

# "Europe's plan for beating cancer"

Opinion of the German Social Insurance dated May 31, 2021

The German Federal Pension Insurance (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) and the national associations for statutory health and longterm care insurance and the Social Insurance for Agriculture, Forestry and Horticulture have all joined forces to form the "German Social Insurance - European working group) in view of their common European policy interests.

The association represents the interests of its members vis-à-vis the bodies of the European Union (EU) as well as other European institutions and advises the relevant participants in the context of current legislative proposals and initiatives.

Health and long-term care insurance, pension insurance and accident insurance, being part of the statutory insurance system, provide effective protection against the consequences of major life risks.

# I. Preliminary remarks

The European Commission presented its Beating Cancer action plan<sup>1</sup> on February 3, 2021.

"Europe's Beating Cancer Plan" (hereinafter called: EU cancer plan) includes ten flagship initiatives and a wide range of other actions in the prevention, early detection, diagnosis and treatment areas as well as the quality of life for cancer patients and survivors. The action plan builds a bridge to the proposal for creating a European Health data space, which is expected at the end of 2021, and links itself to other European initiatives such as the pharmaceutical strategy, the "from farm-to-fork" strategy or the new strategic framework for health and safety at work expected in the second quarter of 2021.

German Social Insurance welcomes the fact that the European Commission wants to fight cancer holistically with its action plan. This opinion focuses on prevention, which should have a major impact on cancer. The early detection, drugs and

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<sup>&</sup>lt;sup>1</sup> COM(2021) 44 final



quality of life issues will also be addressed here. It complements German Social Insurance's statement regarding the roadmap for the EU cancer plan<sup>2</sup> announced on March 2, 2020.

# II. Comments

#### 1. Prevention

The European Commission considers prevention to be the most cost-effective long term cancer control strategy; as around 40 per cent of all cancer cases within the EU could be avoided through prevention.

# 1.1 Health literacy

The action plan includes updating the European Code for Cancer Control<sup>3</sup> and raising awareness of its contents among at least 80 per cent of the population by 2025. A new "Health literacy for cancer prevention and care" project will also be launched with regard to this.

#### German Social Insurance's evaluation

German Social Insurance welcomes the systematic increase in knowledge about cancer risks and protection. The European Code for Cancer Control ranges from risk prevention to the use of screening and prevention services and it is also a comprehensive recommendation aimed at each individual person. It is has to be formally adapted to include more recent developments, i.e. the recommendation about vaccinations against HPV (Human Papilloma Viruses) for boys.

German Social Insurance also welcomes the intention to develop and share best practices on health literacy in cancer prevention and care programmes. When they provide health-related information and health literacy, social insurance institutions can also play a role in further developing proven approaches. The latest knowledge about digital health literacy should be taken into consideration here and social insurance providers should also be involved<sup>4</sup>.

<sup>&</sup>lt;sup>2</sup> https://dsv-europa.de/lib/2020-03-02-DSV-Konsultation-Krebsplan final.pdf

<sup>&</sup>lt;sup>3</sup> https://cancer-code-europe.iarc.fr/index.php/de/

<sup>4</sup> https://www.aok-



# 1.2 A smoking-free Europe

Tobacco use is the leading cause of preventable cancer. The European Commission has set ambitious targets here. By 2040, less than five percent of the population should be using tobacco ("smoking-free generation"). The European legal framework will also be revised<sup>5</sup>. The European Commission has identified taxation of tobacco products, neutral single packs, abandoning the addition of flavourings and restricting sales promotions, etc., as levers that should be used here. The Council's recommendations for smoke-free environments issued in 2009 are to be extended to e-cigarettes and tobacco heaters and more smoke-free environments, including outdoor ones, are to be created.

#### German Social Insurance's evaluation

German Social Insurance welcomes the European Commission's intention to continue developing the legal framework in order to further reduce tobacco consumption. This supports German Social Insurance's behavioural prevention approaches.

According to the German Cancer Research Centre, the annual tobacco tax revenue of more than 14 billion euros collected in Germany is offset by about 80 billion euros being spent on corresponding disease costs. One third of this is borne by the healthcare system. Fiscal measures have already proven effective in the past<sup>6</sup>. Significant increases in tobacco taxes are an effective way to reduce tobacco consumption.

The European Commission also published its evaluation of the impact of excise duty rates on tobacco products last year. It concluded that member states could set ambitious public health targets through imposing high tax rates. However, this strategy has its limits when tobacco products can be sourced from other countries at significantly lower prices<sup>7</sup>.

Therefore German Social Insurance expressly welcomes:

<sup>&</sup>lt;sup>5</sup> <u>Tobacco Products Directive (2014/40/EU)</u>, <u>Rules on the manufacture</u>, <u>packaging and sale of tobacco products and the Tobacco Products Taxation Directive (2011/64/EU)</u>, <u>Legal framework for cross-border purchases of tobacco products by private individuals (2008/118/EC)</u>, <u>Council Recommendation on smoke-free environments</u>

<sup>&</sup>lt;sup>6</sup> See G+G 11-2018

<sup>&</sup>lt;sup>7</sup> https://ec.europa.eu/taxation customs/sites/taxation/files/10-02-2020-tobacco-taxation-report-summary de.pdf



- a complete ban on flavourings being used in tobacco products, the introduction of a neutral single packs as well as consistent action against advertising and sales promotions by the tobacco industry
- extensive use of legislative levers to increase tobacco taxes and extending taxation to include new types of tobacco and nicotine-containing products<sup>8</sup>
- extending and strengthening the Council's recommendation for more smoke-free environments, including outdoors.

# 1.3 Alcohol consumption

Cancer is the leading cause of alcohol-related deaths. A relative reduction in harmful alcohol consumption of at least ten per cent should be achieved by 2025 through:

- reviewing EU taxation legislation<sup>9</sup> and the cross-border purchasing of alcohol by individuals<sup>10</sup>
- reviewing the Audiovisual Media Services Directive (2010/13/EU)<sup>11</sup> with regard to commercial communications about alcoholic beverages
- reviewing existing promotional activities and introducing warnings on labels and packaging.

#### German Social Insurance's evaluation

German Social Insurance fully supports the aim of reducing harmful alcohol consumption. Alcohol causes cancer in almost 10,000 people in Germany every year and the general conditions favour risky consumption. Unlike tobacco advertising, there are few restrictions placed on advertising alcoholic beverages. Teenagers are allowed to buy beer and wine from the age of 16. Unlike tobacco, alcohol taxes have hardly been used to influence consumption over the last 30 years. One exception was the introduction of the "alcopop tax" in 2004, which led to a significant reduction in the demand for sweetened alcoholic beverages. When compared to other European countries, Germany is one of the countries with low alcohol taxes<sup>12</sup>.

<sup>&</sup>lt;sup>8</sup>"New types of tobacco products" is a new tobacco products category introduced under the Tobacco Products Directive. These products do not fall into any of the conventional tobacco product categories. E-cigarettes / shishas have already been categorised.

 $<sup>^9\,\</sup>underline{\text{https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:31992L0083\&from=de}}\\$ 

<sup>&</sup>lt;sup>10</sup> https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32008L0118

<sup>11</sup> https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32010L0013&from=DE



German Social Insurance welcomes the European Commission's intention to:

- revise legislation covering the purchasing of alcohol
- establish a framework for taxing alcoholic beverages that will provide a targeted health stimulus to member states
- set limits on sales promotions, giving priority to protecting children and youngsters

# 1.4 Nutrition and exercise

The risk of cancer increases due to an unhealthy diet and lack of exercise. Therefore, the European Commission intends to:

- reduce the content of carcinogenic pollutants in food and drinking water by setting maximum limits
- inform people about healthy foods, impose advertising restrictions on unhealthy products and have mandatory front-of-pack nutrition labelling
- impose tax measures for sweetened beverages and soft drinks will also be considered
- start the "HealthyLifestyle4All" campaign, which aims to promote physical activity, sport and a healthy diet, during the current year

#### German Social Insurance's evaluation

German Social Insurance welcomes the healthy food and better drinking water proposals. Today, products that have a high sugar, salt or fat content are often cheaper than healthy alternatives. At the same time, almost every fourth person in Germany is obese. A study on diet literacy in Germany showed that: more than half of the respondents had problems with questions about nutrition<sup>13</sup>. The 2021 study by the German Alliance for Non-communicable Diseases clearly highlighted the need for further action: children are seeing 15 commercials a day for unhealthy food. The number of such "unhealthy commercials" per hour has now increased by 29 per cent on TV.<sup>14</sup>

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<sup>13</sup> https://www.aok-

bv.de/imperia/md/aokbv/presse/pressemitteilungen/archiv/2020/pk food literacy studienb ericht 160620.pdf

<sup>14</sup> https://www.dank-



In Germany, the statutory health, pension and accident insurance funds have a wide range of offers for motivating their insured persons into adopting health-conscious behaviour and for helping employers promote health in the workplace. Action at EU level could support these social security efforts and it would be very welcome.

#### German Social Insurance:

- supports tax approaches that will make healthy food more attractively priced. The EU VAT system<sup>15</sup> also offers possibilities for applying differentiated VAT rates in addition to excise duties
- calls for the marketing and advertising of unhealthy products to be restricted and for their ban under the WHO European nutrient profile model in the event of the advertising of unhealthy products being aimed at children and youngsters<sup>16</sup>
- welcomes the HealthyLifetyle4All campaign, which will be especially aimed at people of low socio-economic status and disadvantaged groups without any stigmatisation.

#### 1.5 Exposure to pollutants and radiation in the workplace

German Social Insurance also focuses on the working environment. Their action plan addresses three areas in this context: the strategic framework for health and safety at work, the directive covering carcinogens and mutagens and reducing exposure to asbestos.

#### German Social Insurance's evaluation

German Social Insurance welcomes the European Commission's presentation of a strategic framework for health and safety at work. Cancer is prominently addressed in it.

Occupational cancers are one of the greatest challenges for occupational health screening and, in particular, follow-up screening. The classical methods for early diagnosis are frequently found to be insufficient for adequate early detection of new cancerous formations. The statutory accident insurance already offers follow-up screening services to their insured persons who were previously exposed to

<sup>15</sup> https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32006L0112&from=DE

<sup>&</sup>lt;sup>16</sup> https://www.euro.who.int/ data/assets/pdf file/0005/270716/Nutrient-children webnew.pdf



asbestos in order to detect any new cases of asbestos-associated malignant tumours at an early stage. New approaches can detect up to 50 per cent of such tumours up to one year before clinical diagnosis<sup>17</sup>. The legislative proposal to reduce workers' exposure to asbestos, announced for 2022, is earnestly awaited against this background.

The updating and expanding of the Carcinogens and Mutagens Directive to include acrylonitrile, nickel compounds and benzene will further enhance occupational health and safety. In this context, German Social Insurance proposes:

- initiating a process with member states to establish occupational health and safety limits, including a risk-based approach for non-threshold carcinogens, oriented to the German / Dutch scientific approach to developing exposure-risk relationships for non-threshold carcinogens
- developing an appropriate EU guideline for measuring binding and biological limits
- pursuing a socio-political consensus on the acceptability of cancer risks in the workplace irrespective of the substance.

The European Commission also intends to explore appropriate measures regarding exposure to ultraviolet radiation as a risk factor for melanoma (e.g. sunbeds). German Social Insurance supports this and draws attention to the fact that certain skin cancers can also be caused by work-related UV radiation from the sun over many years. There is still scope for research in this area. The same applies to risks arising from artificial radiation sources, e.g. welding equipment. Therefore, the European Commission should give appropriate priority to further research into work-related causes of cancer as part of its cancer mission.

# 1.6 Infection prevention

Vaccinations are among the most effective measures for preventing infectious diseases. The EU cancer plan calls for at least 90 per cent of the target group of girls in EU countries to be vaccinated against HPV by 2030 and for a significant increase in vaccinating boys.

### German Social Insurance's evaluation

In Germany, HPV vaccinating is usually carried out between the ages of 9 and 14

<sup>&</sup>lt;sup>17</sup> The IPA's Institute for Prevention and Occupational Medicine is currently researching biomarkers for the early detection of asbestos-related tumours of the pleura (mesotheliomas). 7/12



at the expense of the health insurance funds. The Standing Committee on Vaccination has recommended vaccinating as early as possible, not only for girls, but also for all boys of this age, since November 2018.

According to the Robert Koch Institute, the uptake of HPV vaccinating amongst girls needs to be improved<sup>18</sup>. About four years after it was included in the national immunisation calendar, only a good quarter of 15-year-old girls had received the vaccination. The rate had increased by about two to three per cent per year<sup>19</sup> during the following years, but the vaccinations were not always administered on time and in full (two vaccinations are needed in each case).

 German Social Insurance expressly supports the flagship initiative in the EU cancer plan. Implementing it will identify the barriers that lead to incomplete vaccinations or the refusal to have an HPV vaccination and counter strategies can then be developed.

# 2. Early detection

The structuring of the screening programmes is based on the Council's recommendation for organised, nationwide, quality-based screening programmes for breast, cervical and colon cancer from 2003<sup>20</sup>. 25 member states had implemented one or more screening programmes by 2020. However, there are major differences in terms of target group coverage within the EU. Therefore the European Commission intends to initially assess the exact implementation status and to keep abreast of the use and evaluation of cancer screening programmes through an updated cancer information system.

- a new cancer screening programme will be launched as a flagship initiative for early detection and screening for breast, cervical and colon cancer will be offered to 90 per cent of eligible people by 2025
- a proposal to update the Council's recommendations on cancer screening will be made by 2022 and further programmes for prostate, lung and stomach cancer will also be considered
- The guidelines, quality assurance systems and the European cancer information system will also be updated.

<sup>&</sup>lt;sup>18</sup> Robert Koch Institute, Epidemiological Bulletin 2020

<sup>&</sup>lt;sup>19</sup> No reliable statements can be made about boys because of the short observation period.

<sup>20</sup> https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32003H0878&from=EN 8/12



#### German Social Insurance's evaluation

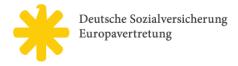
Germany is in the process of transforming its former, random cancer screening programmes into organised programmes with a personal invitation system as well as quality and outcome monitoring. Breast cancer screening for women aged 50 - 69 was introduced in 2005, followed by colon cancer screening for men aged 50 and over in 2019 and a cervical cancer screening programme for women aged 20 - 65 in early 2020. The personal invitations - in addition to the quality and success control features of the screening programmes - are issued by the health insurance companies for the last two programmes.

Population-based screening programmes can significantly improve the health of the population by enabling early intervention and reducing the severity and mortality of certain cancers and even the new incidence rate of some tumour types. However, this is only true if the programme is based on solid evidence that demonstrates sufficient benefits, meets high quality standards and is implemented effectively.

- German Social Insurance welcomes the fact that the EU4Health programme will provide funding for a new cancer screening programme to help reduce inequalities in the access to screening
- extending the screening programmes to other cancer types only seem
  justified if there is sufficient evidence of their benefits. Therefore, the
  development, validation and evaluation of evidence from new screening
  programmes is of huge importance when it comes to implementing the EU
  cancer plan.

# 3. Medicines

According to the European Commission, progress in cancer medicines is offset by significant inequalities in availability, high costs and the increasing shortages of cancer medicines. The EU cancer plan refers to the EU's pharmaceutical strategy, which describes initiatives for secure supply chains and responding to medicine shortages. Innovations should also be promoted, unmet needs should be met and treatments should remain affordable.



#### German Social Insurance's evaluation

Cancer medicines (oncologics) are amongst the top-selling medicines in Germany. Orphan medicinal products occupy a special position. 55 per cent of the daily doses of orphans are oncologics<sup>21</sup>.

Oncologics also represent the largest group of medicines among the annual new approvals with patent protection. Patent-protected medicines are usually 12.5 times more expensive than non-patented medicines. Therefore, the forthcoming review of the regulatory framework for medicines must be carried out from the perspective of the financial sustainability of health systems and take into account the high prices of medicines. In particular, combination therapies of personalised medicine in the oncology sector show the urgent need for reforming the pricing regulations.

In the case of a high unmet medical needs, manufacturers can already place medicinal products on the market under the accelerated marketing authorisation procedure if their efficacy and safety have not yet been sufficiently proven. Since 2011, the percentage of accelerated marketing authorisations issued by the European Medicines Agency (EMA) has increased from 8 to 27 per cent. At the same time, the highest prices are demanded for these medicines with little evidence at the time that they were approved.

# German Social Insurance:

- demands that the costs of research and development of medicines be made transparent in the future so that they can be taken into account in pricing and reimbursement decisions. Donations, research results from publicly funded institutions and government funding that contributes to the development and production of medicines should also be disclosed.
- Data about treatment results and the side effects of medicinal products with accelerated approval must be collected from the time of market launch and transferred into a European level independent indications register in order to enable the shared, comparative use of this data.

For orphan medicinal products, the German Social Insurance proposes that:

 therapeutic areas that continue to have a high unmet medical need be clearly defined

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 $<sup>^{21}</sup>$  Figures according to Ulrich Schwabe, et al., Medication report 2019 10/12



- only those medicinal products, which genuinely added value and are aimed at meeting an unmet should be promoted as orphan medicinal products in future
- the market exclusivity system should be replaced by an incentive system of targeted vouchers to reduce wrong incentives<sup>22</sup>
- in principle, prevalence measuring should be carried out across all authorised indications and "orphaning" due to bio-markers should be counteracted
- funding bodies should also be involved in an early dialogue between the EMA and the HTA authorities<sup>23</sup> in which medicines should be considered for the accelerated approval and which evidence level should be achieved before marketing authorisation.

Supply bottlenecks can also be seen in oncological care. However, the reporting processes in this respect are inconsistent and subject to uncertainties. German Social Insurance also suggests that:

- manufacturers and wholesalers keep larger quantities of active pharmaceutical ingredients or medicinal products available than before
- a common, digital report be established as an early warning system for stocks so that bottlenecks can be better managed
- such reporting be made mandatory at all levels of trade and EU-wide criteria and deadlines be established for this purpose
- violations of the reporting requirements should be sanctioned

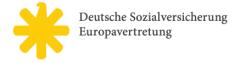
# 4. Improving the quality of life

The EU cancer plan aims to help cancer survivors live not only a long but also a good life after the disease. Oncological rehabilitation is an important instrument for this. It supports coming-to-terms with the illness and promotes reintegration into working life or the restoration of independence with the aim of living independently at home.

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<sup>&</sup>lt;sup>22</sup> also applies to paediatric medicinal products

<sup>&</sup>lt;sup>23</sup> National authorities or institutions involved in HTA (Health Technology Assessment). 11/12



#### German Social Insurance:

- stresses the need for good access to rehabilitation measures for those affected and especially for children. This corresponds with the WHO's efforts to strengthen the importance of rehabilitation
- welcomes the intention to specifically promote retraining and continuing education programmes for reintegrating cancer survivors into the labour market.
- supports the study on return to work planned for 2022, which will draw up proposals on how member states' employment and social policy measures can be usefully supplemented.