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| From: | Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director |
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| To: | General Secretariat of the Council |
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| Subject: | ANNEX to the REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare |

Delegations will find attached the annex of document COM(2022) 210 final (annex1).

Encl.: COM(2022) 210 final (annex1)



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COM(2022) 210 final

ANNEX

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to the

**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND
THE COUNCIL**

**on the operation of Directive 2011/24/EU on the application of patients' rights in cross-
border healthcare**

{SWD(2022) 200 final}

ANNEX

Follow-up actions to enhance the implementation of the Directive

| | Objectives | Actions | Indicative Timeline |
|---|--|--|----------------------|
| <i>Better implementation of patients' rights to cross-border healthcare</i> | | | |
| 1 | Reduce & simplify administrative procedures for access to cross-border healthcare | <ul style="list-style-type: none"> - Organise (new) bi-lateral dialogues with those Member States to investigate the proportionality of administrative procedures and where healthcare treatments requiring prior authorisation do not ensure legal certainty - Exchange of practices between Member States on streamlining procedures to access cross-border healthcare through digitalisation - Proposal for Regulation to create a European Health Data Space to scale up the e-health digital service infrastructure, including the use and electronic exchange of health data, to support the continuity of care for cross-border patients | 2022-2023 |
| 2 | Reduce financial risk to patients | <ul style="list-style-type: none"> - Exchange of practices between Member States on the transparency of prices for cross-border patients and on the estimated level of reimbursement (with a view to extend the voluntary prior notification system applied by eight Member States) | 2023 |
| 3 | Improve information to patients, raise awareness of patients' rights to cross-border healthcare, including recognition of | <ul style="list-style-type: none"> - Support knowledge and capacity-building workshop with the NCPs to improve information to patients - Promote and monitor implementation of the guiding principles on information provision on cross-border healthcare and the multi-lingual Manual for Patients | 2022 On-going |

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| | prescriptions | <ul style="list-style-type: none"> - Encourage all NCPs to make available information on the European Reference Networks and ensure their websites are accessible for people with disabilities - Organize an awareness-raising event at EU level on patients' rights to cross-border healthcare with the participation of Member States, National Contact Points, patient organisations, health insurers, health professionals, ERNs, and regional stakeholders in cross-border healthcare - Continue cooperation with Member States to increase the interoperability of electronic health services, including e-prescriptions, to improve mutual recognition of prescriptions | <p>On-going</p> <p>2023</p> <p>on-going</p> |
| 4 | Clarify the relationship between the Directive and the Social Security Coordination Regulations | <ul style="list-style-type: none"> - Update 2012 guidance note on the Directive and Regulation 883/2004 with the Administrative Commission of Member States - Organise workshop with the National Contact Points on updated guidance on the interplay between the Directive and Regulation with participation of patient organisations | 2023-2024 |
| <i>Strengthen European cooperation in cross-border healthcare: safeguarding the sustainability of the European Reference Networks</i> | | | |
| 5 | Improve integration of ERNs into national health systems | <ul style="list-style-type: none"> - Launch new Joint Action on the ERNs' integration into national healthcare systems - Support open-source development to create a new version of the Clinical Patient Management System (CPMS) to ensure the interoperability with and easy customisation of national IT systems | <p>2023-2026</p> <p>2022-2023</p> |
| 6 | Assess the potential mechanism (s) for reimbursement of healthcare providers for virtual expert panels consultations | <ul style="list-style-type: none"> - Support pilot schemes for the partial reimbursement of CPMS panel costs as part of ERN grants funded by the EU4Health Programme - Support the identification of other potential options for the reimbursement mechanisms at EU and national level and the development of corresponding guidelines/recommendations as part of the Joint Action on | <p>2022-2023</p> <p>2023-2026</p> |

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| | | ERN integration into national healthcare systems. | |
| 7 | Improve the IT infrastructure, including for ERN virtual expert panel consultations | <ul style="list-style-type: none"> - Support the development of a new version of the Clinical Patient Management System (including a mobile version), taking into account the lessons learnt over the last four years and users' feedback - Support the ERNs in the deployment of the new version of the Clinical Patient Management System once available - Develop and deploy the new virtual ERN Academy, a new IT tool to host and support the dissemination of all the knowledge and training materials generated by the 24 ERNs | <p>2022-2023</p> <p>2023-2024</p> <p>2022</p> |
| 8 | Simplify administrative burden related to EU funding for ERNs via the EU4Health Programme | <ul style="list-style-type: none"> - Streamline the current diverse EU funding support into single ERN direct grants, subject to the appropriate budget being available from the EU4Health programme - Conduct a study on the feasibility of and framework for the financial simplification to be introduced in the ERN direct grants - Introduce <i>Financing Not Linked to Cost or Simplified Cost Options</i> to the new ERN direct grants based on the above study results and subject to EU4Health programme funding | <p>2023</p> <p>2022</p> <p>2023</p> |
| <i>Strengthen European cooperation in cross-border healthcare: cross-border regional cooperation in healthcare</i> | | | |
| 9 | Strengthen regional cooperation in cross-border healthcare | <ul style="list-style-type: none"> - Encourage Member States to use funding from the Interreg programme, the Technical Support Instrument and the ERDF in order to cooperate and coordinate in the development of strategic approaches, implementation of reforms and Smart Specialisation Partnerships in healthcare across borders - Support the exchange and replication of best practices between Member | <p>On-going</p> <p>2023-2024</p> |

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| | | <p>States with funding from the EU4Health programme</p> <ul style="list-style-type: none"> - Promote the use of B-solutions project¹ which provides specialised technical support to address legal and administrative border obstacles - Promote and raise awareness of NCPs at regional level by sign-posting on websites of cross-border regional healthcare platforms and projects - Encourage Member States and regional stakeholders to collect data to monitor patient flows to better understand the extent of cross-border healthcare in the border regions | <p>On-going</p> <p>2022</p> |
| Strengthen monitoring and enforcement | | | |
| 10 | Improve data reporting on cross-border healthcare | <ul style="list-style-type: none"> - Produce a multi-lingual manual on questionnaire to improve consistency of Member State data collection on patient mobility - Bi-lateral dialogues with MS to find solutions to improve data completeness and robustness as required by the Directive (article 20) | <p>2022</p> <p>On-going</p> |
| 11. | Make full use of the current legal framework for cross-border healthcare | <ul style="list-style-type: none"> - Structured bi-lateral dialogues with Member States to achieve best possible transposition of the Directive (see actions on disproportionate administrative procedures) - Enforcement actions in cases of non-compliance (currently infringement cases pending against three MS on lower reimbursement rates) - Review the applicability of existing EU legislation to telemedicine services² | <p>On-going</p> <p>On-going</p> <p>2024</p> |

¹ <https://www.b-solutionsproject.com/>

² <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52012SC0414>