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PROPOSALS ON POSSIBLE FUTURE CDCJ ACTIVITIES

(Agenda item 5)

Document prepared by the secretariat
Directorate General of Human Rights and Rule of Law – DGI

CONTEXT AND ACTION EXPECTED:

The CDCJ Bureau (at its 122nd meeting on 20-21 March 2025) proposed possible topics for future activities of the Committee, which was further discussed by the CDCJ at plenary at its 104th plenary meeting (16-18 June 2025). These topics included medical liability, which was the object of a conference organised by the CDCJ in 2008; maintaining trust in public institutions by providing safeguards for public officials; and the connection between justice (civil, commercial and administrative law) and economic growth.

The secretariat has prepared proposals for the possible future work of the committee on medical liability and safeguarding democratic institutions and public service, based on these discussions, provided in the document below.

The Bureau is invited to examine the proposals contained in the document and to advise the committee in view of their examination at the next CDCJ Plenary (18-20 November 2025).

POSSIBLE FUTURE WORK ON MEDICAL LIABILITY

I. Background

1. Medical liability is the civil responsibility of healthcare actors (professionals, institutions, platforms, manufacturers) for patient harm. Classical claims require: (i) breach of the standard of care or of patient-rights duties (e.g. informed consent), (ii) damage, and (iii) a causal link - generally to be established by the patient. Some states complement or replace fault-based tort with strict/no-fault schemes.

2. Across the Council of Europe member states, the legal landscape is highly fragmented: some states rely on classic fault-based tort, others supplement or replace it with no-fault insurance funds. New pressures - telemedicine, Artificial Intelligence (AI) decision support, cross-border care, data-driven harm and pandemic emergency schemes - present challenges that have not been addressed by any international standards or legal instruments yet.

3. The CDCJ has previously dealt with this issue, and relevant research and preparations were made at the time. A Comparative Study (CDCJ (2005) 3 rev1), led by Prof. Herman Nys and entitled *"Medical Liability in Europe"*, mapped national liability rules and exposed long-standing difficulties such as proving causation, diverse damage heads, insurance crises and the spread of defensive medicine.[1] The study still offers a solid analysis and bibliography that could be updated in case of need.

4. The Group of Scientist Experts on Medical Liability (CJ-S-MED), an ad hoc group set up under the authority of the CDCJ, was established in 2008 and tasked with organising a multilateral seminar, drafting a questionnaire and suggesting follow-up action. The Group confirmed the importance of four core themes (concepts and burden of proof; informed consent and damage; remedies including alternative dispute resolution (ADR) or no-fault; financing and insurance), approved the questionnaire and identified national focal points. Following the seminar, the CJ-S-MED advised to draft a legal instrument or compile good-practice guidance. The CDCJ decided however to postpone this activity owing to a lack of available funds at the time.[2]

[1] Positive defensive medicine corresponds to a situation where many tests are ordered to cover all possible risks, including remote ones. Negative defensive medicine describes situations where higher-risks patients are refused.

[2] CDCJ 85th meeting (11-14 October 2010) meeting report CDCJ(2010), paragraph 50.

5. This four-theme matrix, also followed for the programme of the seminar, would appear to be still relevant as a basis for any new Council of Europe text, and the list of national focal points could simplify an update of the situation in member states. Transversal cooperation with relevant bodies of the Council of Europe will also be important, in particular the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO).

II. Overview of international standards

A. Relevant Council of Europe and other international standards

6. The international legal framework offers a series of legally binding and soft-law instruments that together outline the basic configurations of civil liability for patient harm.

7. At the human-rights level, the Council of Europe Convention on Human Rights and Biomedicine (ETS No. 164), known as the Oviedo Convention, makes liability a rights issue. Article 24 guarantees every person "fair compensation" for undue damage resulting from an intervention, ensuring that redress is not merely a matter of domestic tort law but a treaty obligation. The Oviedo Convention sets out a civil-remedy principle for medical harm across its Parties. The Oviedo Convention is the only binding treaty that explicitly anchors a civil-liability right in biomedical care. The authorities should ensure that an effective civil remedy exists and courts should apply domestic rules to make a compensation right effective.

8. The case law of the European Court of Human Rights in respect of Articles 2 and 8 of the European Convection on Human Rights reinforce the duty to secure effective civil remedies.[3]

9. For product-related harm, the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (CETS No. 211), known as the MEDICRIME Convention, obliges states to provide compensation to victims of falsified or sub-standard medical products. Article 19 (c) states that "Parties must provide, in [their] domestic law, for the right of victims to compensation from the perpetrators." Article 18 obliges states to secure the supply chain (quality, safe distribution), creating compliance duties that courts can treat as evidence of negligence if breached. The MEDICRIME Convention fills a gap that classic malpractice law misses, i.e. harm caused by sub-standard or falsified products, which becomes especially important as supply chains globalise. A future CDCJ legal instrument could incorporate some of the duties of the MEDICRIME Convention (secure distribution, victim compensation), placing them in a specific civil-liability context, ensuring patients have both criminal law and tort/insurance avenues.

10. When an injury claim crosses borders, the Convention of 2 July 2019 on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters of the Hague Conference on Private International Law (HCCH) offers the possibility of enforcement. Article 1(1) makes the treaty applicable to "the recognition and enforcement of judgments in civil or commercial matters" and Article 4(1) requires Contracting States to recognise foreign judgments unless a limited refusal ground applies.[4] Once ratified by more states, including by more of the Council of Europe members, it will become easier to enforce cross-border claims, addressing the issues of mutual recognition of medical malpractice judgements and settlements, facilitate establishing standardised certificates to support the enforcement. A

[3] *Calvelli and Ciglio v. Italy [GC]*, application no 32967/96, judgment of 17 January 2002; *Vo v. France [GC]*, application no 53924/00, judgement of 8 July 2004; *Šilih v. Slovenia [GC]*, application no. 71463/01, judgment of 9 April 2009; Lopes de Sousa Fernandes v. Portugal [GC], application no 56080/13, judgment of 19 December 2017; *K.H. and Others v. Slovakia*, application no. 32881/04, final judgement of 6 November 2009; *Csoma v. Romania*, application no. 8759/05, final judgement of 15 April 2013.

[4] Outline of the Convention, available at: https://assets.hcch.net/docs/36b240ac-8228-481d-a33b-3716baf4c656.pdf

CDCJ legal instrument could support the ratification of this convention, and further elaborate on the use of Hague certificates in medical-injury cases, especially telemedicine disputes.

B. European Union standards

11. Within the European Union (EU) substantive and procedural rules already outline possible liability outcomes:

- Directive 2011/24/EU on cross-border healthcare obliges EU member states to ensure professional-liability insurance (or an equivalent guarantee) and to inform incoming patients about redress pathways. Article 4(2)(d) stipulates that EU member sStates must ensure "systems of professional liability insurance or a comparable guarantee" for providers treating incoming EU patients.

- The Medical Devices and In Vitro Diagnostic Regulations (2017/745 and 2017/746) require manufacturers to hold adequate financial coverage and make regulatory non-compliance strong evidence in any civil claim. In accordance with Article 10(11), manufacturers must ensure that every device is accompanied by information on residual risks and must have "sufficient financial coverage" for potential liability. A breach of these duties feeds into product-defect findings and gives patients another target (manufacturer, importer) if the clinician is not at fault.

- Finally, the Rome II Regulation (864/2007) informs courts about which national law governs a cross-border tort, defaulting to the place where the damage occurs. Article 4.1 defined that law of the place where the damage occurs governs a non-contractual claim. This intends to give predictability for cross-border telemedicine cases.[5]

12. These EU instruments set relevant rules in connection with medical liability which are applicable to EU member states. Any new Council of Europe work should therefore aim to complement these rules and extend their implementation to all Council of Europe member states. Some gaps can be identified which could usefully be plugged, for example fault-based standards of care, evidentiary presumptions, ADR or no-fault models.

III. Proposals for possible future activities

13. Considering the time that has elapsed since the first consideration of medical liability, the CDCJ could consider an updated comparative study of the situation in Europe pertaining to medical liability to take on board developments since the publication of the previous study some 20 years ago. The development of telemedicine and AI, including issues of compensation in connection with digital health, as well as cross-border care and data harm situations would need to be addressed. In the light of the results of this updated study, if deemed necessary, a new seminar on medical liability in Europe could be considered to reassess any developments impacting liability issues identified in the updated comparative study, involving experts from different relevant areas such as from the CDBIO. The results of the updated study – and a possible new seminar – could inform the decision of the CDCJ on any subsequent standards or tools to be developed and what areas they should cover.

14. Without prejudice to the results of this refreshed assessment, it is worth noting that the topics previously identified included the burden of proof, compensation, cross-border liability, and ADR. However, the increasing use of AI and telemedicine have added complexity that will need to be factored in. By way of example, the CDCJ could consider preparing a recommendation or guidelines on medical liability with a focus on compensation. Such a

[5] Telemedicine/telehealth cases are disputes that arise from delivering healthcare at a distance (video, phone, chat, remote monitoring, AI triage platforms, etc.). Telemedicine disputes commonly are patient against provider, provider against platform, insurer against provider, or state against platform.

recommendation could provide member states with guidance on civil liability and compensation pathways, integrating traditional issues (proof, damages, ADR) and new ones (telemedicine, AI, data incidents).[6] A more practical tool could also be contemplated which could delve into a variety of aspects, including digital cases (how to secure medical records, teleconsultation logs, AI model versions used, etc), telemedicine disputes (mediation clauses, online platforms).

[6] The scope and possible topics could cover the issues already identified in 2007 such as grounds of liability (fault, strict/product, vicarious, platform liability); causation and burden-of-proof tools (presumptions, loss of chance, evidence preservation for AI/software logs); remedies and damages (economic/non-economic, periodic payments); ADR/no-fault schemes; interaction with tort claims; insurance and financial security (minimum coverage, cross-border telehealth); as well as cross-border law, jurisdiction and enforcement.

POSSIBLE FUTURE WORK ON SAFEGUARDING DEMOCRATIC INSTITUTIONS AND CIVIL SERVICE

I. Democratic Backsliding

1. In the opening words to his annual report, the Secretary General describes the current situation as a "perfect storm" of war, disinformation and democratic backsliding that "threatens to undo the peace, stability and hard-won progress" achieved since 1949. His predecessor, Marija Pejčinović Burić, linked the Reykjavík Declaration adopted on the occasion of the 4th summit of Heads of State and Government (16-17 May 2023) to the need to "address democratic backsliding in many parts of the continent" and in her annual report of 2023 she explicitly called on member states "to reverse democratic backsliding in Europe".

2. The trend of democratic backsliding has also been reported by independent research institutes. By way of example, the World Justice Project's Rule of Law Index 2024 shows a global decline of their indicators for the seventh consecutive year. In addition, several research initiatives point to attacks on the "institutional state", such as mass dismissals of officials, introduction of politicised civil service laws and politically-motivated removals.[7]

3. In May 2025, the Secretary General launched the New Democratic Pact for Europe as a roadmap designed to reverse democratic backsliding and rebuild public trust in democracy and the rule of law. It translates the Reykjavík Summit's Principles for Democratic" into concrete action lines for member states and Council of Europe bodies.

4. The Pact envisages its work under three interconnected pillars:
   - Learning and Practising Democracy - civic and digital-media education, youth participation, dialogue across political, cultural and generational divides.
   - Protecting Democracy - safeguarding judicial independence, electoral integrity, media pluralism, and fighting corruption and disinformation to guarantee "democratic security."
   - Innovating for Democracy - using AI and other technologies, deliberative processes and hackathons to broaden participation and make institutions more agile.

5. The Pact commits the Council of Europe to further enhance and strengthen new monitoring tools (e.g. a Transition-Risk Barometer) in order to spot early signs of institutional capture, targeted capacity-building and peer-review for member states, as well as partnerships and funding linking Council of Europe and external donors' assistance to measurable rule of law benchmarks.

6. Possible future work of the CDCJ for the protection of public administration and agents in the context of democratic backsliding could contribute to the implementation of the Pact, in particular its second pilar.

II. Existing Council of Europe legal standards relevant to institutional integrity

7. The Council of Europe's existing instruments already outline how an apolitical, professional and resilient public administration should function and the safeguards that should be in place to avoid attacks on their independence. Several existing legal instruments are particularly relevant when the executive of the day seeks to capture, hollow-out or politicise public institutions.

8. Recommendation CM/Rec(2000)6 on the Status of Public Officials in Europe was prepared by the CDCJ and is of direct relevance when discussing the issues of merit and

[7] Indicators and dashboards on the current state of democracy include: Freedom House, *Freedom in the World 2025* (annual scores, narrative on elected leaders undermining checks); World Justice Project, *Rule of Law Index 2024*.

tenure for civil servants. Importantly the introduction to the recommendation underlines that "the establishment and consolidation of democratic institutions require a public administration that complies with the rule of law, is neutral and is loyal to the democratic institutions and is respectful of the people it serves". According to this recommendation, member states should ensure "recruitment … based on merit, fair and open competition and an absence of discrimination" (Article 4). Once appointed, officials may be dismissed only "in the cases and for the reasons provided for by law", with a legal remedy to contest any termination (Article 16). The recommendation also lists duties which include respect for the rule of law, loyalty to the democratic institutions, neutrality, impartiality, respect for the public and accountability" (Article 13). These standards provide safeguards against which large-scale and/or biased dismissals of public officials together with politicised recruitments and appointments of public officials.

9. Recommendation CM/Rec(2000)10 – Model Code of Conduct for Public Officials was prepared by a working group of the former Multidisciplinary Group on Corruption (GMC) in consultation with the CDCJ. It deals with the issues of integrity and conflicts of interest and the monitoring of its implementation was entrusted to the Group of States against Corruption (GRECO), which it did as part of its second evaluation round initiated in 2003. According to Article 5, every official should "serve loyally the lawfully constituted authority", whilst Article 8 tackles conflicts of interest, and Article 19 underlines that behaviour must "preserve public confidence and trust" in the administration.

10. Recommendation CM/Rec(2007)7 on Good Administration was prepared by the CDCJ and served as the main reference point for the handbook "The administration and You". Its appendix contains the Code of Good Administration which sets out a number of principles which are paramount for the proper delivery of public service by administrative authorities. It enshrines legality (Article 2), equality (Article 3) and impartiality (Article 4, subparagraphs 1 - 4) and provide for internal remedy followed by judicial review (Articles 22 - 24). Also of relevance, it requires transparency and access to documents (Article 10).

11. Recommendation CM/Rec(2014)7 on the Protection of Whistleblowers was also drafted under the responsibility of the CDCJ. It builds on the Civil Law Convention on Corruption (ETS No. 174), also prepared under the authority of the CDCJ, whose Article 9 provides that "each Party shall provide in its internal law for appropriate protection against any unjustified sanction for employees who have reasonable grounds to suspect corruption and who report in good faith their suspicion to responsible persons or authorities". Falls under the term "corruption" such situations as conflicts of interest, cronyism and nepotism, which can be relevant for politically biased recruitments and appointments. Recommendation CM/Rec (2014)7 goes further with Principles 15 to 17 which call on employers to establish internal reporting procedures, whilst Principle 21 guarantees protection "against retaliation of any form" – including dismissal and transfers - for anyone who raises a public-interest concern. The establishment of such safeguards can prove particularly important in cases where attempts are made to politicise recruitments and appointments in public authorities, hence reducing independence and impartiality in the delivery of public service.

12. The Convention on Access to Official Documents (CETS No. 205, the Tromsø Convention) confers a general right of everyone to obtain official documents (Article 2); limitations must be "necessary in a democratic society" and proportionate (Article 3). Treating access to official document as a right of the public may also serve to limit risks of attempts to conceal or erase administrative records, for instance during political transitions, which could reveal a politicisation of the administrative authorities.

13. Recommendation CM/Rec(2019)6 on the Development of the Ombudsman Institution promotes the setting up of an independent oversight body that can respond to situations where public administration does not fulfil its role to serve public interest and can be challenged for it before an ombudsperson. Such an oversight is also a way of detecting political capture of public administration. Principle I-1 requires an ombudsman to be "directly and easily

accessible to everyone"; Principle I-2 calls for a strong legal basis, preferably constitutional, that guarantees independence and adequate resources; Principle I-3 prescribes a transparent, merit-based appointment.

III. Proposals for possible future activities

14. The abovementioned instruments lay down standards that enable the proper functioning of a public administration that complies with the rule of law, including the requirement of neutrality. They place obligations on the authorities of member states to provide the right conditions for that, which is of particular relevance against a backdrop of democratic backsliding.

15. The CDCJ may consider organising a conference, involving other committees (in particular, the Steering Committee on Democracy, CDDEM) to identify challenges and ways to improve the protection of public administration and officials against politicisation which impacts their composition and the delivery of public service.

16. Alternatively, or as a follow-up to this conference, the CDCJ may also consider:

- consolidating the most relevant principles spread out across those different instruments, whilst also taking into account the findings of bodies such as GRECO and the European Commission for Democracy through Law (Venice Commission) Such work could lead to the adoption of guidelines on the resilience of public administration through enhanced protection of the status of public officials; or

- reviewing and updating Recommendation CM/Rec(2000)6 on the Status of Public Officials in Europe and Recommendation CM/Rec(2007)7 on Good Administration, which appear to be of particular relevance in the rapidly evolving context, also taking into account that both instruments were adopted more than 18 years ago.

17. Any future work in the area would take as reference point the Reykjavík Principles for Democracy adopted at the 4th Summit of Heads of State and Government of the Council of Europe to counter democratic backsliding. Given this context, such work would imply co-ordination with the CDDEM.