to secure personal data flows between the EU and Switzerland.

Canada is itself modifying its legislation to come closer to GDPR requirements in view of the adequacy decision future revision.

An agreement or arrangement

Such agreements or arrangements contain appropriate data protection safeguards (Art 46 GDPR), including any of the following instruments.

STANDARD CONTRACTUAL CLAUSES (SCCs).

It is up to the exporter and importer of data to assess in practice whether the third country's legislation allows for the level of protection required by EU law and the safeguards provided by the SCCs. On 4 June 2021, the European Commission issued modernised standard contractual clauses for data transfers from controllers or processors in the EU/EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU/EEA (and not subject to the GDPR).

BINDING CORPORATE RULES (BCRs)

These rules are defined as data protection policies adhered to by companies established in the EU for transfers of personal data outside of the EU within a group of undertakings or enterprises.

CERTIFICATION MECHANISM

As referred to in Articles 42 and 43 of the GDPR, certification may also be an efficient tool to secure transfers of personal data (as provided by Art 46 (2) (f) of the GDPR). In this respect, the European Data Protection Board (EDPB) has published new guidelines 07/2022 on certification as a tool for transfers, which was submitted for opinion until 30 September 2022 (https://edpb.europa.eu/our-work-tools/documents/public-consultations/2022/guidelines-072022-certification-tool-transfers_en). A final version of these guidelines will be available soon. Europrivacy is the first and now unique EU data protection certification mechanism (and label) to have been approved by the EDPB (on 1 October 2022).

CODES OF CONDUCT

Article 40 of the GDPR outlines a possibility for actors to elaborate codes of conduct for the effective implementation of the GDPR in specific sectors or for specific processing activities, including international transfers. Codes of conduct are not compulsory but constitute potential tools that can be used to promote compliance. The competent data protection authority (in France, the CNIL), to which the code owner shall submit the draft code for validation, must determine whether this code fulfils the admissibility criteria before proceeding, with a subsequent approval of the EDPB. Except for the cloud computing market, none have been adopted so far by the CNIL or the EDPB, including none relating to telemedicine.

23. Is there any registration of databases requirement that companies must observe? Are there requirements regarding the recording of data in the patient's medical records?

As detailed in the response to Question 16, medical professionals, pharmacists or paramedics involved in telehealth shall enter a given list of information into the patient's file and, where applicable, in the shared medical file and where appropriate the medical record.

The patient's electronic file referred to in Article L 1111-14 of the FPHC is now integrated into the patient's digital health space. The digital health space (*Mon Espace Santé* or 'My Health

Space' for each patient) is opened automatically, and each professional, whatever his method or place of practice, must report the required data in the patient's shared medical file, at the time of each act or consultation, including the diagnostic and therapeutic elements necessary for the coordination of care (Art L 1111-15). The patient owning this 'Health Space' may access it by using the electronic identification means made available to them by the health insurance fund, or by any other electronic means of identification likely to guarantee their authentication (Art R 1111-32 of the FPHC).

A patient may give temporary or permanent authorisation to a professional, health institution or social or medico-social institution or service to access their digital space (Art R 1111-32 of the FPHC). They may also access the list of professionals who have access to their shared medical file. This can be modified by the patient, at any time. They can also note any traces of access to their file (Art L 1111-19 of the FPHC).

According to Art R 1112-7 of the FPHC, patients' medical records may be retained by physicians and health care institutions for 20 years.

LIABILITIES

24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.

Healthcare professionals must comply with several obligations, the violation of which may result in liabilities:

- Failure to comply with medical secrecy is punishable by civil, criminal and professional sanctions.
- Except in cases where their liability is incurred due to a defect in a health product, health professionals, as well as any establishment, service or organisation in which individual acts of prevention, diagnosis or care are carried out, are only liable for the harmful consequences of acts of prevention, diagnosis or care, in the event of fault. The above-mentioned establishments, services and organisations are also liable for damages resulting from nosocomial infections, unless they can prove a foreign cause. In line with the above, a no-fault liability regime applies to health professionals or health establishments, bound by an obligation of safety-result, for the safety default of any telemedicine equipment assimilated to a medical device (L 1142-1 I of the FPHC).
- In brief, when the liability of a professional, an establishment, a service or a body mentioned above, or a producer of products is not engaged, a medical accident, an iatrogenic condition or a nosocomial infection gives rise to the right to compensation under the national health insurance scheme. This percentage, which may not exceed 25 per cent, is determined by the decree which contains the full terms of liability. (L 1142-1 II of the FPHC)

Liability is shared between healthcare institutions and healthcare professionals as follows:

- Public health institutions are responsible for the organisation of care and therefore, as such, for any harmful consequences of telemedicine.
- If the requesting doctor (the one who performs the telemedicine) or the requested doctor (the one who designates the requesting doctor to the patient) is a salaried employee, the health establishment will be responsible for the telemedicine's harmful consequences on a patient with whom it has concluded a care contract.
- The private physician practicing telemedicine is in a contractual relationship with their patient and is therefore responsible for any harmful consequences. This may be a joint liability in the event of dual fault between the requesting and requested physicians.
- Regarding physicians from public health institutions and doctors from private health institutions or private practitioners, the projected scenario is that of a co-diagnosis and/or

co-prescription by two doctors whose legal status differs. The situation will vary depending on whether the physician requested or requesting the service is an employee of the private establishment. However, the applicable legal rules remain those set out above, with the possibility of a joint liability for the parties involved.

For tele-expertise, the requested physician is responsible for the diagnosis they make with regard to the information provided by their colleague. The local 'requesting' physician is responsible for the information collected and transmitted, for the information given to the patient, and for the final decision on therapeutic choice.

If following a tele-expertise or tele-consultation, a patient suffers from harm directly related to an error in the expertise of the requesting physician, the requested physician may be held liable in tort. For this, the patient will have to prove that the requested physician gave the requesting physician erroneous medical information which directly and definitely caused them such damage.

If the diagnostic error constitutes a common fault, the judge will declare the requesting physician or institution and the requested physician or institution jointly and individually liable.

TELEMEDICINE NUMBERS AND TRENDS

25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?

Telemedicine data and statistics are regularly published in France. For instance, in collaboration with the polling institute Odoxa, the ANS published in January, September and October 2020, three 'Telemedicine barometers', which show that telemedicine is now more widely used and accepted. Each of these surveys was carried out with a sample of 2,000 to 3,000 French people and 500 health professionals and covered specific periods, including the post Covid-19 crisis period.

The outcome of the latest polling findings are as follows:

Regarding patients

- patients have used teleconsultation three times more over a one-year period;
- 73 per cent of French people have a favourable opinion of telemedicine (the figure only stood at 60 per cent in 2019);
- 88 per cent of French people who have used teleconsultation, have enjoyed the experience;
- 92 per cent of French people are now aware of teleconsultation.

Regarding health professionals

- there has been a six-fold increase in the use of teleconsultation by general practitioners;
- 64 per cent of doctors no see teleconsultation as part of their professional routine;
- nearly 91 teleconsultations were carried out on average by doctors offering this practice.

26. What are the perspectives and trends in relation to the matter for the next few years? Please outline any unresolved issues, proposed changes or trends for the telemedicine sector and briefly indicate how these may foreseeably affect medical practice in the near future.

A recent key development has been the ending of the ETAPES programme (*Experimentations de Télémédecine pour l'Amélioration des Parcours en Santé*). This programme encouraged and financial support the deployment of telemonitoring projects throughout French territory. Article 54 of the Health Insurance Financing Act of 2018 had renewed the ETAPES experimentation for a four-year period (ie, until 2022). The experiments concerned five pathologies: (1) heart failure;

(2) renal failure; (3) respiratory insufficiency; (4) diabetes; and (5) implantable cardiac prostheses.

The ETAPES experiments ended on 1 July 2022, with Article 36 of the Health Insurance Financing Act for 2022 providing transitional financing between ETAPES and the common law system, including:

- a date of entry into force of remote monitoring in common law by 1 July 2022 at the latest (but which was postponed until 2023);
- transitional funding was to take over until 31 December 2022, provided that applications for registration under common law had been submitted by the sector;
- in any event, remote monitoring has now entered into common law of the reimbursement of medical acts by the Health Insurance pursuant to Decree No 2022-1767 of 30 December 2022.

Telemedicine is now well anchored in the French healthcare system and developing steadily, having a greater impact on how healthcare is delivered. More transparency and stricter security, interoperability and ethics requirements are now about to be applied through the new approval and certification of teleconsultation platforms. Apart from new trends of 'augmented' telemedicine are arriving on the scene, such as the further use of IoT and AI, including social robots, the creation of new professional actors contributing to telemedicine delivery (including digital referents being physically close to the patient), the development of platforms as a service (PaaS) and a greater inclusion of telemedicine services in private health insurance policies. Healthcare professionals will also be urged to and trained for the enhanced use of telemedicine and more generally e-health in the next few years. These tendencies are all the more plausible as France is facing a steadily increasing medical wasteland phenomenon, which leaves a number of patients insufficiently taken care of.