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PHARMIG
Verband der pharmazeutischen Industrie Österreichs

# Personalised medicine in oncology

In Austria there are about 350,000 people living with cancer and more than 40,000 people are newly diagnosed every year. Cancer is the second most common cause of death after cardiovascular diseases[1].

In its latest "Comparator Report on Cancer in Europe 2019", the Swedish Institute of Health Economics (IHE) reports a 50% increase in cancer incidence between 1995 and 2018, mainly due to an ageing population and better diagnostics[2]. Cancer research and innovative diagnostic and therapeutic measures in clinical routine have improved 5-year survival rates for cancer patients across Europe, especially in the employable age groups under 65. Cancer mortality has increased by 20% between 1995 and 2018.

Costs of cancer treatment in Austria remain constant at around 6.4% measured as a proportion of total health care expenditure, despite significantly higher incidence rates and longer treatment periods (see 2014: 6.5%[3]). There is a clear correlation between the level of expenditure on cancer care and treatment outcomes or survival rates: The higher the investment in innovation-oriented cancer care, the better the prognosis for cancer patients.

## Industry is a pioneer of personalised medicine in oncology

Personalised medicine is an integral part of Oncology. We understand it to mean the interaction of state-of-the-art diagnostic solutions and targeted or precise cancer therapies to enable patients to achieve better treatment success and a better quality of life.

The first targeted cancer drugs were approved more than 20 years ago. Technological developments and a high level of research have further advanced the possibilities of personalised medicine. Today, more than 70 targeted therapies are available in Europe[4]. In recent years, approximately 10 new cancer therapies have been approved each year. One milestone in this development is a novel therapy that targets a specific gene fusion in the tumour, regardless of where the cancer is located in the body. Up to now, cancer therapies have been specified for a particular form of cancer or organ (e.g. breast cancer or lung cancer). Personalised medicine is increasingly looking at the genetic fingerprint of the cancer.

The rapid developments of personalised medicine in oncology bring new opportunities and challenges. The latter can only be addressed by patients, physicians, health care providers, decision-makers in politics and industry together.

[1] Statistics Austria, Austrian Cancer Registry (as of 19 December 2018) and causes of death statistics, URL: https://www.statistik.at/web_de/statistiken/menschen_und_gesellschaft/gesundheit/krebserkrankungen/120148.html, visited 25.10.2019
[2] Comparator Report on cancer in Europe 2019 – disease burden, costs, and access to medicines, IHE 07/2019
[3] Comparator Report on patient access to cancer medicines in Europe revisited 2014, IHE 04/2016
[4] Drugs authorised in Germany for personalised medicine, https://www.vfa.de/de/arzneimittel-forschung/datenbanken-zuarzneimitteln/individualisierte-medizin.html?sort=MedikamentName#listmedikamentepersonalisiert-90747, access 04.07.2019

## The industry's position on personalised medicine in oncology

Many countries around the world have already launched programs or initiatives between public and private institutions for the use of personalised medicine. In Austria, personalised medicine in oncology must become a central topic of health policy. The pharmaceutical industry is prepared to participate in this as a partner at the federal and state level.

To further improve the level of personalised cancer care in Austria, broad access to diagnostic and therapeutic innovations in clinical routine is necessary.

Personalised medicine starts with precise diagnostics. This requires high-quality, certified, and validated diagnostic tests according to the latest state of the art. The pharmaceutical industry stands behind the EU regulations for medical devices and in-vitro diagnostics that have come into force[5].

Personalised medicine will require broad access to “molecular guided cancer therapies” and real-world-data management. For this purpose, a program was developed in the Netherlands which, based on high-quality diagnostics, enables patients to access targeted therapies even outside the approval status and thereby ensures funding. The findings are collected, documented, and made publicly available in a structured manner in order to support regulatory bodies during approval procedures[6]. Precisely because Austria wants to continue to maintain state-of-the-art cancer care for patients in the future, more commitment to personalised medicine is needed in health policy.

This also requires a discussion on new funding models for these therapies. In this context, purely economic considerations must not negatively affect the level of cancer care. New funding models must be developed jointly, and this - without reservation - for the benefit of cancer patients in Austria. The pharmaceutical industry, together with hospital and social insurance carriers, wants to make the far-reaching benefits of these therapies more clearly visible and work on a correspondingly robust and high-quality real-world-data basis.

Access to clinical research is also particularly relevant for cancer patients. Here, the pharmaceutical industry is and remains a reliable partner for all cancer research institutions in Austria.

[5] Regulation EU 2017/745 and 746
[6] D. L. van der Velden et al, The Drug Rediscovery Protocol, Nature volume 574, pages 127-131(2019)

## Industry demands for personalised cancer care for patients and relatives in Austria

1. Personalised medicine in oncology must be anchored as a central topic in health policy. The industry is an active and reliable partner and is willing to participate in pilot projects and reform plans.
2. Implementation of the EU regulations for medical devices and in-vitro diagnostics, which have already come into force, so that cancer patients have unrestricted access to high-quality, state-of-the-art diagnostics (Regulation EU 2017/745 and 746)
3. Inclusion of state-of-the-art molecular tumour profile analyses in the laboratory catalogue and in the performance-oriented hospital financing system (leistungsorientiertes Krankenanstalten-finanzierungssystem, LKF system).
4. The current high level of cancer care must not be endangered by purely economic considerations or financing issues[7]. Cancer patients have the right to receive personalised state-of-the-art at any time and at any place, regardless in which federal state in Austria they life and where they are insured as well as cancer care centre where patients are treated and approval status of innovative therapy.[8] [9]
5. Consistent implementation of digitisation in the health care sector and the introduction of a digital molecular open access cancer registry for all oncological centres and institutions in Austria. Only in this way, personalised medicine in oncology can enable its full potential for every cancer patient.
6. Joint development of new sustainable funding models that include diagnostic services as well as molecular guided treatment options and enable a robust exchange of data and insights between hospital and insurance carriers, cancer centres and industry.

## Our word is our bond: pilot projects in cooperation with the industry

The pharmaceutical industry is an active and reliable partner. We have a high interest in participating in pilot projects with public authorities and health care institutions. We are always available to our partners in politics and administration for the exchange of ideas and for project ideas.

[7] M. Mayrhofer „Das rechtliche gebotene Niveau der Arzneimittelversorgung in Krankenanstalten“ in RdM Manz Verlag 2019/5, S. 9 - 12
[8] G. Bachinger & ML Plank "Off label Use von Arzneimitteln" in RdM Manz Verlag 2008/5, S. 21-27
[9] M. Sieb & St. Strasser "Rechtliche Situation von Off Label Use bis Heilversuch" in Springer Verlag 06/2009 Wiener Klinisches Magazin, S. 20-24