

# POLICY MAPPING ON EHEALTH POLICIES AND INITIATIVES (INCLUDING ON CANCER CARE) IN **BULGARIA**

This Country Factsheet was prepared for the eCAN Joint Action. It is prefilled with publicly available information and was sent for review to country experts on eHealth and cancer care. The Country Factsheet serves as the basis for the preparation of an overview of eCAN relevant policies and initiatives in all EU and EEA countries.

**eCAN** is a Joint Action (JA) of 16 partners in EU-Member States on 'Strengthening eHealth including telemedicine and remote monitoring for health care systems for cancer prevention and care'. eCAN aims to bring the benefits of eHealth to all citizens and patients across EU-Member States (MS) focusing on cancer prevention and care. There is a need to harmonize telemedicine regulations and to explore the efficacy of teleconsultation programs and telemonitoring in the cancer field.

This country factsheet has been pre-filled with publicly available information and pre-reviewed by

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The country factsheet includes chapters on:

- **1 definitions**
- 2 governance
- **3 strategies/policies**
- **4** legislation
- 5 cancer specific eHealth solutions

## Any questions? - Please get in touch via <u>ecan@goeg.at</u>.





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## **1 DEFINITIONS**

Table 1 : Deviations in the use of international definitions for eHealth terms - Bulgaria

| Term         | Definition   | Deviation  |
|--------------|--|--|
| eHealth      | The WHO defines eHealth as « the use of information and communication technologies (ICT) for health ». It also says that « eHealth is the transfer of health resources and healthcare by electronic means. » <sup>1</sup>  | No deviation from<br>definition; Defined only in<br>one publicly available<br>document. <sup>2</sup> |
| mHealth      | « Mobile health (mHealth) is defined by the World Health Organization's (WHO)<br>Global Observatory for eHealth as « medical and public health practice supported<br>by mobile devices, such as mobile phones, patient monitoring devices, personal<br>digital assistants (PDAs), and other wireless devices ». <sup>3</sup>   | No deviation from<br>definition. Not officially<br>defined.  |
| dHealth      | The EU defines digital health (dHealth) and care as referring to « tools and services that use information and communication technologies (ICTs) to improve prevention, diagnosis, treatment, monitoring and management of health-related issues and to monitor and manage lifestyle-habits that impact health ». <sup>4</sup><br>The WHO defines digital health as « the field of knowledge and practice associated with the development and use of digital technologies to improve health. Digital health expands the concept of eHealth to include digital consumers, with a wider range of smart-devices and connected equipment. It also encompasses other uses of digital technologies for health such as the Internet of things, artificial intelligence, big data and robotics. » <sup>5</sup> | No deviation from<br>definition. Not officially<br>defined.  |
| telehealth   | The WHO defines telehealth broader than telemedicine « as it includes computer-<br>assisted telecommunications to support management, surveillance, literature and<br>access to medical knowledge. » <sup>6</sup>  | No deviation from<br>definition. Not officially<br>defined.  |
| telemedicine | The EU Commission defines telemedicine as follows (EU Commission definition, COM(2008)689) : « Telemedicine is the provision of health care services, through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves the secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients. » <sup>7</sup>  | No deviation from<br>definition. Not officially<br>defined.  |

<sup>&</sup>lt;sup>1</sup> <u>6. eHealth, Factsheet for European Parliament (who.int)</u>

<sup>&</sup>lt;sup>2</sup> <u>E - e-health - Електронно здравеопазване | Министерство на транспорта и съобщенията (government.bg)</u>

<sup>&</sup>lt;sup>3</sup> World Health Organization *Frequently asked questions on Global Task Force on digital health for TB and its work.* [2017-02-27]. <u>http://www.who.int/tb/areas-of-work/digital-health/faq/en/ webcite.</u> In mHealth Assessment: Conceptualization of a Global Framework - PMC (nih.gov)

<sup>&</sup>lt;sup>4</sup> Events - Smart4Health

<sup>&</sup>lt;sup>5</sup> Digital health EURO (who.int)

<sup>&</sup>lt;sup>6</sup> <u>Telehealth – DigitalHealthEurope</u>

<sup>&</sup>lt;sup>7</sup> <u>Telemedicine – DigitalHealthEurope</u>



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| Term             | Definition   | Deviation   |
|------------------|--|---|
| teleconsultation | PAHO describes teleconsultation (also sometimes referred to as remote consultation or telehealth), as « interactions that happen between a clinician and a patient for the purpose of providing diagnostic or therapeutic advice through electronic means. » <sup>8</sup>  | No deviation from<br>definition. Not officially<br>defined. |
| health app       | Essén et al. 2022 define health apps as « a computer program or software application (designed to run on a mobile device) "intended to be used specifically for managing, maintaining, or improving the health of individual persons, or the delivery of care" (ISO <u>https://www.iso.org/standard/78182.html</u> (2021), p 5). » | No deviation from<br>definition. Not officially<br>defined. |

## **2 GOVERNANCE**

| Table 2 : | Overview | on | eHealth | governance - | Bulgaria |
|-----------|----------|----|---------|--------------|----------|
|           |          |    |         |              |          |

| Question  | Answer | Comments/Experience  |
|---|--------|--|
| Is there a Ministry or State Secretariat Yes <sup>9</sup> |        | The Ministry of Health <sup>10</sup> oversees the development and implementation |
| explicitly in charge of eHealth/dHealth? If so,           |        | of eHealth initiatives in Bulgaria, including electronic health records, e-      |
| which Ministry?   |        | Recipe (e-Rx) and other digital health solutions.                                |
| Does the Ministry who oversees health care                | Yes    | The Ministry of Health in Bulgaria has a dedicated department                    |
| also have a specific Department or Unit in                |        | responsible for eHealth. The department is called the "International             |
| charge of eHealth/dHealth                                 |        | Projects and e-Health Directorate" and is responsible for developing and         |
|   |        | implementing eHealth policies and programs in the country. <sup>11</sup> It      |
|   |        | coordinates the preparation, updating and implementation of an e-                |
|   |        | healthcare strategy as part of the overall e-governance strategy,                |
|   |        | including in relation to the implementation of the measures for                  |
|   |        | secondary budget managers to the Minister. It is responsible for                 |
|   |        | integrating the systems and services in the ministry to the central e-           |
|   |        | government systems.  |
| Is there a national eHealth governance board?             | No     | No further information available.  |
| Is there a public eHealth agency such as Elga             | No     | No eHealth agency is in place, but the Ministry of Health maintains the          |
| GmbH in Austria or ANS in France? At which                |        | National Health Information System (NHIS), which provides centralized            |
| level (national, regional)? Which functions               |        | management and storage of information on electronic referrals and                |
| does this agency cover?                                   |        | electronic prescriptions. The programs' interfaces and nomenclature for          |
|   |        | information exchange between the software of medical care contractors,           |
|   |        | pharmacies and NHIS are updated on an ongoing basis in accordance                |
|   |        | with the stages of construction and implementation of new                        |
|   |        | functionalities in NHIS. <sup>12</sup>   |

<sup>&</sup>lt;sup>8</sup> https://www3.paho.org/ish/images/docs/covid-19-teleconsultations-en.pdf?ua=1

<sup>&</sup>lt;sup>9</sup> Електронно здравеопазване (government.bg)

<sup>&</sup>lt;sup>10</sup> <u>http://www.mh.government.bg</u>

<sup>&</sup>lt;sup>11</sup> <u>https://www.mh.government.bg/en/ministry/structure/</u>

<sup>12</sup> https://www.his.bg /bg/dev/specifications

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| Question  | Answer                     | Comments/Experience   |
|---|----------------------------|---|
| Are dHealth / eHealth tools in the outpatient<br>sector publicly paid or covered in your benefits<br>package (e.g. by sickness fund or national<br>health service). If yes, please describe how.                            | Yes,<br>some <sup>13</sup> | <ul> <li>The National Health Information System (NHIS)<sup>14</sup> covers all actors and major information flows in the healthcare sector to realize a "Minimum Viable Product" in relation to eHealth, which includes: <ul> <li>Electronic health record (patient file) with limited personal health information and accessible to the citizen only with e-signature issued by the National Revenue Agency;</li> <li>Electronic prescriptions (e-prescriptions);</li> <li>Electronic directions (e-directions);</li> </ul> </li> <li>The unified health information portal provides public information, medical statistics and access to public information from registers in the health sector.</li> </ul> |
| Are dHealth / eHealth tools in the inpatient<br>sector automatically covered in your benefits<br>package or do you need to pay extra (e.g. for<br>telehealth consultations or telereha)<br>compared to standard treatments? | No                         | There are only eHealth tools or solutions accessible and covered as out-<br>of-pocket service by patients. There is no legal instrument for<br>reimbursement and health insurance fund coverage of such eHealth<br>instruments.   |
| Are there any comprehensive cancer centres<br>focussing on eHealth or telehealth<br>treatments? If yes, which ones and for which<br>specific fields?  | No                         | There is no registered CCC for eHealth or telehealth in Bulgaria. Bulgaria<br>has the National Cancer Hospital together with BJCN and the Ministry of<br>Health and the Ministry of Innovations and Growth working on national<br>priorities for tele-oncology. In Bulgaria there is one private solution<br>registered as virtual Comprehensive Cancer Centre compliant with<br>GDPR and EHDS.   |

# **3 STRATEGIES/POLICIES**

| Question   | Answer  | Comments/Experience  |
|--|---------|--|
| Is there a national eHealth strategy?  | Yes     | The National Health Strategy 2020 refers to the development of<br>electronic health care in its policy 2.6 (page 89). <sup>15</sup><br>The Draft National Health Strategy 2030 refers to the<br>development of electronic healthcare and digitization of the<br>healthcare system in its policy 2.5 (page 58). <sup>16</sup> |
| If yes, which stakeholder groups have been included in drafting the national eHealth strategy?   | Several | Ministry of Health, Ministry of e-Governance, National Health<br>Insurance Fund. The related NGO's and Cluster organizations<br>with the capacity in the field of Medical Science or Digital Health<br>Innovations are not invited   included.   |
| Are there regional eHealth strategies? If so, can you<br>indicate whether in all regions or only some? Can you<br>provide some (exemplary) documents ? | Yes     | The regional municipalities' eHealth strategies in general are<br>following the centralized Governmental one. Burgas region<br>Municipality have introduced at the mid. 2023 simple,<br>synchronized telemedicine in outpatient segment.   |

<sup>13&</sup>lt;u>https://his.bg/ezdrave/</u>

<sup>&</sup>lt;sup>14</sup> <u>https://www.his.bg/bg/about</u>

<sup>&</sup>lt;sup>15</sup> https://www.mh.government.bg/media/filer\_public/2016/09/12/nzs\_2020.pdf

<sup>&</sup>lt;sup>16</sup> <u>Проект на Националната здравна стратегия 2030</u>

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| Question  | Answer            | Comments/Experience   |  |  |
|---|-------------------|---|--|--|
| If yes, which stakeholder groups have been included in drafting such regional strategy/ies?   |                   | Municipality of Burgas and General hospital for active treatment, Burgas.   |  |  |
| Are there strategy/ies explicitly referring to / including<br>eHealth cancer care?  | Yes               | Memorandum of Understanding (MoU) and Pact to Act signed on<br>the 15 December 2023 between the Bulgarian Joint Cancer<br>Network and Ministry of Health   Ministry of Innovations and<br>Growth of Republic Bulgaria. The MoU is addressed by the<br>Bulgarian Joint Cancer Network in partnership with National<br>Patient Organization, Digital Health and Innovation Cluster<br>Bulgaria and Junior Achievement Bulgaria. |  |  |
| If not, are there discussions ongoing to develop a national eHealth strategy?   | Yes               | A national tele-oncology strategy is under development with an<br>engaged working group including representatives of both<br>Ministries and engaged under the MoU Stakeholders.   |  |  |
| Is there a National Cancer Plan? And does it refer to eHealth?  | Yes <sup>17</sup> | The National Cancer Plan of the Republic of Bulgaria 2027 is available in Bulgarian. <sup>18</sup>  |  |  |
| In the light of the EU "Beating Cancer Plan" – are there<br>any recent plans to update or modify existing plans? If<br>yes, what is the timeline? | Yes               | The National Cancer Plan of the Republic of Bulgaria is under<br>update with concrete acts of international collaboration for<br>implementation of the strategic objectives, aligned with the<br>EBCP.  |  |  |
| Are there any indicators in eHealth policy or national programmes on cancer care measuring the progress of the use of eHealth in cancer care?     | No                | Such indicators are not yet implemented.  |  |  |
| Are there any other cancer care specific eHealth<br>initiatives, f.e. by other stakeholders than policy makers<br>/ public authorities?           | Yes               | The ' <i>Mission 3.0. Tele-oncology in the social triangle – science, technology, and policies</i> ' with MoU and Pact to Act is under implementation by Bulgarian Joint Cancer Network in collaboration with other stakeholders in health and innovations and the 1 <sup>st</sup> collaborative project regarding the next-generation telemedicine with AI prediction with SME is implemented.                               |  |  |

## **4 LEGISLATION**

| Question                                    | Answer Comments/Experience   |  |  |
|---|--|--|--|
| How would you evaluate the current state of | Bulgaria is significantly lagging in the implementation connected to the             |  |  |
| legislation of eHealth in your country in   | development of e-Healthcare legislative and administrative regulatory initiatives    |  |  |
| general?                                    | and supportive instruments in the country. The lack of institutional openness for    |  |  |
|   | collaboration and partnership with the non-governmental sector stops the             |  |  |
|   | implementation of the modern e-health, health-education and economic policies,       |  |  |
|   | and significantly slows down the development of national priorities under the        |  |  |
|   | National Recovery and Resilience Plan. This creates barriers for stimulation of the  |  |  |
|   | science and innovation in the direction of improving public health, particularly the |  |  |
|   | cancer care, developing sustainable systemic solutions.                              |  |  |

 <sup>&</sup>lt;sup>17</sup> <u>https://www.mh.government.bg/media/filer\_public/2023/01/10/23rh003pr.pdf</u>
 <sup>18</sup> <u>НАЦИОНАЛЕН ПЛАН ЗА БОРБА С РАКА В РЕПУБЛИКА БЪЛГАРИЯ 2027</u> and <u>Report on the basis of the analysis of data from the survey on National Cancer Control</u> Programmes/Cancer documents in EU (p. 21, 93)

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| Question   | Answer  | Comments/Experience   |  |
|--|---|---|--|
| Is there legislation on how to use telemedicine<br>in general?   | Yes   | Electronic health is an integral part of the implementation of electronic management policies, digital transformation of public institutions, improving the quality of administrative services, moving towards rational electronic processes in the public sector, and accessing information electronically through public institutions. The development of electronic health is part of the policy for the development of electronic management in the Republic of Bulgaria and the Law on Electronic Management, providing operational compatibility, standards, procedures, and technological means for their maintenance, construction, digitization, and development of basic registers and their integration, as well as providing reliability, network and information security, and shared resources for electronic management. <sup>19</sup> |  |
| Is there legislation explicitly referring to cancer prevention?  | Yes   | The cancer prevention policy is advocated as a strategic goal in The<br>National Cancer Plan of the Republic of Bulgaria adapted in July 2022<br>with no concrete national activities, excluding the International,<br>HORIZON EU programs engagement by the Bulgarian NGO's.   |  |
| Is there legislation explicitly referring to / including eHealth cancer care?  | No  | Such a legislative or policy activities are missing under the Bulgarian priorities in the healthcare sector.  |  |
| If yes, which of these legislation(s) do you<br>consider most important in the context of<br>eHealth and cancer care? And why?   | The rapid adaptation of legislative and administrative changes related to the introduction of regulatory acts that stimulate the e-Health, including telemedicine is key to addressing health care inequality compared to other EU countrie addressing the backlog, and driving the development of policies and solutions to accelerate access to care. The adaptation and implementation of best-EU practices in e-Health building bridges, the EHDS and AI Act under the national legislative provisions is critical element for the development of the Bulgarian vision and strategy in the healthcare, stimulating the competitiveness and collaboration between the public and private innovative sectors. |   |  |
| If no, are there any reasons or barriers to the<br>fact that there is no or only limited cancer<br>specific eHealth legislation (i.e., discussions<br>still ongoing, conflicting opinions or other). | The lack of political dialogue, concrete instruments for implementation of public partnership between and involving the Stakeholders' groups creates difficulties in the adoption of specific, cancer and e-Health related policies and strategies, or solutions as a proxy for in the development of such.   |   |  |
| What could be improved or would need to be<br>done to improve these legislation for eHealth<br>in cancer care in your country?   | European engagement based on and guided by common European values, building   |   |  |

<sup>&</sup>lt;sup>19</sup> See Draft National Health Strategy 2030 р. 58 <u>Проект на Националната здравна стратегия 2030</u>

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## **5 CANCER SPECIFIC EHEALTH SOLUTIONS**

Table 3 : Overview on cancer specific eHealth solutions in use – Bulgaria

| Area of<br>application/<br>type of<br>solutions | Login Websites              | Apps                        | Webinars                         | Multi-disciplinary teleconferences<br>(HCP-HPC)      | Teleconsultation<br>(HCP-patient) | Telemonitoring via<br>devices |
|---|-----------------------------|-----------------------------|----------------------------------|--|-----------------------------------|-------------------------------|
| Ecosystem                                       | Yes                         | Yes                         | Yes                              | Yes  | No                                | Yes                           |
|   | https://my.his.bg/          | https://superdoc.bg/        | Driven by Bulgarian Joint Cancer | Driven by Bulgarian Joint Cancer Network             | ONLY private, NO public           | In research and               |
|   | https://his.bg/erx/         | https://www.healee.com/     | Network and Digital Health and   | including onboarding of Bulgarian Physician          | infrastructure/tool provided      | development by SME's          |
|   |                             | <u>https://propa.health</u> | Innovations Cluster Bulgaria     | Union and the Union of General Practitioners in      | for teleconsultations in          |                               |
|   |                             |                             |                                  | Bulgaria   | general                           |                               |
| Prevention of                                   | Yes                         | No                          | Yes                              | Yes  | Yes                               | Yes                           |
| Cancer  | https://bjcn.bg             |                             | Bulgarian Joint Cancer Network   | Bulgarian Joint Cancer Network                       | https://propa.health              | Kelvin Health in breast       |
|   | https://cancercare.bg       |                             | The Association of Patients with |  |                                   | cancer Al-monitoring under    |
|   | https://www.credoweb.bg/    |                             | Oncology Diseases                |  |                                   | research                      |
| Treatment of                                    | Yes                         | Yes                         | Yes                              | Yes  | Yes                               | Yes                           |
| Cancer  | https://bjcn.bg             | www.findmecure.com          | Bulgarian Joint Cancer Network   | Bulgarian Joint Cancer Network                       | https://propa.health              | www.findmecure.com            |
|   | https://cancercare.bg       | https://sqilline.com        | The Association of Patients with | e-Guidelines and e-CME-O                             |                                   |                               |
|   | https://www.credoweb.bg/    | https://propa.health        | Oncology Diseases                | ( <u>https://eguidelines.more-darzalas.com/</u> ) by |                                   |                               |
|   | https://oncologos.eu/       |                             | https://www.credoweb.bg/         | Bulgarian Joint Cancer Network                       |                                   |                               |
|   | https://www.sbaloncology.bg |                             |                                  | https://oncologos.eu/                                |                                   |                               |
| 'Living with                                    | Yes                         | Yes                         | Yes                              | Yes  | Yes                               | No                            |
| cancer'   | https://npo.bg/             | https://propa.health        | https://npo.bg/                  | Bulgarian Joint Cancer Network Onco-                 | https://propa.health              |                               |
|   | https://cancercare.bg       |                             | https://cancercare.bg            | psychology webinars                                  |                                   |                               |
| Rehabilitation                                  | Yes                         | Yes                         | https://ednaot8.bg/              | Yes  | Yes                               | No                            |
| from Cancer                                     | https://npo.bg/             | https://propa.health        | https://oncobg.info/             | Bulgarian Joint Cancer Network                       | https://propa.health              |                               |
|   | https://cancercare.bg       |                             |                                  |  |                                   |                               |
|   | https://ednaot8.bg/         |                             |                                  |  |                                   |                               |
|   | https://oncobg.info/        |                             |                                  |  |                                   |                               |
| Palliative                                      | Yes                         | Yes                         | No                               | Yes  | Yes                               | No                            |
| Cancer Care                                     |                             | https://propa.health        |                                  | Bulgarian Joint Cancer Network                       | https://propa.health              |                               |



#### Table 4 : Number of eHealth solutions available and in use – Bulgaria

| Question  | Answer   | Comments/Experience   |  |  |
|---|--|---|--|--|
| How many eHealth solutions (in the sense of       | Yes  | There are two eHealth solutions in the sense of a medical device in             |  |  |
| medical devices and thus 'authority               |  | Bulgaria. <sup>20</sup> One private comprehensive cancer care e-Health solution |  |  |
| approved/certified') solutions are existing       |  | certified under the GDPR procedure ( <u>https://his.bg/ezdrave/</u> ) is not an |  |  |
| currently in your country in the context of       |  | eHealth solution but the national e-Health record system.                       |  |  |
| cancer care/treatment?                            |  |   |  |  |
| Is there a website or other information on        | Yes <sup>21</sup>  | There are NGO's activities and websites.  |  |  |
| solutions that are recommended to the public      |  |   |  |  |
| for use (e.g. a selection of health apps that are |  |   |  |  |
| recommended to cancer patients or in              |  |   |  |  |
| general)?   |  |   |  |  |
| Can you give an estimation on how the split       | 20/80  | 20% (if 20% is EHR!) to 80% in private.   |  |  |
| between private and public apps are               |  |   |  |  |
| available? Give an estimate percentage of         |  |   |  |  |
| public solutions.                                 |  |   |  |  |
| How can providers and patients assess if the      | No   | No further information available.   |  |  |
| apps are reliable? Is there a certification or    |  |   |  |  |
| quality approval procedure in place? If yes,      |  |   |  |  |
| which kind of procedure?                          |  |   |  |  |
| How many Health Care Providers use such           | The Governmental eHealth system is used by 100% of Bulgarian physicians. eHealth |   |  |  |
| solutions? Which sector uses rather which         | solutions such as monitoring apps and telemedical solutions are used at 20% in   |   |  |  |
| types of solutions?                               | outpatient GP's segment and less than 5% usage of telemedicine in inpatient /    |   |  |  |
|   | specialized care especially cancer care.   |   |  |  |

<sup>&</sup>lt;sup>20</sup> <u>https://his.bg/ezdrave/</u> and <u>https://propa.health</u>