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Sino-EU and Sino-German Cooperation in Health

*How to Unleash the Health Care Sector's Full
Potential for Health and Wealth*



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Key Recommendations

The health sector is increasingly becoming a focus of political and public attention, and not only since SARS-CoV-2 and COVID-19. Megatrends such as an aging society, a growing number of diseases including cardiovascular disease, cancer, and diabetes, and the need to ensure the long-term financial sustainability of health care systems have made it urgent for the international community and policy makers to act. All United Nations member states have placed such important social needs at the core of the global sustainability agenda and made health the number three goal of all the UN Sustainable Development Goals.

Moreover, the health sector has always been an important economic driver. Europe's health care industries are crucial contributors to health, innovation, and productivity. The industries' investments in research and production lead to highly paid employment for highly skilled professionals, sophisticated products, and tax revenues. In 2018 in Germany, for example, the health sector was responsible for 12 percent of gross value added and employed over seven million people¹. Its capacity for innovation has created novel preventive, diagnostic, and treatment options for patients, and generated for society above average growth rates of 5.2 percent². In some fields, up to 13 percent of companies' turnover is reinvested in innovation³. Thus, investments in the health care sector can also help to mitigate the global recession, that after COVID-19 and alone for the EU economy is considered to contract by 8.3 percent in 2020⁴. With the EU recovery fund

and the long-term budget for 2021–2027 now aiming to invest in a green, innovative, and digital future, the health care sector can help to realize these endeavors.

China can also benefit from products and services offered by European health companies and the Chinese government, even before COVID-19, had set the target to strengthen its health care system. Now in times with and after the COVID-19 crisis, the government also plans to invest and shape the health care sector both, to ensure even better health care coverage for its people and also to mitigate recession. European companies are not only willing to participate in the Chinese market but also to improve the health and wellbeing of the Chinese people. To enhance the benefits of this cooperation, some essential preconditions must be met and further developed by policy makers.

In order for the German health industry to maintain its competitiveness and unleash its full potential, it is therefore making an appeal for a suitable framework of open markets based on the principles of a "level playing field" and mutual benefit. In concrete terms, the German industry is calling for German and European decision-makers to put health care high on the political agenda as they redefine their own health and industry strategies, help to mitigate the recession after COVID-19, shape the multilateral agenda, and negotiate with China. The industry asks the decision-makers to do so by highlighting the following topics.

¹ Federal Ministry for Economic Affairs and Energy, Gesundheitswirtschaft – Fakten & Zahlen, 03.2019, p. 4, <https://www.bmwi.de/Redaktion/DE/Publikationen/Wirtschaft/gesundheitswirtschaft-fakten-zahlen-2018-sonderthema-industrielle-gesundheitswirtschaft.pdf?__blob=publicationFile&v=6>.

² Ibid. p. 38.

³ Verband forschende Pharmaunternehmen, Pharmaforschung: Injektion für Innovation und Wachstum, <<https://www.vfa.de/de/wirtschaft-politik/wirtschaft/pharmaforschung-wirkt-auch-wirtschaftlich>> (accessed on 17.07.2020).

⁴ European Commission Summer 2020 Economic Forecast: An even deeper recession with wider divergences <https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1269> (accessed 21.07.2020).

Federation of German Industries (BDI) – German Health Alliance (GHA) recommendations

1 EU health policy concerns cross-industry interests and society as a whole. It therefore needs to be high on the EU's political agenda.

Health care innovation and digitalization can help improve patient access while creating new opportunities for outpatient, inpatient, and nursing care. Digitalization in health care is increasing the degree of interdependence between its different sectors (pharmaceutical, medical technology, biotechnology, IT services, and insurers). Thus, the health care sector needs to be perceived as a cross-industry endeavor rather than being looked at in silos.

The COVID-19 pandemic response has shown we can only be strong when governments, industry, and other actors work together. It also has made clear our need to stimulate the economy to mitigate recession and thus ensure the health and wealth of society. A German and EU-wide “health in all policies” must reflect this approach. In the area of international health policy, Berlin and Brussels should upgrade health policy in Germany and the EU, further promote global health policy, and initiate a structured dialogue with the People's Republic of China. The aim of this dialogue should be to identify and remove barriers to trade and investment and to expand these efforts by promoting collaboration in selected fields.

2 To remain competitive, the health care sector in Germany and the EU needs to do more to promote digitalization and innovation.

The European Commission's EU recovery plan, the EU's 2021–2027 budget, and the EU4Health program are welcome initiatives. They now need to be well equipped with budget lines, further detailed and connected to existing strategies. The European Commission's AI strategy needs to place greater emphasis on the health care sector. The process of creating an EU health data space and establishing a single European health market should be accelerated. Efforts to promote research should also be increased, including better support for start-ups and a more attractive framework for venture capital.

3 Access to key export and investment markets, such as China, needs to be secured and designed to be innovation friendly

In particular, more innovation-friendly policies need to be secured in public procurement policies. It is important to avoid promoting market access asymmetries. In the health care sector, too, there is a need to ensure a level playing field. Good progress has been made in reforming health-related intellectual property protection in China, but there is still work to do with regard to promoting the enforcement of intellectual property rights safeguards. In the area of procurement, competition is still distorted by mandatory localization rules, and procurement criteria tend to emphasize price over quality and innovation.

4 An EU-China structured dialogue on health-related market access topics should be supplemented by cooperation in the field of health.

Potential areas for cooperation include digitalization, harmonizing approval processes, establishing and developing innovation-friendly cost/benefit analysis procedures, and promoting personalized medicine. European and Chinese capabilities in these areas are highly complementary.

5 The EU and China need to work together to promote health through multilateral forums such as WHO, the G20, and the WTO

Multilateral cooperation in this area can help provide strong momentum and direction. The key topics here are strengthening health systems, universal health coverage, pandemic prevention and response, open borders and international supply chains, digital health, and development cooperation on health.

Introduction

Forecasts indicate China's health care market will be worth USD 2.4 trillion by 2030⁵, with double digit growth rates expected⁶. China's large population of 1.4 billion people, its growing health care market, and Chinese government commitments and activities in the health care sector make China a primary market for health care - and one of the most dynamic. The Chinese government is supporting this growth through its strategic industrial and social policies, with Made in China 2025 and Healthy China 2030 as the most prominent examples. Developing homegrown high-tech industries, creating national and international champions and to position China as a globally competitive powerhouse in high-tech industries is a high priority for the Chinese government.⁷ A further goal is to improve the social security system. The Chinese government sees both as crucial for guaranteeing economic and social cohesion and for ending rural poverty.⁸ In the eyes of EU companies, these policies create great opportunities but also several challenges for the EU health care industry.

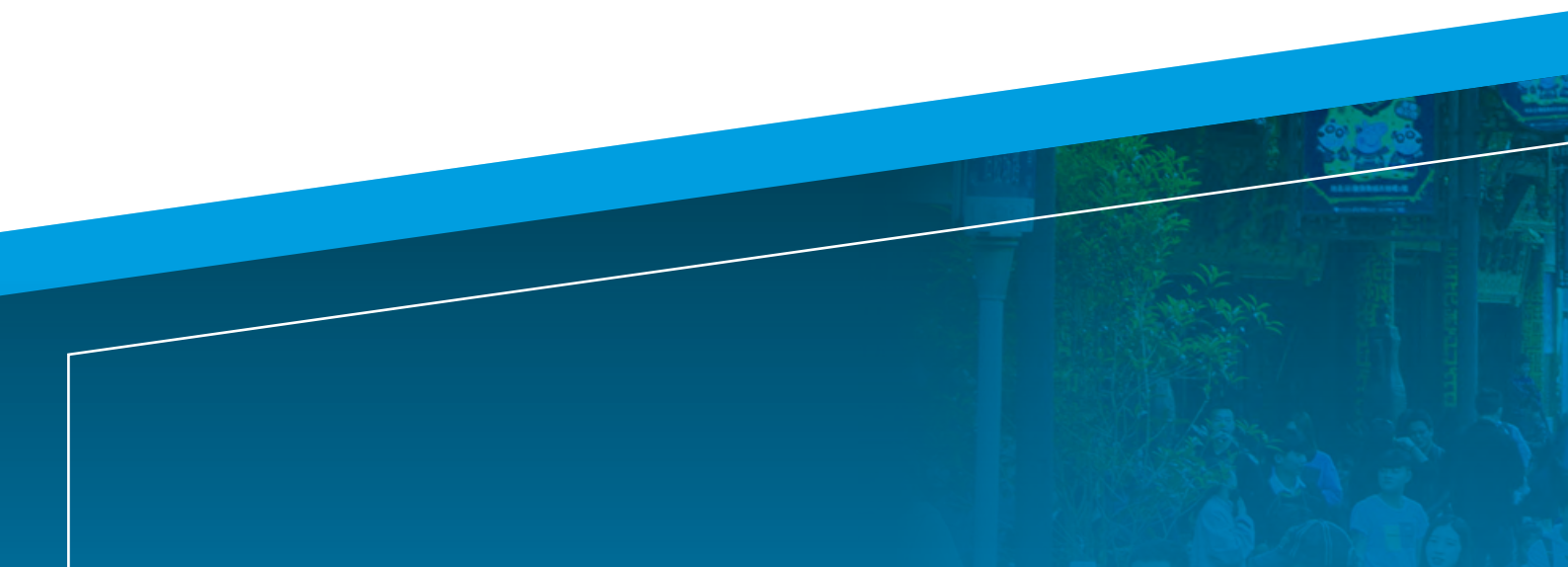
Therefore, the dynamics of the Chinese health care market and the competition between the European health industry and Chinese companies should be taken into consideration with regard to current reviews of internal and external policies, the COVID-19 recovery funds being set up by the European Commission (EC), and similar reviews at a national level. In a globalized world, health should not only be promoted in all policies and at all levels in the EU's single market and in its external policy. It also should be embedded in a coherent global framework. In the coming years there will be a chance to make considerable progress in multilateral forums on health and trade and in bilateral relations with China. To ensure the European health care industry remains in a strong position in the future, the Federation of German Industries (BDI) and the German Health Alliance (GHA) call on decision-makers in Berlin and Brussels to take a proactive approach to health policy, both domestically and in bilateral cooperation with China.

⁵ "China's health service industry to reach 16 trillion yuan by 2030", in China Daily, 15.08.2017, <https://www.chinadaily.com.cn/life/2017-08/15/content_30638162.htm> (accessed on 17.07.2020).

⁶ The Economist: Navigating through China's evolving healthcare market: Healthcare 2020 https://www.eiu.com/public/topical_report.aspx?campaignid=Chinahealthcare2020 (accessed 21.07.2020)

⁷ Institute for Security and Development Policy, Made in China 2025, <<https://isdsp.eu/publication/made-china-2025/>> (accessed on 17.07.2020).

⁸ International Monetary Fund, Seeking Balance: China strives to adapt social protection to the needs of a market economy, <<https://www.imf.org/external/pubs/ft/fandd/2018/12/social-protection-in-china-wills.htm>> (accessed on 17.07.2020)



Germany and the EU: Valuable partners for global health

The German health care industry makes an important contribution in Germany, Europe, and around the world by enabling high-quality health care for patients and society. On average, the German health care industry invests about 6 billion Euro in research and development, leading to new and innovative products and services and triggering an economic footprint of about 11 billion Euro.⁹ The health care industry is an important economic driver. The German health care industry contributes 12 percent of Germany's economic growth.¹⁰ One in eight jobs¹¹ are in the health care sector—and even one in six jobs, according to a broader definition¹². In the EU and in EU Member States, the health care industry provides jobs for highly qualified people and

generates growth and tax contributions. Health care is high-tech. The European health care industry contributes to this growth in innovative, knowledge-based, and cross-industry sectors such as medical technology, pharmaceuticals, biotechnology solutions, digital technologies, diagnostics, insurance, and education. German and European health care companies today also provide various products and services aimed at meeting demand in the health care system in China's large and growing market. Chinese patients benefit from innovative German and European therapeutic, diagnostic, and rehabilitative medical devices, assistive technology and medicines, hospital management, other health care and nursing services, and research collaborations. These activities and investments provide China with high-quality employment opportunities, health care innovation, and tax revenues.

⁹ Federal Ministry for Economic Affairs and Energy, Gesundheitswirtschaft – Fakten & Zahlen, 03.2019, pp. 39, <https://www.bmwi.de/Redaktion/DE/Publikationen/Wirtschaft/gesundheitswirtschaft-fakten-zahlen-2018-sonderthema-industrielle-gesundheitswirtschaft.pdf?__blob=publicationFile&v=6>.

¹⁰ Ibid, pp. 4

¹¹ Federal Ministry of Health, Gesundheitswirtschaft als Jobmotor, <<https://www.bundesgesundheitsministerium.de/themen/gesundheitswesen/gesundheitswirtschaft/gesundheitswirtschaft-als-jobmotor.html>> (accessed on 17.07.2020).

¹² Ibid.



A background image of a surgeon in blue scrubs and a surgical mask, focused on a procedure. The image is partially covered by a blue overlay containing text.

**The Chinese health care sector and China's
response to the society megatrends**

Aging Society Rising Middle Class Digitalization

China's health care sector and health care economy

Market Overview

China's enormous health care market continues to expand, driven by an aging population, changing consumer habits, increasing urbanization, and economic growth. Roughly 15 percent of China's population is currently aged 60 or older, a number that is expected to reach 37 percent by 2050¹³. It is expected that one-quarter of the country's population will be 65 or older by 2050, and that half will be 45 or older¹⁴. The health care system is not yet prepared for the additional burden this will bring, particularly regarding non-communicable diseases (NCDs) and chronic diseases such as cancer and cardiovascular disease. In 2014, about 87 percent of all premature deaths were caused by NCDs¹⁵. By 2016, the percentage had already increased to 89 percent¹⁶. According to a World Bank report from 2011, the number of NCD cases among Chinese people over 40 will double or even triple over the next two decades until 2030¹⁷. Naturally, COVID-19 has brought about additional challenges for the handling of pandemic response and infectious diseases. And indirectly, the pandemic also entailed negative consequences for the management of chronic disease, the monitoring and treatment of chronic disease patients¹⁸.

Health care expenditure data

Market Size: China is the second largest health care market in the world, with total health care spending of USD 558 billion in 2016¹⁹. Forecasts indicate China's

health care market will be worth USD 2.4 trillion by 2030²⁰, with double digit growth rates expected²¹.

Health Care Spending: In 2014, health care expenditure as a share of GDP was 5.6 percent²² and by 2020, China's healthcare spending is expected to account for 6.5 to 7 percent of its total GDP²³ while the economy still grew by 6.1 percent before the COVID-19 crisis²⁴. In 2017, Chinese domestic general government health expenditure per capita was equivalent to USD 440²⁵ compared to an average of over USD 5,200 in the world's eighth largest health care markets.²⁶ Analysts estimate that health care expenditures in China could reach USD 1 trillion as early as 2020, as China converges with health care spending patterns in developed markets.²⁷

Health Care Spending Growth: Since 2003, health care expenditure has grown by 20 percent annually in China²⁸. Roughly 36 percent of all health care spending is in the form of out-of-pocket expenses²⁹. In the long term, China's growing prosperity and aging population are expected to lead to a 10–15 percent increase in the rate of health care growth.³⁰ How COVID-19 will influence health care spending remains to be seen. The SARS epidemic in 2003 had triggered meaningful government reforms and investments.

¹³ Ulrike Reisach, Das Gesundheitswesen in China, Berlin 2017, pp. 8.

¹⁴ EY, The rise of private health insurance in China, 2016, p. 5, <[https://www.ey.com/Publication/vwLUAssets/EY-the-rise-of-private-health-insurance-in-china/\\$FILE/EY-the-rise-of-private-health-insurance-in-china.pdf](https://www.ey.com/Publication/vwLUAssets/EY-the-rise-of-private-health-insurance-in-china/$FILE/EY-the-rise-of-private-health-insurance-in-china.pdf)>.

¹⁵ World Health Organization, Noncommunicable Diseases (NCD) Country Profiles – China, 2014, <https://www.who.int/nmh/countries/2014/chn_en.pdf?ua=1>.

¹⁶ World Health Organization, Noncommunicable Diseases (NCD) Country Profiles – China, 2016, <https://www.who.int/nmh/countries/chn_en.pdf?ua=1>.

¹⁷ World Bank, Toward a Healthy and Harmonious Life in China: Stemming the Rising Tide of Non-Communicable Diseases, 2011, p. 2, <https://www.worldbank.org/content/dam/Worldbank/document/NCD_report_en.pdf>.

¹⁸ World Health Organization, China shows COVID19 responses must be tailored to local context <<https://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/news/news/2020/4/china-shows-covid-19-responses-must-be-tailored-to-the-local-context>> (accessed 21.07.2021).

¹⁹ Krane shares, China Healthcare: Potential Opportunities From One Of The Fastest Growing Major Global Healthcare Markets <http://kraneshares.com/resources/presentation/2018_12_31_kure_presentation.pdf>;

²⁰ China Daily, according to the Chinese National Health and Family Planning Commission, "China's health service industry to reach 16 trillion yuan by 2030," Aug 15, 2017

²¹ The Economist: Navigating through China's evolving healthcare market: Healthcare 2020 <https://www.eiu.com/public/topical_report.aspx?campaignid=Chinahealthcare2020> (accessed 21.07.2020).

²² Ulrike Reisach, Das Gesundheitswesen in China, Berlin 2017, pp. 21.

²³ Healthcare reforms underscore market growth in The China Briefing <<https://www.china-briefing.com/news/healthcare-reforms-underscore-market-growth-china/>> (accessed 21.07.2020).

²⁴ World Bank, China GDP growth <<https://data.worldbank.org/indicator/NY.GDP.MKTP.KD.ZG?locations=CN>> (accessed 21.07.2020).

²⁵ WHO, Domestic health expenditure, <<https://data.worldbank.org/indicator/SH.XPD.GHED.GD.ZS?locations=CN&view=chart>>, (accessed 16.07.2020)

²⁶ WHO, <http://kraneshares.com/resources/presentation/2018_06_30_kure_presentation.pdf>, 2015. (accessed on 30.06.2018)

²⁷ Global X, China Sector Analysis: Health Care, <<https://www.globalxetfs.com/china-sector-analysis-health-care/>>, Apr 25, 2019

²⁸ Council on Foreign Relations, China's Healthcare Sector and U.S - China Health Cooperation, <<https://www.cfr.org/report/chinas-healthcare-sector-and-us-china-health-cooperation>> (accessed on 17.07.2020).

²⁹ World Bank, Out-of-pocket expenditure (% of current health expenditure) – China, <<https://data.worldbank.org/indicator/SH.XPD.OOPC.CH.ZS?locations=CN>> (accessed on 17.07.2020).

³⁰ Global X, China Sector Analysis: Health Care, <<https://www.globalxetfs.com/china-sector-analysis-health-care/>> (accessed on 17.07.2020).

The Chinese health care system

China's central government is responsible for national health legislation, health policy, and health administration. Every citizen is entitled to receive basic health care services³¹. Local governments (provinces, prefectures, cities, counties, or towns) are responsible for providing them. Health authorities include the National Health Commission (NHC) and local Health Commissions, which are responsible for organizing and delivering health care, and for supervising providers. Over the past two decades, China has undergone reforms aimed at improving access to health care through infrastructure investment, insurance reform, and expansion of the private hospitals and health facilities market³².

Health insurance

More than 95 percent of the Chinese population benefits from basic health care coverage³³. But financial coverage is still quite low and patients in 2017 still paid 36.1 percent of health care costs themselves on average³⁴. Costs of assistive treatments in particular (such as prosthetics) are not reimbursed by national health insurance and have to be covered by out-of-pocket payments in most cases. Health insurance is also provided by employers. Many Chinese companies offer group health insurance to attract and retain their employees. The Chinese government has continuously increased financial coverage in recent years, but it still faces ever-growing demand for better health care from the rising middle class.

China's public social health-care system has three levels of funding

So far, the public health-care system has provided for differentiated health care coverage depending on the place of residence (rural/urban) and employment status. In concrete terms, this included:

- Urban Employee Basic Medical Insurance (UEBMI) funded by both the employer and the employee (the latter with yearly contributions equivalent to EUR 90–220))
- Urban Resident Basic Medical Insurance (URBMI) funded by both the state and the resident (the latter with yearly contributions equivalent to EUR 19–90)
- The new Rural Cooperative Medical Scheme (NRCMS) funded by the state and the rural resident (the latter with yearly contributions equivalent to EUR 19–50 but depending on relative levels of wealth and prosperity in the different regions)³⁵.

In addition, there is a supplemental level—with critical illness insurance (CII) to reduce citizens' health care expenditure.³⁶ Starting in 2018, however, the Chinese government announced that a unified health insurance scheme would be implemented for all urban and rural residents, with equal payments by 2019–2020³⁷. The Chinese government is offering incentives to attract private foreign companies to enter the health insurance market.

³¹ The Commonwealth Fund, International Health Care Systems Profiles – China, <<https://www.commonwealthfund.org/international-health-policy-center/countries/china>> (accessed on 21.07.2020).

³² Ibid.

³³ Ulrike Reisach, Das Gesundheitswesen in China, Berlin 2017, p. 20.

³⁴ World Bank, Out of pocket expenditure, <<https://databank.worldbank.org/reports.aspx?source=2&series=SH.XPD.OOPC.CH.ZS&country=CHN>> (accessed 17.7.2020).

³⁵ Ulrike Reisach, Das Gesundheitswesen in China, Berlin 2017, pp. 20–21.

³⁶ Pengqiang Fang et al., The effect of critical illness insurance in China in *Medicine Journal Baltimore* <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6076100/>> Published online 2018 Jul 6. doi: 10.1097/MD.00000000000011362

³⁷ “China to complete standardizing urban, rural medical insurance by 2019”, in *China Daily*, 25.07.2018, <<http://www.chinadaily.com.cn/a/201807/25/WS5b58716ba31031a351e90204.html>> (accessed on 17.07.2020).

How China is responding to the three megatrends: health in all policies

China is responding to three dominant megatrends by trying to meet the needs of its aging society and rising middle class as well as to fully leverage the opportunities offered by digitalization. It has been doing this through a number of wide-ranging industry and social reforms and has a successful track record: In the past two decades China has expanded accessibility to health insurance, with coverage for over 95 percent of the population³⁸. And over the last three decades it has succeeded in lifting 600 million people out of poverty³⁹. In the last ten years it has steadily increased total expenditures on health. In 2017, China's total health expenditures reached about 5.2 percent of GDP, compared to under four percent of GDP in 2006⁴⁰, while China's overall GDP increased almost fivefold within the same time⁴¹. And China's government is determined to continue this progress. Recognizing health's effect on social and economic development, President Xi Jinping has placed it at the heart of policymaking. To this end, the government has set up industrial and social policies under Made in China 2025 (MIC 2025)⁴² and Healthy China 2030 (HC 2030)⁴³, and today these programs are guiding all health care-related decision-making in China. With MIC 2025, China is pushing its independent technology development. It also is opening up for cooperation, and it has triggered reforms to improve the business environment. Within these policies, China has also set out concrete measures to tackle the increasing cancer burden caused by an aging demographic. China has set up action programs in areas such as digitalization and AI. These programs are promoting concrete ideas

on how to advance health services and meet the needs of an aging society and a growing middle class.

China: Ambitious policies for challenging megatrends

Chinese government policies such as Healthy China 2030 and Made in China 2025 aim to tackle three megatrends, which are having significant impact on various areas of health care:

1 An aging population

The aging of China's population is making non-communicable diseases (NCDs) such as diabetes, stroke, and cancer more prevalent. It also is causing increased demand for prevention, better diagnostics and treatment, rehabilitation and care, and nursing services for the elderly.

2 Digitalization

Digitalization has started to penetrate and shape all levels of health care, and it will continue to do so. The use of health registries and information systems, artificial intelligence (AI), and other approaches to process health data has the potential to improve various stages of the patients' journey and make evidence-based and cost-effective decisions about interventions.

3 The rising middle class

The increasing disposable income available to China's growing middle class is likely to lead to increased demand for health care services and financial coverage for them⁴⁴.

³⁸ Zhang, Yan et al., National Health Insurance Development in China from 2004 to 2011: Coverage versus Benefits., Ed. Yue Wang. PLoS ONE 10.5 (2015): e0124995. PMC. <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4447421/>> (accessed on 17.07.2020).

³⁹ World Bank; Healthy China: Deepening Health Reform in China, 2019, p. 1, <<https://openknowledge.worldbank.org/bitstream/handle/10986/31458/9781464812637.pdf?sequence=2&isAllowed=y>>.

⁴⁰ World Bank; Data: Current health expenditure (% of GDP) China, <<https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.ZS?locations=CN>> (accessed on 20.07.2020).

⁴¹ World Bank; Data China's GDP growth in USD: <<https://data.worldbank.org/indicator/NY.GDP.MKTP.CD?locations=CN>> (accessed 20.07.2020).

⁴² LexisNexis, Circular of the State Council on Issuing the Made in China 2025, <http://china.lexiscn.com/law/law-english-1-2588408-T.html?access=content_detail&lang=cn&eng=0&keyword=TWfKZSBpbIDaGluYSAyMDI1&t_kw=TWfKZSBpbIDaGluYSAyMDI1&act=detail&prid=e068fb69-2975-ed76-4656-ef1c397e9065&crd=b64957a2-4271-40b9-890e-04e822720439> (accessed on 17.07.2020).

⁴³ LexisNexis, Outline of the Plan for "Healthy China 2030", <Circular of the State Council on Issuing the Made in China 2015: <http://china.lexiscn.com/law/law-english-1-2961294-T.html>> (accessed on 17.07.2020).

⁴⁴ EY 2018, White Paper on China's Healthcare Insurance: [https://www.ey.com/Publication/vwLUAssets/ey-white-paper-on-china-commercial-health-insurance/\\$File/ey-white-paper-on-china-commercial-health-insurance.pdf](https://www.ey.com/Publication/vwLUAssets/ey-white-paper-on-china-commercial-health-insurance/$File/ey-white-paper-on-china-commercial-health-insurance.pdf) (accessed 16.7.2020)

1. Key strategic policies: Made in China 2025 and Healthy China 2030

MIC 2025 is in part a response by the Chinese government to the country's slowing economic growth. The initiative aims to ensure growth by (further) expanding China's high-technology industries and reducing dependency on foreign technologies. Specifically, MIC 2025 identifies key industries in which China should achieve world leadership in innovation or be at the forefront by 2025⁴⁵. These industries include information technology, the pharmaceutical sector, robotics, medicines, and medical devices. Consequently, the Chinese government has (and should have) a strong interest in establishing not only an innovation-friendly environment in the health care sector, but also related legislation in areas such as IPR. The MIC guidelines therefore aim to ensure an innovation-driven basis, quality first, green development, structural reorganization, and talent-orientation. However, the degree to which foreign companies will be able to benefit from MIC 2025 remains to be seen. There are still doubts in this regard because the domestic and global market shares defined in MIC would also have to be realized at the expense of foreign companies, i.e., German and European. The initiative's aim to foster domestic innovation and reduce dependency on foreign technologies presents a challenge to the Chinese government's stated goal of promoting open and equal market conditions. HC 2030 describes how industrial and social reforms should be integrated into all legislation that is relevant for the health care sector. It defines how health services and financial coverage should improve nationwide, particularly in rural areas. It has triggered a wholesale institutional reshuffle, capacity building, and numerous legislative proposals. HC 2030 outlines four specific strategies:

Controlling major risk factors, increasing the capacity of health services, expanding the health care industry, and continuously improving the health care system. These strategies are based on four core principles: health as a priority, reform and innovation, scientific development, and justice and equity (e.g. closing the urban-rural gap in health care infrastructure and coverage)⁴⁶.

Health-related factors that influence this concept include health literacy, diet, regular activities for physical fitness, tobacco use, mental health, and environmental health. Life-long health interventions target women, children, adolescents, workers, primary and middle school students, and senior citizens. Communicable and non-communicable diseases alike are on China's radar, with cardiovascular disease, cancer, chronic respiratory disease, and diabetes management⁴⁷ assigned special importance. Specific action plans containing detailed goals and actions have been released. These include the Healthy China Action Plan 2019–2030 programs⁴⁸ for upgrading equipment and improving treatment at regional hospitals, supporting e-health and care for the elderly, and prevention.

Policies for an aging society: How Healthy China 2030 is tackling NCDs and cancer

As in Europe, the increase of NCDs such as cancer, diabetes, and cardiovascular disease is a major challenge that impacts the health and financial well-being of the Chinese population. This is one consequence of China's aging demographic. These diseases are already contributing to rising health care costs and will do so increasingly in the future.⁴⁹ A joint report by the World Bank and the Chinese government found that without reform, health spending would increase to USD 2.5 trillion by 2035, up from USD 543.5 billion in 2014⁵⁰. This will increase health expenditure from 5.3 percent of GDP in 2015 to 9.1 percent of GDP in 2035.⁵¹ HC 2030 therefore includes specific oncology strategies, which include promoting cancer research and development, reducing customs duties for oncology drugs, and better reimbursement⁵². The Healthy China action

⁴⁵ Institute for Security and Development Policy, Made in China 2025, <<https://isdsp.eu/publication/made-china-2025/>> (accessed on 17.07.2020).

⁴⁶ Xiaodong Tan, Xiangxiang Liu, Haiyan Shao, "Healthy China 2030: A vision for health care" in Researchgate, 2017 https://www.researchgate.net/publication/317128652_Healthy_China_2030_A_Vision_for_Health_Care (accessed: 16.7.2020)

⁴⁷ David Lee, "China unveils largest public health plan in history", in China Daily, 17.07.2019, <<http://www.chinadaily.com.cn/a/201907/17/WS5d2ed95ea310d830563ff8f6.html>> (accessed on 17.07.2020).

⁴⁸ Chinese National Health Commission, <http://en.nhc.gov.cn/HealthyChinaActionPlan.html> (accessed 16.7.2020)

⁴⁹ Cheng, Tsung-Mei et al., China's Healthcare System and Reform, pp. 150–176 (The Challenge of Non-communicable Diseases (NCDs). Cambridge: Cambridge University Press. doi:10.1017/9781316691113.008.

⁵⁰ World Bank Ibid p.3; Currency converted from Chinese Yuan to US Dollars: June 21, 2018

⁵¹ Ibid, p.3.

⁵² Bayer, Healthy China 2030: Spotlight on China's Strategy to Tackle Cancer, <<https://pharma.bayer.com/healthy-china-2030-spotlight-chinas-strategy-tackle-cancer>> (accessed on 17.07.2020).

plan defines additional action points⁵³. These include promoting early screening and treatment, developing diagnosis and treatment criteria for common cancers, implementing health care practitioner training and education, establishing a comprehensive clinical evaluation system for cancer medicines, and incorporating eligible medicines into the national reimbursement drug list. Additionally, HC 2030 aims at reducing the imbalance between rural and urban health care coverage, and the action plan's goal is to strengthen diagnostic and medical assistance for cancer patients in rural areas.

2. Digitalization and artificial intelligence in health care

MIC 2025 aims to promote innovation and digitalization of the industry. It has been followed by specific action plans with regard to the internet and Big Data in 2015, a development plan for the robotics industry in 2016, and a three-year action plan for the internet and AI in May 2016. In April 2019, the Chinese government also announced plans for a Digital Silk Road and is thus engaging in strategic technological development and competition.⁵⁴ More specifically with regard to health care, the Chinese State Council published a national strategy for artificial intelligence entitled the "New Generation Artificial Intelligence Development Plan"⁵⁵ in July 2017. These guidelines expand the government's efforts to achieve high technology leadership as part of MIC 2025 and are aimed at making China a global leader in AI by 2030. They will not only enable a more technically sophisticated and efficient economy, but also help build a society with the safeguards and convenience related to AI, particularly in education and health care⁵⁶.

More specifically, AI will be used in all corners of the health care systems, e.g., to create intelligent medical care through innovations such as smart hospital construction and surgical robots and for research and

development. It will further research and development of flexible, wearable, and biologically compatible monitoring systems. It also will lead to advances in human-computer collaboration in intelligent clinical diagnosis and treatment programs to achieve image recognition, pathology classification, and intelligent multi-consultation. AI will make possible large-scale genome recognition, proteomics (large-scale studies of proteins), metabolomics (chemical processes involving metabolites, the small molecule substrates, intermediates and products of metabolism), and research and development of new drugs. Intelligent monitoring, prevention, and control in the event of epidemics should also be improved by AI. Finally, AI will also enhance intelligent health management and care, e.g., in institutions and equipment for home care.

Funding strategies to promote AI in all industries and in the health field

Funding and incentives from both the government and multi-channel private investments are at the heart of China's AI strategy for all key industries⁵⁷. Financial support is to be increased, and leading enterprises will be encouraged to contribute to AI development funds. One important funding program is 1+N, which includes R&D project funding, investment in start-ups, and development of AI technologies and talent. The project is set up jointly with the five national AI champions Baidu, Alibaba, Tencent, iFLYTEK, and SenseTime. There also is clearly a dimension beyond China's borders—leading Chinese AI companies are being encouraged to explore investment options abroad. Services will be established that pursue overseas mergers and acquisitions, equity investment, venture capital, and establishment of overseas R&D centers. Conversely, foreign AI companies and research institutions will be encouraged to set up R&D centers in China, and collaboration will be encouraged. In addition to the national program, 1+N is also replicated at the local and provincial levels (direct-administered municipalities), for example in Beijing, Jiangsu, Guangdong, Sichuan, and Shanghai.

⁵³ LexisNexis, Outline of the Plan for "Healthy China 2030", <Circular of the State Council on Issuing the Made in China 2015: <<http://china.lexiscn.com/law/law-english-1-2961294-T.html>> (accessed on 17.07.2020).

⁵⁴ Ashley Dutta et. al., "Introduction to China's Digital Silk Road", Roundtable in Asia Policy 15.1, The National Bureau of Asian Research, January 2020.


⁵⁵ Foundation for Law & International Affairs, China's New Generation of Artificial Intelligence Development Plan, <<https://flia.org/notice-state-council-issuing-new-generation-artificial-intelligence-development-plan/>> (accessed on 17.07.2020).

⁵⁶ Foundation for Law & International Affairs, New Generation Artificial Intelligence Development Plan, 08.07.2017, p. 19, <<https://flia.org/notice-state-council-issuing-new-generation-artificial-intelligence-development-plan/>>.

⁵⁷ Ibid. p. 24

Recommendations for action

Competitiveness
Innovation
Digitalization



Set the agenda in Berlin and Brussels: We need health in all policies

01

China's approach to health and the health care sector is largely holistic and more structurally integrated than was the case in the EU until only very recently. Now the European Commission has proposed its EU long-term budget for 2021–2027. The Multiannual Financial Framework (MFF) legislation empowers the EU recovery plan⁵⁸, including the EU4Health program promoting the health and prosperity of EU citizens in an integrated approach. These are welcome initiatives that now need to be well equipped with budget lines, further detailed and connected to existing strategies. In China, the view that an integrated health policy approach is beneficial for the country's health, wealth, and social stability was evident throughout Healthy China 2030 and Made in China 2025. Of course, challenges remain in China with regard to raising health care coverage nationwide for all citizens, but tremendous progress has been made in China's health care system particularly in the last three years. By contrast, EU countries had already been enjoying an overall high level of health-care coverage for decades. High standards of health and financial well-being have characterized Europe's image for a long time: Europe has excelled at providing a solid social security system, including excellent health services. It has led the way in advancing innovation and high technology. However, until very recently the EU and most of its member states had not yet set up pro-active and holistic health policies to sufficiently secure these standards. Fortunately, that now seems to have changed with the recently proposed EU recovery fund and EU4Health programs that are part of the EU's COVID-19 pandemic response. Their three pillars are aimed at creating a green, digital, and resilient Europe and assign a key role to the health care sector.

Welcome EU initiatives now need to be embedded in innovation-friendly policy environment

The health care industry welcomes the European Commission's proposals and the EU Member States' governments' approval of the Coronavirus recovery fund⁵⁹. It urges policymakers in Berlin and Brussels to now not only strive to uphold those values and achievements within the EU, but it also calls on all European legislators and governments to support this budget and proactively examine and ensure that all possible measures to advance health in all policies and create the most innovation-friendly environment possible are being taken.

Concretely, it seems very unfortunate that EU Member States slashed down the EU Commissions' budget line proposals for health and innovation to such a large extent. Also highly needed funds for digitalization were not accorded. According to first sources in the time of writing, the EU4Health budget proposal was cut down from originally 9.3 billion Euro to 1.7 billion Euro, thus an 84 percent cut compared to the original EU Commission proposal from May 2020. Additionally, the Horizon Europe program is cut in both the MFF and Next Generation EU (NGEU) instrument, decreased to €75.9 billion in the MFF, €80.9 billion with the NGEU "boost". This means a -14 percent cut compared to the Commission May 2020 proposal and even more than 30 percent less than what the EU parliament had previously asked for to ensure a globally competitive EU economy⁶⁰.

⁵⁸ European Commission, EU long-term budget 2021–2027: Commission Proposal May 2020, <https://ec.europa.eu/info/strategy/eu-budget/eu-long-term-budget/2021-2027_en> (accessed on 17.07.2020).

⁵⁹ European Council, Council Conclusions of EU Summit on EU Coronavirus Recovery Fund 21 July 2020, <<https://www.consilium.europa.eu/media/45109/210720-euco-final-conclusions-en.pdf>>; (accessed on 21.07.2020).

⁶⁰ Forschung erhält weniger EU-Geld als geplant, in: Handelsblatt, 21.07.2020, <<https://www.handelsblatt.com/politik/deutschland/beschluesse-des-eu-gipfels-forschungspolitik-erhaelt-weniger-eu-geld-als-geplant/26025042.html>>; (accessed on 22.07.2020).

EU Funds need to be used wisely and effectively

In times of highly needed investment to improve health care, uphold competitiveness in high tech industries and mitigate recession, it is crucial to quickly accord the overall budget lines by national legislators and then use the fund wisely and even more effectively. It therefore needs concrete measures, incentives and improved frameworks, to refine and fully unfold the potential of the EU4Health program and other relevant strategies such as the EU industrial strategy and innovation and pharmaceutical strategy. Now is the time to respond appropriately to the challenges of an aging society, the opportunities of digitalization, and the need to ensure growth, by investing in innovation and high technology. By this, more resilient health care systems and economies can be ensured. As health care becomes more and more digitalized, protecting private health care data is becoming more crucial. Europe and Germany should

use their high data protection standards as a competitive advantage, rather than viewing it as a hindrance compared to China and the United States. Citizens rely on policy makers to protect their data while allowing digital innovation to flourish. Data governance should allow for appropriate and safe use of data at scale, to enable critical insights and accelerate innovation in order to achieve an overall faster, safer, and better administration of health care.

The health industry is calling on the EU and Germany to integrate health in all policies and to combine provision of better health services for patients with incentives for further economic growth. The EU should focus on and further develop the internal and external dimensions of health policy in order to safeguard jobs, sustainable growth, and people's wellbeing.



Enhance competitiveness of health care industries in Europe and Germany

Revise internal industry and innovation policies

On the national level, revise internal industry and innovation strategies and funding opportunities, such as Industriestrategie 2030⁶¹, the KI-Strategie der Bundesregierung (AI-Strategy of the German Federal Government)⁶², the Nationale Dekade gegen Krebs (National Decade against Cancer)⁶³ to ensure their comprehensive approach to health care. At the EU level, the European Commission has been very active in 2020, in part specifically in response to the SARS-CoV-2 pandemic and its economic, social, and political ramifications. Most recently, the European Commission proposed Next Generation EU, an expansive recovery instrument to initiate a multi-faceted recovery throughout the EU. The Commission also proposed the EU budget for 2021–2027 and the MFF legislation powering the

EU recovery plan⁶⁴, including the EU4Health program. Secondly, the Commission adjusted its Work Program for 2020 to account for the challenges posed by the pandemic. Thirdly, the program of the European Council Trio Presidency (Germany, Portugal, and Slovenia) was released to set out the council's priorities for 2020 and 2021.

Ensure implementation

All these activities are highly promising because they show a common European thrust to improve and rebuild the EU in the wake of the pandemic, including in health care. However, it is important for these ambitious targets to also be met with equally rigorous implementation to ensure Europe's well-being and competitiveness during health and economic crises. Also, France who will be residing over the EU's Council Presidency in 2022, could be a good ambassador for an ambitious health policy agenda, innovation, digitalization

⁶¹ Made in Germany: Industriestrategie 2030, <https://www.bmwi.de/Redaktion/DE/Dossier/industriestrategie-2030.html> (accessed 23.07.2030).

⁶² Strategie Künstliche Intelligenz der Bundesregierung, https://www.bmbf.de/files/Nationale_KI-Strategie.pdf.

⁶³ National Decade against Cancer, <https://www.dekade-gegen-krebs.de/en/index.html> (accessed 23.07.2020).

⁶⁴ European Commission, MFF Legislation, https://ec.europa.eu/info/publications/mff-legislation_en (accessed on 17.07.2020).



and investment incentives, as the French government even before the pandemic had shown interest in and initiatives for promoting innovation and digitalization in the health care sector⁶⁵. Also, French (health care) associations have started to resemble health care actors' interests in innovation and digitalization promotion⁶⁶ and now with COVID-19, France together with Germany called for a meaningful EU recovery fund to mitigate the recession and set the right investment incentives⁶⁷. In addition, all countries and actors must support the European Commission in implementing the Commission's agenda that preceded the pandemic where applicable. This includes its strategic priority of creating a "Europe fit for the digital age", which includes the EU's strategies on artificial intelligence and data. The roadmap "Shaping Europe's digital future" indicates the key policy actions the Commission intends to take over the next four years. These include creating a European Health Data Space, developing the European Plan to Beat Cancer, and creating an environment of excellence and trust that enables use of AI in Europe. The European Commission's White Paper on Artificial Intelligence underlines the benefits for the health care sector, e.g., making diagnoses more precise and enabling better prevention of diseases⁶⁸. These topics must be further addressed in the aftermath of the pandemic where possible. Furthermore, in an Industry Strategy draft the European Commission plans to strengthen and

incentivize manufacturing capabilities of the pharmaceutical sector. The European Parliament has also published a study of EU public health policies⁶⁹. The health industry welcomes the areas of focus outlined by the President of the European Commission and Germany's priorities for its presidency of the European Council. These include projects to address a pan-European code of conduct for sharing of health data, genome sequencing, and cancer. Also, harmonizing efforts such as the OECD Digital Health Recommendations and Digital Europe's proposals under "A stronger digital and industrial Europe" should be swiftly implemented.

Enhance dialogue with Chinese stakeholders

Enhance dialogue and cooperation with China and Chinese stakeholders in the health care sector on innovation topics and frame the EU's external trade strategy and all China strategies accordingly. The InnoHealth China campaign is an excellent example of promoting closer Sino-German collaboration by companies, particularly SMEs and start-ups. Also, the EU should enhance EU-Chinese bilateral cooperation in R&D and innovation and enhance exports of health care products and trade promotion.

⁶⁵ French Healthcare Industries and Technologies Strategic Committee, Healthcare made in France, April 2017, <https://www.diplomatie.gouv.fr/IMG/pdf/sante_made_in_france_en__bd_cle0e12b1.pdf> (accessed 21.07.2020)

⁶⁶ BusinessFrance, 10 points clefs santé, <https://www.businessfrance.fr/Media/PRODUCTION/PROCOM/Kits/Santé/10%20PTS%20CLES%20SANTE%202019%20-%20Sante%20numerique_EN.pdf>, French Healthcare: <https://frenchhealthcare.fr/en/our-members/>; (both accessed on 21.07.2020).

⁶⁷ Covid-19: France and Germany propose €500 billion EU recovery fund, in: France24, <<https://www.france24.com/en/20200518-live-macron-and-merkel-present-joint-covid-19-recovery-plan-for-eu>>, (accessed 21.07.2020).

⁶⁸ European Commission, White Paper On Artificial Intelligence A European approach to excellence and trust, 19.02.2020, p. 1, <https://ec.europa.eu/info/sites/info/files/commission-white-paper-artificial-intelligence-feb2020_en.pdf>.

⁶⁹ European Parliament, EU Public Health Policies - State of play, current and future challenges, 09.2019, <[https://www.europarl.europa.eu/RegData/etudes/STUD/2019/638426/IPOL_STU\(2019\)638426_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2019/638426/IPOL_STU(2019)638426_EN.pdf)>.

Promote innovation and improve knowledge transfer in health

We need a reliable framework for promoting and protecting innovation in Germany and Europe. Before investing in development of new active substances and products, the health industry needs an adequate level of certainty regarding the regulatory environment.

Against a backdrop of increasing international competition, the EU should create a coherent legal framework to remove structural barriers to innovation. This is essential for ensuring that scientific excellence is rapidly translated into economic benefits and industrial competitiveness. The mission letter to the new EU health commissioner highlights the need for the European health industry to remain an innovator and world leader.

Europe therefore needs to develop a coordinated strategy for creating a framework that will enable a supportive business environment. This in turn can lead to development of sustainable innovation and digital change while facilitating the creation of start-ups and the growth of existing businesses. This necessitates close cooperation between EU Member States. Only by working together will Europe remain globally competitive in the future.

Germany also needs to boost its innovation strategies. It has already taken steps to strengthen innovation partnerships with other countries. InnoHealth China, for example, is part of the fourth phase of the German Federal Ministry of Education and Research's International Research Marketing initiative. For the period 2019–20, it is being led by the Fraunhofer-Gesellschaft.

Recommendations on Innovation Promotion in Europe and Germany:

Support innovation and digital change: We need a coordinated strategy and coherent legislation in Germany and Europe for creating a business environment that will support sustainable innovation and digital change in the health industry.

Assess innovation capacity: We recommend that the European Commission's revised impact assessment procedure should include regular assessments of the impact on innovation capacity.

Boost knowledge transfer: To enable breakthrough innovations in the health industry, we need to strengthen the European Research Area and EU framework programs, and boost knowledge transfer between academic and industrial health research sectors.

Upgrade research funding: The EU's Horizon Europe (2021–2027) research funding program needs to have at least EUR 120 billion available to make the European ecosystem globally competitive for research and innovation.

Promote partnerships: Health undertakings within Horizon Europe should involve partners from the entire industrial health care sector and the pharmaceutical industry, following the example of the Innovation Medicines Initiative (IMI), a public private partnership (PPP).

Involve industry: To enable risk-based, technology-adjusted measures rather than uniform solutions in the health industry, we recommend strong industry participation in the planned Digital Europe program. Protection of intellectual property is a critical factor in promoting investment in research and development both in Germany and in Europe, especially in the highly innovative field of health technology. The health industry should therefore continue to be closely involved in developing this system.

Learn from one another: We recommend implementing institutions that observe and analyze health-related developments in China, as well as discussions of relevant insights with the European health industry.

04

Advance digital health care in Europe and Germany

Digitization
Data exchange
Early detection

Digital technologies offer multiple benefits and are transforming the health care sector. New technologies enable better and more efficient medical care, as well as broader access to medical expertise, especially in rural and remote areas. Digital technologies can also help us to better cope with an aging society.

Digital health is an integral part of the European Commission's Digital Single Market strategy. In Europe, Germany urgently needs to catch up in implementing digital technologies in the health care system. A 2018 comparative study carried out by the Bertelsmann Foundation ranked Germany 16th out of 17 countries in a digital health care index.⁷⁰ There are signs that the German health care system is moving in the right

direction, but the road to a digital health care system remains long. The German Federal Ministry of Health (BMG) has put forward a number of laws to advance digitalization of Germany's health care system, including the Digitales-Versorgungs-Gesetz⁷¹ (Digital Supply Act, DVG) in 2019 and the Patientendaten-Schutz-Gesetz⁷² (Patient data protection act) in 2020. These laws aim to provide access to and reimbursement for digital health care solutions, and protect patients' health care data. The BMG has also initiated a participatory process called Digital Health 2025 to work on the future of digital health and come up with actionable solutions.

⁷⁰ Bertelsmann Stiftung, #SmarthHealthSystems – Digitalisierungsstrategien im internationalen Vergleich, 10.2018, <https://www.bertelsmann-stiftung.de/fileadmin/files/Projekte/Der_digitale_Patient/VV_SHS-Gesamtstudie_dt.pdf>.

⁷¹ Digitales Versorgungsgesetz, <https://www.bundesgesundheitsministerium.de/digital-healthcare-act.html>.

⁷² Patientendatenschutzgesetz, <https://www.bundesgesundheitsministerium.de/patientendaten-schutz-gesetz.html>.

For Europe and Germany, improving health care requires a system of cross-border exchanges of health data, one that takes into consideration data privacy and data protection requirements. Appropriate, resilient data networks are essential for fully developing the innovative power of digital health care solutions. For this reason, there is an urgent need to put in place a data-sharing framework and a coherent, innovation-oriented legal framework throughout Europe and in Germany.

While first steps have been taken by the European Commission and the German federal government, industry urges all stakeholders to keep up the pace and even step up their efforts in the area of health care digitalization.

Recommendations on Digitization Promotion in Europe and Germany:

Remove regulatory barriers within the European single market: We recommend a strategy for a Digital Single Market for Health (DSM-H) to remove regulatory barriers between national health care markets in EU Member States. The European Commission's e-Health strategy should include a clear implementation framework with specific targets and deadlines to accelerate the exchange of health data. For the benefit of patients, secure use of data for academic and industrial research should be facilitated both in Germany and at the European level. This requires the establishment of a European health data space.

Promote the exchange of data and interoperability: In order to promote the exchange of data, e.g., in the context of health care research, the European Commission and political stakeholders in Germany should advocate a legally certain demarcation between anonymization and pseudonymization of personal data. To ensure efficient research and development of innovative therapies, the European Commission should drive the debate about the design and functionalities of an EU health data space. The Commission also should promote development of a legal framework for the use of existing data (e.g. for Big Data analysis) between (and within) EU Member States. Interoperability of digital health care solutions must be strengthened both in Germany and at the European level. This requires EU-wide agreement

on mandatory application of international standards, and specifications for their implementation.

Promote early detection and screening: Update the 2003 Council recommendations on early detection and screening and make better use of digital and AI technologies.

Support digital solutions in cancer care: We suggest using EU funds to support deployment of digital solutions in cancer care Europe-wide. Resources from Digital Europe and the structural funds should be earmarked to improve investments in digital cancer care solutions throughout Europe.

Improve digital health skills: Utilize the Digital Innovation Hub infrastructure to address organizations and professionals in health care to improve their digital health skills and training.

Promote compliance: Push compliance with the electronic health record exchange format recommendations (EHRxF) through funding and procurement.

Facilitate cross-border exchange of health data: The German health care industry is committed to flexible project groups of interested EU Member States for implementation of innovative services within the framework of the eHealth digital service infrastructure (eHDSI). A uniform solution for trust centers throughout Europe will help to facilitate the cross-border exchange of health data over the long term.

Ensure implementation and investment: Secure digitalization of the industrial health care sector in Germany and Europe requires uniform implementation of the EU General Data Protection Regulation (GDPR) and more investment in digital expertise.

Ensure cybersecurity: Cybersecurity is a concern in the field of medical technology. Within the framework of the EU Cybersecurity Act, due attention should be given to this situation by ensuring that the health industry is actively involved in implementation of the EU Medical Devices Regulation.

05

Advance global health

Multilateralism Pandemic Response Digitalization



The 2030 Agenda for Sustainable Development was adopted by all United Nations member states in 2015. Its health-related Sustainable Development Goals (SDGs) particularly SDG 3 aim to “ensure healthy lives and promote well-being for all”⁷³. National and EU efforts to implement “health in all policies” therefore naturally contribute to the global sustainability agenda. Bilateral cooperation can complement and support the global agenda. It enables the countries to not only support one another’s policies and improve health for the EU and China (whose populations combined account for about 1.8 billion people - one quarter of the world’s population), but also act in alliance to drive minilateralism, plurilateralism, and multilateralism. The World Health Organization’s commitments and activities, and its agenda-setting in the G20, are therefore key to achieving advances in areas such as the strengthening of health

systems. These formats provide the right combination of health system expertise and financing. And they involve issues such as securing free trade, resilient international supply chains, and the promotion of innovation and science. In the same line of thought, promoting and facilitating formats such as Business20 and Science20⁷⁴ is also key to strengthening valuable global networks and thinking as important contributors of expert knowledge. Furthermore, the WTO is also an important forum thanks to its customs liberalization and trade facilitation capacities and agreements. At the multinational level too, “health in all policies” should therefore be an obligatory requirement that is viewed as essential.

Germany, the EU, and China have all signaled willingness to assume global responsibility for strengthening

⁷³ United Nations, Goal 3: Ensure healthy lives and promote well-being for all at all ages, <<https://www.un.org/sustainabledevelopment/health/>> (accessed on 17.07.2020).

⁷⁴ G20, Improving Global Health – Strategies and Tools to Combat Communicable And Non-Communicable Diseases, <<https://royalsociety.org/-/media/about-us/international/g-science-statements/2017-improving-global-health.PDF?la=en-GB&hash=BC6B2343D6133377920849DCDACED01E>>.



health systems. They also have emphasized the importance of multilateralism in joint efforts to improve health around the globe. This was reinforced by statements by German Chancellor Angela Merkel⁷⁵, European Commission President Ursula von der Leyen⁷⁶, and Chinese President Xi Jinping at the virtual 73rd World Health Assembly on May 18th. In the mission letters to the commissioners, European Commission President Ursula von der Leyen calls on every commissioner to contribute to the overarching goal of achieving the UN SDGs⁷⁷. This is a much-appreciated sign. Considering the size of the Chinese and EU populations, their economic strength, and their penetration into global supply chains, they would be well positioned to jointly advance global health efforts.

The challenges

The list of global health challenges is long and growing. Two goals in particular have dominated the multilateral agenda over the last two years: 1) achieving universal health coverage and strengthening health systems (and since late 2019 and early 2020,) handling the response to the SARS-CoV-2 pandemic. German industry is calling for further advances of these global health goals and for including them in bilateral cooperation. In addition, the health care industry is ready to support these endeavors through collaborations and public-private partnerships with stakeholders from science, civil society, and the public sector⁷⁸.

1. Strengthening health systems and Universal Health Coverage

The G20 and the UN have become important actors for global health. Since 2015, the G20 member states have begun to advocate for concrete global health action and strengthening health systems. In addition, the United Nations' General Assembly devoted the 2019 UN High-Level Meeting to UN SDG goal 3.8: Universal Health Coverage (UHC)⁷⁹. In the run-up to the UN HLM on UHC, governments and non-governmental stakeholders (including industry) coordinated efforts to advance the UHC policy agenda, e.g., through an interactive multi-stakeholder hearing convened by the President of the General Assembly⁸⁰. At least half of the world's population still lacks access to essential health services, and almost 100 million people a year are pushed into extreme poverty by the costs of essential health care⁸¹, consequently this is an important joint action. The aim of UHC is to ensure that all individuals and communities have access to high-quality essential health services without risk of financial hardship. Both Germany and China have contributed to UHC, either by promoting multilateralism or by advancing their respective domestic health policies in particular.

The German government has demonstrated its commitment to global health and UHC through a number of initiatives and institution-building decisions, such as, by placing the establishment of effective health systems on the agenda for the G8 and by establishing the Science 20 Dialogue Forum on Improving Global Health during Germany's G20 presidency in 2017⁸².

⁷⁵ World Health Organization, 73rd World Health Assembly – Speeches and News Releases, <<https://www.who.int/about/governance/world-health-assembly/seventy-third-world-health-assembly/speeches-and-news-releases>> (accessed on 17.07.2020).

⁷⁶ European Commission, Speech by President von der Leyen at the World Health Organization's 73rd Assembly, <https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_20_916> (accessed on 17.07.2020).

⁷⁷ European Commission, Mission letter to Stella Kyriakides Commissioner-designate for Health, 10.09.2019, p. 2, <https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides_en.pdf>.

⁷⁸ For example: Innovative Medicines Initiative: <https://www.imi.europa.eu/news-events/press-releases/imi-announces-covid-projects-boosts-funding-potential-72-million>; Accelerator: World Health Organization, Access to COVID-19 Tools (ACT) Accelerator, <<https://www.who.int/publications/m/item/access-to-covid-19-tools-act-accelerator>>; Action fund on Anti-Microbial Resistance: <<https://www.ifpma.org/partners-2/the-amr-action-fund/>> (all accessed on 17.07.2020).

⁷⁹ United Nations, Political Declaration of the High-level Meeting on Universal Health Coverage “Universal Health Coverage: Moving Together to Build a Healthier World, 23.09.2019, <<https://www.un.org/pga/73/wp-content/uploads/sites/53/2019/05/UHC-Political-Declaration-zero-draft.pdf>>.

⁸⁰ <https://www.uhc2030.org/news-events/uhc2030-events/multi-stakeholder-hearing-in-preparation-for-the-united-nations-general-assembly-high-level-meeting-on-uhc-542996/> UHC2030, Multi-stakeholder hearing in preparation for the United Nations General Assembly high-level meeting on UHC, <<https://www.uhc2030.org/blog-news-events/uhc2030-events/multi-stakeholder-hearing-in-preparation-for-the-united-nations-general-assembly-high-level-meeting-on-uhc-542996/>> (accessed on 17.07.2020).

⁸¹ World Health Organization, Half the world lacks access to essential health services, 100 million still pushed into extreme poverty because of health expenses, <<https://www.who.int/news-room/detail/13-12-2017-world-bank-and-who-half-the-world-lacks-access-to-essential-health-services-100-million-still-pushed-into-extreme-poverty-because-of-health-expenses>> (accessed on 17.07.2020).

⁸² G20, Improving Global Health – Strategies and Tools to Combat Communicable And Non-Communicable Diseases, <<https://royalsociety.org/-/media/about-us/international/g-science-statements/2017-improving-global-health.PDF?la=en-GB&hash=BC6B2343D6133377920849DCDACE01E>>.

Beyond agenda-setting, the German government—the fourth largest contributor to the WHO⁸³—has provided and advocated for adequate funding of global health initiatives in multilateral organizations. The German government has also triggered an inclusive policy process with non-state actors to prepare the governments' new global health strategy, and it has set up a parliamentary sub-committee⁸⁴ dedicated solely to global health (the Subcommittee on Global Health of the German Bundestag). Looking to the second half of 2020, Germany's presidency of the European Council is expected to add another layer to its efforts to promote multilateralism in the strengthening of global health systems.

China, in turn, has integrated global health and UHC goals into a very ambitious national health strategy. Its wide-ranging health policy reforms under the Healthy China 2030 initiative also aim to achieve UHC by working to improve health care services and health insurance coverage countrywide⁸⁵. At a plurilateral and multilateral level, China has repeatedly called for efforts to strengthen multilateral efforts aimed at improving global health, most recently in President Xi's speech at the 73rd WHA. President Xi called for a global response to COVID-19, proposed global reserves of medical supplies, and announced financial support for developing countries⁸⁶. His call for multilateralism was followed by a white paper titled "Fighting Covid19: China in Action"⁸⁷. The white paper elaborated comprehensively on China's fight against the epidemic, but also further outlined the steps to build a successful global community capable of providing health for all. In concrete terms, the white paper stresses the value of international solidarity and cooperation, calling on the international community to recognize WHO's leading role in pandemic response and to adequately fund the organization. The white paper also emphasizes the importance

of multilateral organizations including the G20, APEC, and BRICS, reiterates the G20 consensus reached at the Extraordinary Leaders' Summit on COVID-19, calls on the IMF and World Bank to provide emergency aid to African countries, and appeals to the WTO to safeguard the multilateral trading system and secure international supply chains. Finally, it emphasizes that the global community needs to work together to stabilize and rehabilitate the world economy and mitigate recession. China expressly warns that decoupling and deglobalization may divide the world⁸⁸. The WTO shall therefore have all support to cut tariffs, remove barriers, facilitate flow of trade, and keep international supply chains secure and smoothly functioning.

Finally, the EU has played an increasingly major role in UHC, e.g., through its Beating Cancer Plan, despite the EU having limited health care responsibilities or competencies from the treaties. With new ideas promoting new EU competencies in health, for example during the Merkel-Macron summit on May 18, 2020⁸⁹, and with the new EU4Health program, the EU may play an even more dynamic role in strengthening health systems in the future. Looking forward, industry is encouraging governments to push issues including digital health, better patient access to innovative diagnostics, treatments and medicines able to support better access to care in rural areas, and monitoring and treatment of elderly patients with chronic diseases. A more detailed position on UHC is included in the German Health Alliance Position Paper on Global Health⁹⁰.

2. Pandemic preparedness and pandemic response

By definition, a pandemic is the worldwide spread of a new disease⁹¹. Effective pandemic prevention, preparedness, and mitigation policies therefore need to be planned and coordinated internationally. Implementing the International Health Regulations, collaboration between WHO member states, and coordination

⁸³ World Health Organization, Assessed contributions overview for all Member States As at 31st December 2019, 31.12.2019, p. 3, <https://www.who.int/about/finances-accountability/funding/AC_Status_Report_2019.pdf?ua=1>.

⁸⁴ Bundestag, Unterausschuss Globale Gesundheit, <https://www.bundestag.de/globale_gesundheit> (accessed on 17.07.2020).

⁸⁵ Tan, Xiaodong et al., Global commitments and China's endeavors to promote health and achieve sustainable development goals, *Journal of health, population, and nutrition* vol. 37, 1 8, 12.04.2018, <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5898031/>>.

⁸⁶ Globaltimes, Full text: Speech by President Xi Jinping at opening of 73rd World Health Assembly, <<https://www.globaltimes.cn/content/1188716.shtml>> (accessed on 17.07.2020).

⁸⁷ China State Council Information Office, Fighting Covid-19 – China in Action, <http://www.xinhuanet.com/english/2020-06/07/c_139120424.htm> (accessed 17.07.2020).

⁸⁸ Ibid.

⁸⁹ Bundeskanzlerin, Emerging stronger from the crisis, <<https://www.bundeskanzlerin.de/bkin-en/news/dt-franz-initiative-1753890>> (accessed on 17.07.2020).

⁹⁰ German Health Alliance, Globale Gesundheit: Eckpunkte der Wirtschaft für die Strategie der Bundesregierung, <https://gha.health/wp-content/uploads/Globale-Gesundheit_Eckpunkte-der-Wirtschaft.pdf>.

⁹¹ World Health Organization, What is a pandemic?, <https://www.who.int/csr/disease/swineflu/frequently_asked_questions/pandemic/en/> (accessed on 17.07.2020).

of actions by the WHO are therefore vitally important. The G20 can act as an additional forum for agenda setting, provide political support and financing for coordinating pandemic responses, and address trade and financial issues such as customs measures and development aid. The current COVID-19 crisis has shown how quickly and severely international supply chains, national economies, and state budgets can be impacted when national governments fail to initiate necessary pandemic responses. During the current crisis, the 73rd WHA and Chinese President Xi in particular recognized vaccines against COVID-19 as a global public good⁹², and industry has acknowledged the unique situation created by the pandemic⁹³. However, some stakeholders have even gone so far as to question the intellectual property rights (IPR) system as a whole. It should be noted that strong IPR is a key foundation for availability of treatment options against COVID-19 that are currently being studied and for development of candidate vaccines against COVID-19. IPR has been a driver in the fight against the current pandemic, not a barrier to it.

The BDI and GHA have identified an initial first set of necessary adjustments and actions that should be addressed by the G20 and WHO. Naturally, those adjustments cannot yet be viewed as the last word in terms of lessons to be learned, since at the time of writing the world is still in the midst of the pandemic. Instead, a constant analysis of prevention and reaction measures and their effects should be undertaken, and further actions performed as necessary.

3. Maintain supply chains and the flow of goods

Trade barriers

Trade barriers can significantly impede national and international efforts to mitigate a pandemic, because they may prevent much needed supplies from getting to where they are most needed. In the early stages of COVID-19, a number of countries had imposed export restrictions, most notably on personal protection equipment (PPE) for personnel and active pharmaceutical

ingredients (APIs). This made it challenging to avoid disruptions to production of medicines and medicinal products, which in turn affected diagnosis and treatment of patients. PPE is essential for maintaining hygiene standards in medical production facilities and laboratories. At a multilateral level, a number of countries are now aiming for better crisis-preparedness by identifying emergency health care products and services prior to a pandemic. To that end, industry requires that these products should be subject to multilateral agreements that stipulate no ad hoc hoarding, as well as protection from export restrictions. President Xi's proposal at the 2020 World Health Assembly to establish a global stockpile of essential medical products⁹⁴ can be considered a strong signal for greater solidarity and for a more coordinated global approach to humanitarian aid preparedness. There is, however, a need to thoroughly discuss stockpiling modalities with all relevant partners, including industry experts. Sudden and purely national stockpiling solutions could even be counterproductive and endanger patient access. To that end, industry experts' views on issues including product supply and supply chain management need to be taken into account, in order to prevent unintended trade divergencies or disruption in of trade in goods, to make good on supply commitments, and thus not cause supply difficulties that might impact patients. In the EU and around the world, there is much discussion at the public and government levels about overdependence on single countries for strategic goods and reshoring of production facilities and warehousing. A holistic analysis and integrated approach are required to find the right balance between competing interests in this area. The health care sector as a whole opposes an imposition of mandatory localization of industries' production sites and supply chains. There is a need to find alternative means for achieving better pandemic prevention and creating resilient international supply chains that continue to function in the event of a crisis. When stockpiling is considered, international public stockpiling seems more favorable and workable for a number of reasons. Sudden and purely national solutions are critical to patient access and supply chain management. Initiatives such as the regional reserve of essential medical supplies by the ASEAN Plus Three are thus a welcome alternative to national

⁹² Globaltimes, Full text: Speech by President Xi Jinping at opening of 73rd World Health Assembly, <<https://www.globaltimes.cn/content/1188716.shtml>> (accessed on 17.07.2020).

⁹³ International Federation of Pharmaceutical Manufacturers & Associations, Joint Statement – Innovative Health Industries @WHA 73, <<https://www.ifpma.org/resource-centre/joint-statement-innovative-health-industries-wha73/>>.

⁹⁴ Globaltimes, Full text: Speech by President Xi Jinping at opening of 73rd World Health Assembly, <<https://www.globaltimes.cn/content/1188716.shtml>> (accessed on 17.07.2020).

solutions⁹⁵. In all of these areas, German, EU, and Chinese government agencies are being encouraged to lay the groundwork through bilateral talks, while using the G20, WHO, and WTO to promote this idea globally. In addition, export authorizations should be introduced wherever export restrictions are still being considered so as to avoid interrupting intra-company trade.

Medical goods imports should be facilitated to ensure better patient treatment and crisis-preparedness. This can be achieved by reducing or eliminating tariffs on medical goods. Industry therefore welcomes Phil Hogan's signal that the European Commission, in collaboration with the WTO, is willing to not only temporarily liberalize tariffs on medical goods during the pandemic, but also to advocate for a respective multilateral agreement to eliminate duties on global medical trade⁹⁶. From an industry perspective, a multilateral agreement between all WTO member states would be the preferred option. The next best option would be an extension of the scope and membership of the zero-for-zero agreement. For both options, China can be an important ally, as it most recently repeated its call for the removal of trade barriers in its white paper on fighting COVID-19. Countries that envision creating strategic stockpiles of medicinal products at the national or international levels should take advantage of industries' capabilities and expertise in international supply chains. Emergency plans drawn up unilaterally by governments may fail to reflect actual industrial capacity. To avoid this scenario, industry needs to be involved in designing any such plans.

Border controls

By shutting down domestic and international borders as part of their COVID-19 responses, governments have imposed severe constraints on global supply chains. Stricter border controls have meant that road transport in particular has been backed up, with traffic jams several kilometers long, or even denied entry⁹⁷—even

within the Schengen Area. While air and sea freight was allowed to continue in China, there was significant disruption to imports of medical goods by road and rail. Some companies have stated this was due to additional controls conducted at a small number of major entry points at ports and airports. Open borders for goods are, however, imperative for maintaining the flow of essential goods, especially during a crisis. Governments have understandably wished to impose stricter controls on the movement of people coming into the country. As an unintended consequence, at some borders, entry bans and measures such as temperature checks and preventive quarantining of lorry drivers have brought international trade to a complete halt. To ensure continuity of critical supply chains, government pandemic response measures would benefit from being developed in close collaboration with representatives from essential industries and their suppliers. These measures would include dedicated fast lanes for freight vehicles carrying medical equipment, API, and medical products, much like the European Union's green lanes for ensuring the flow of essential goods during COVID-19. One early lesson to be learned from the crisis is that criteria for classifying such freight should be elaborated on and agreed upon ex ante. Any such agreements should be aimed at operations at the G20 level and potentially be inserted as an annex to the WTO Trade Facilitation Agreement—ideally elaborated on in close consultation with WHO. In addition, consideration should be given to digital testing solutions that could potentially replace current border practices.

4. Strengthen multilateralism and collaboration

World Health Organization (WHO)

A pandemic requires a coordinated multilateral response. With its global reach and expertise, WHO plays a crucial, central role in coordinating member states and collaborating with partners in industry. WHO's role includes establishing ongoing transparency with respect to information on novel pathogens, with the aim of enabling member states to continuously update their pandemic countermeasures. In addition, WHO acts as a focal point for non-government stakeholders to facilitate and ensure transparency with respect to possible treatments, vaccines, and diagnostics. In this context, WHO works closely with organizations such as business associations and universities to facilitate the

⁹⁵ Association of Southeast Asian Nations, Joint Statement of the Special ASEAN Plus Three Summit on Coronavirus Disease 2019 (COVID-19), <<https://asean.org/joint-statement-special-asean-plus-three-summit-coronavirus-disease-2019-covid-19/>> (accessed on 17.07.2020).

⁹⁶ European Commission, Coronavirus: European Commission backs international initiative to facilitate trade in healthcare products, <https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1042> (accessed on 17.07.2020).

⁹⁷ "Traffic chaos at German-Polish border a threat to local supply chains?", in Deutsche Welle, 19.03.2020, <<https://www.dw.com/en/traffic-chaos-at-german-polish-border-a-threat-to-local-supply-chains/a-52834298>> (accessed on 17.07.2020).

pooling of resources and information across sectors in order to make diagnostics, therapeutics, and vaccines available. One example is the recently established Access to COVID-19 Tools Accelerator⁹⁸, a direct result of WHO's leadership and ability to bring together relevant organizations on a global scale. This enables industry (a founding member of this new coalition) to make valuable contributions to the development of diagnostics, therapeutics, and vaccines. Industry-specific initiatives, such as repurposing manufacturing facilities to produce disinfectant and protective equipment, planning to reserve and re-dedicate production facilities for the time when a vaccine or effective treatment is found or opening up compound libraries to speed up R&D of vaccines and treatments⁹⁹, are also making important contributions to overall efforts to combat the pandemic. Together with necessary extra facilities, additional testing capacity, and effective isolation of newly infected individuals, these efforts will enable governments to implement alternative strategies for exiting or coping with the current arduous lockdowns. These lockdowns pose a major challenge to the achievement of other public health goals, such as meeting social and economic needs. Once a certain degree of protection for people's health and control in providing life-saving health care treatments is ensured or regained, this rebalancing of interests will therefore make an important contribution to public health goals, mitigating the recession and safeguarding the health and prosperity of people in the future. It is important that all countries do their utmost to strengthen WHO. This requires a transparent, long-term approach and will maximize WHO's ability to fulfil its role of initiating innovation and coordinating research.

Detect and diagnose

Before and during a pandemic, early detection and diagnosis help to trigger rapid preventive and response measures. Systems such as WHO's Global Influenza Surveillance and Response System act as global alarm systems and are therefore critically important. This system encompasses Germany, China, and 113 other WHO

member states¹⁰⁰. In order to allow new pathogens to be detected as early as possible, it should be a common goal to extend this network's coverage to all WHO member states. If evidence of a pandemic is detected, targeted and large-scale testing needs to be rapidly available and deployable. To this end, rapid development and availability of diagnostics for new infectious diseases should be a common goal and facilitated within the network. Collaboration with specific international organizations such as FIND¹⁰¹ would further contribute to that goal. The ability and agility to react and combine knowledge, capabilities, and forces across borders is key to combating pandemics. Where and how a specific virus or disease will spread is by definition unpredictable. This challenge will always require expertise from the business world. In addition, the capacities and personnel needed for testing large parts of the population should be assessed, trained, and tested prior to and in the event of an outbreak, ideally with the support of public-private partnerships. In a similar vein, consideration should also be given to regulatory requirements for global use and compatibility of contact-tracing apps.

5. Deploy diagnostics, therapeutics and vaccines

Facilitate clinical trials

Overcoming a pandemic requires new treatments. Clinical trials for therapeutics and vaccines therefore need to commence quickly and be held back by a minimum of bureaucracy, while still maintaining quality and patient safety. During a pandemic, the ability to conduct ongoing and new clinical trials is impeded by measures such as social distancing and a reluctance among trial participants to visit hospitals. Governments therefore need to prepare frameworks that include digital approaches to clinical trials, such as remote monitoring. These frameworks should be extended to cover global and electronic licensing of any products that have undergone successful trials. These measures obviously require tremendous amounts of coordination. WHO's Solidarity

⁹⁸ World Health Organization, Access to COVID-19 Tools (ACT) Accelerator, <[https://www.who.int/publications/m/item/access-to-covid-19-tools-\(act\)-accelerator](https://www.who.int/publications/m/item/access-to-covid-19-tools-(act)-accelerator)> (accessed on 17.07.2020).

⁹⁹ European Federation of Pharmaceutical Industries and Associations, European pharmaceutical industry response to COVID-19, <<https://www.efpia.eu/covid-19/member-updates/>> (accessed on 17.07.2020).

¹⁰⁰ World Health Organization, Global Influenza Surveillance and Response System (GISRS), <https://www.who.int/influenza/gisrs_laboratory/en/> (accessed on 17.07.2020).

¹⁰¹ Foundation for Innovative New Diagnostics <<https://www.finddx.org/>>.

Trial for COVID-19¹⁰² treatment is a promising first step towards much needed multi-stakeholder collaboration.

Fundamental steps for overcoming a pandemic include consolidating clinical knowledge about a new pathogen and making it available to health authorities around the globe including early information and specimen sharing, virus sample labs, global platforms, and producing interim treatment guidelines. These tasks are carried out by WHO¹⁰³.

Facilitate production and distribution

Without a treatment or vaccine, many governments have responded to the COVID-19 pandemic with non-pharmaceutical measures such as social distancing, hand washing, coughing etiquette, and mask wearing. Some of these have given rise to their own political, economic, and social challenges. A medical breakthrough is a key requirement for lifting social distancing and mask-wearing requirements. Once developed, diagnostics, treatments, and vaccines will require rapid, large-scale production and distribution networks. These networks will require multilateral, multi-industry coordination, with government financial support to enable industrial technology, facilities, and expertise. The G20 should therefore agree to provide for tax and investment facilitation when production, warehousing, and/or distribution sites are set up or existing sites are repurposed.

6. Digital health

Digital health tools can contribute to achieving universal health coverage (UHC), improving global health security, and advancing patient-centered health care. The global response to COVID-19 has also shown the potential of digital health tools as pandemic response measures. In recent weeks, for example:

- Health care providers have turned to telehealth and telemedicine tools for diagnosing COVID-19 patients safely and remotely.

- Insurers and other private sector organizations have developed mobile phone apps to help patients recognize COVID-19 symptoms and learn about treatment options.
- Tools such as artificial intelligence are being used to diagnose COVID-19 virus, track disease development, investigate possible treatments and vaccines, and accelerate data collection for clinical trials.
- Policy makers are benefiting from epidemiological models developed using advanced data analysis, while maintaining high standards for data security and privacy.

Recent advances in digital health technologies improve patient care in terms of outcome, access, and costs. Broader use of digital health tools can benefit all stakeholders in the health care system, including patients, government, doctors, health care providers, medical goods manufacturers, and other health care stakeholders. Data analysis tools, for example, can improve tracking of patient outcomes and the value of treatments delivered. Remote diagnosis, monitoring, control, training, and maintenance have been essential tools during the current pandemic and will remain essential for building up resilience. Better tracking of patient records can reduce unnecessary health interventions, while improved use of telemedicine can reach marginalized and remote communities.

Some challenges remain regarding the adoption and better use of new digital health tools. In particular, the access to and ownership of health care data must be valued. This includes the need to safeguard patient privacy, data security, regulatory uncertainty (which can reduce the usefulness of digital platforms), and inconsistencies in approaches to digital health taken by different countries and health care stakeholders.

G20 and WHO leadership in digital health

The G20, as a forum for agenda-setting, and WHO, with its greater capacity for policy implementation, can complement each other's efforts on digital health. At the time of writing, WHO has published its draft Global

¹⁰² World Health Organization, "Solidarity" clinical trial for COVID-19 treatments, <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments> (accessed on 22.07.2020).

¹⁰³ World Health Organization, Country & Technical Guidance - Coronavirus disease (COVID-19), <<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance>> (accessed on 17.07.2020).

Strategy on Digital Health 2020–2024¹⁰⁴. Industry is still assessing it, but overall the comprehensive framework for governance, cooperation, and alignment of WHO stakeholders on digital health has been well received, as has the respect the draft strategy pays to regional and national circumstances. However, industry would appreciate a clearer vision for how WHO will collaborate with other multilateral organizations such as WIPO and WTO.

The BDI and GHA encourage the G20 (and in the long term potentially also WHO) to promote use of digital tools for diagnosing and treating patients. It would serve to enhance the broader health care ecosystem, remove policy barriers that hinder use and adoption of digital tools, leverage health data to improve care, and optimize use of health data in regulatory systems. This would improve patient access, achieve more equal access, better meet patient needs, improve preventive care, and enhance efficiency. Digital learning and remote education of students and professionals can also be enhanced. Specifically, the G20 can:

Recommendations on Digitalization:

Facilitate adoption of digital health tools: To facilitate adoption of digital health tools, push for regulatory consistency, also by establishing transparent and fair regulatory frameworks for use of such tools and guidance governing their use. These should include suitable adaptive measures to account for the dynamic nature of new technologies.

Include industry: Include industry in discussions on regulatory and other policy barriers that impede adoption of new health technologies.

Bring together digital technology experts: Convene regular forums to bring together digital technology experts from different sectors and industries to consider issues, emerging trends, and policy recommendations.

Ensure interoperability: Ensure cross-border interoperability throughout health care systems.

Establish appropriate data security: Establish appropriate data security and privacy policies that safeguard digital information, without preventing the cross-border flow and use of health data for the purpose of research and development and innovation.

Support research and innovation: Support continuous access to scientific discoveries and facilitate appropriate access to national health data sets to support research and innovation.

Develop joint language: Develop a common lexicon to facilitate further adoption of digital R&D tools and technologies or start to develop one before the next G20 summit.

Promote the value of digital health solutions: Advocate to adopt reimbursement systems to appropriately fund new digital health tools, such as payments for telemedicine and digital therapeutics.

Encourage new technologies, R&D, and collaboration: Promote an innovation ecosystem that encourages new technologies, R&D, and collaboration in the digital health sector, including innovations related to deployment and operationalization of products and services.

Engage with business: Create a mechanism for engaging with business to enhance pandemic preparedness and leverage national information centers for disease surveillance, diagnostics, virtual hospitals, and digital therapeutics.

7. Health development cooperation

Achieving UHC requires a collective effort, especially in developing countries in Southeast Asia, Central Asia, the Middle East, Africa, and South America. Improved efforts for strengthening health systems should be considered a joint undertaking on the African continent, which has some of the fastest growing economies but also the poorest countries and fast-growing populations. This applies especially to the EU and China¹⁰⁵, the biggest lenders to African governments. Thereby, it

¹⁰⁴ World Health Organization, Draft global strategy on digital health 2020–2024, 22.03.2020, <https://www.who.int/docs/default-source/documents/gsd4dhdaa2a9f352b0445bafbc79ca799dce4d.pdf?sfvrsn=f112ede5_42>.

¹⁰⁵ Brookings, Competing in Africa: China, the European Union and the United States, <<https://www.brookings.edu/blog/africa-in-focus/2018/04/16/competing-in-africa-china-the-european-union-and-the-united-states/>> (accessed on 17.07.2020).

is important to consider that access to health care not only serves to better meet the basic health needs of individuals, it also makes an important contribution to the economy. Health centers and hospitals provide sustainable jobs for highly skilled people. Because large numbers of women are employed in health care, especially in care delivery roles, efforts to strengthen health systems also boost gender equality¹⁰⁶. In African countries, where there is a large divide between larger cities and more remote areas, digital and telemedicine solutions offer an opportunity to deliver health care to everyone.

The EU, Germany, and China all have a strong presence across continental Africa. President von der Leyen has recently vowed to boost Europe's geopolitical role, including with regard to strengthening health systems around the globe¹⁰⁷. China and the EU therefore have a particular responsibility to support African governments in their efforts to modernize their health infrastructures and create health systems that guarantee universal access to health care. It is also their responsibility to convince governments that investing in measures to strengthen health systems contributes to economic strength. This can only be achieved if the EU and China are in alignment with international organizations such as WHO. In that regard, the G20's Debt Service Suspension Initiative¹⁰⁸ was a clear signal for joint action in development cooperation. Furthermore, China only recently stressed its commitment to strengthening development cooperation, particularly with Africa. Particularly in the Chinese government's white paper on COVID-19¹⁰⁹, China calls on multilateral organizations including the UN, WHO, the IMF, and the World Bank to provide emergency aid to African countries. It also calls on developed countries to take on greater responsibility, play a bigger role in the global battle, and provide more material, technological, and personnel support to their developing counterparts, especially in Africa. A further important requirement

is a shared understanding of sustainable development aid and international cooperation.

The EU, Germany, and China should therefore also use their influence in collaboration with the G20 to strongly support the aforementioned initiatives for health, trade, financial matters, and initiatives for peace, to help end intra-African conflicts that lead to high levels of migration and erode health care provision. Achieving SDG3 will require access to health care, good health literacy in all communities, ongoing training to improve skills of medical staff, modern health infrastructure, and access to innovative diagnostics and treatments. This applies particularly to the African continent. The EU and China can strengthen Africa's health care systems. However, it is important that this be done on a level playing field for all stakeholders. The EU and China share the need to strengthen health care systems in their partner countries and regions, and to collaborate through the WHO and through trilateral EU-China-African partnerships where appropriate and useful.

Recommendations for the overall multilateral agenda:

Strengthen multilateralism: To achieve the health-related goals of the UN SDGs, national and multilateral efforts need to complement each other. Germany, the EU, and China should assume a leading role by jointly advocating for these goals in WHO, the G20, and WTO. The Global Action Plan for Healthy Lives and Wellbeing strengthens collaboration among multilateral health organizations to accelerate progress on the health-related SDGs at the country level. Progress should be reported on and critically discussed at established global health forums like the World Health Summit in Berlin.

Support and enable WHO: WHO is key to advancing all health-related global goals such as UHC and pandemic prevention and response. German and Chinese efforts should work towards positioning and strengthening WHO as the central actor that requires sustainable funding and transparent collaboration. In addition to coordinated government action, cooperation in public private partnerships can be promoted where appropriate and information exchange with equal benefits for all relevant actors is ensured.

¹⁰⁶ World Health Organization, Gender equity in the health workforce: Analysis of 104 countries, 03.2019., <<https://apps.who.int/iris/bitstream/handle/10665/311314/WHO-HIS-HWF-Gender-WP1-2019.1-eng.pdf?ua=1>>.

¹⁰⁷ "Into Africa: Von der Leyens visit kicks off "geopolitical Commission", in Politico, 12.07.2019, <<https://www.politico.eu/article/into-africa-von-der-leyen-visit-kicks-off-geopolitical-commission/>> (accessed on 17.07.2020).

¹⁰⁸ G20, Communiqué - G20 Finance Ministers and Central Bank Governors Meeting 15 April 2020 [Virtual], 15.04.2020, p.1, <[https://g20.org/en/media/Documents/G20_FMCBG_Communique%C3%A9_EN%20\(2\).pdf](https://g20.org/en/media/Documents/G20_FMCBG_Communique%C3%A9_EN%20(2).pdf)>.

¹⁰⁹ China State Council Information Office, Fighting Covid-19 – China in Action, <http://www.xinhuanet.com/english/2020-06/07/c_139120424.htm> (accessed 17.07.2020).

Enhance health-related action within the G20: The G20 are key to advancing a coordinated pandemic response, particularly with respect to all trade barriers that affect the resilience of international supply chains. These include tariffs, export restrictions, and invasive border controls. Also, the competence mix provided by ministers of health and finance will be key to advancing important health budget questions and possible action on customs elimination for medicinal goods. Among the urgently needed actions in the run up to the Saudi Arabian G20 presidency, G20 members should call for a worldwide stop to proliferating export restrictions. They should also move to quickly eliminate all customs duties on medical equipment, diagnostics, and medicines.

Promote Digital health: Digital health tools have particular relevance to global goals for improving health equity, achieving universal health coverage (UHC), improving global health security, and advancing patient-centered health care. They can improve patient care in terms of outcome, access,

and costs. Moreover, the COVID-19 pandemic has revealed that digital health measures can replace and improve existing pandemic response measures. Germany and China should promote these benefits and work to promote investment in digital health globally and enable a regulatory framework that facilitates use of these measures during emergency and non-emergency situations.

Advance cooperation—international and intersectoral—in other global health topics, including development cooperation, e.g., with Africa. Here, a common understanding on the grounds of sustainable development aid, a needs assessment, and leveled international cooperation are essential before fruitful collaboration can take place. Since improvement of public health is always an interdisciplinary task, cooperation should be across sectors and include science, civil society, politics, and the private sector.

06

Intensify dialogue on IPR in health care

Intellectual property Regulations

Ensure intellectual property protection and proper implementation

Protecting intellectual property is key when building an innovation-driven economy. And for a large proportion of health care companies, intellectual property rights (IPR) are the foundation of their business models. They ensure that developers and manufacturers have an incentive to invest the significant resources required to develop innovative products. To ensure sufficient incentives for these risky investments, patents provide a time-limited right to exclude others from making, using, or selling an invention. This is particularly critical for sectors with long innovation cycles that require large and risky investments. In some cases, such as in the pharmaceutical sector, these cycles normally take eight to twelve years¹¹⁰. According to some sources, drug

R&D across all therapeutic areas takes on average even 14 years.¹¹¹ In addition, patent rights are granted for 20 years, beginning at the time the application is filed. Given that filing a patent is required in the earliest days of discovery, the term of protection during which the product can be marketed for pharmaceuticals is often less than half of the total patent term. If that is not the case, for example, supplemental protection certificates or similar mechanisms compensate for some time. Furthermore, although IP protection is for a limited time period, the benefits are long term, and the goal of patent law is to transfer innovation to the public by making the details of patented inventions broadly available. It does so by requiring a patent application to contain information that is sufficient to enable any “person skilled in the technological area to which the invention pertains

¹¹⁰ Bundesverband der Pharmazeutischen Industrie, Pharma-Daten 2019, 11.2019, p. 13, <https://www.bpi.de/fileadmin/user_upload/Downloads/Publikationen/Pharma-Daten/Pharma-Daten_2019_DE.pdf>.

¹¹¹ Paul SM, et al. How to improve R&D productivity: the pharmaceutical industry's grand challenge. *Nature Reviews Drug Discovery*. 19.02.2010, p. 6., <<https://www.nature.com/articles/nrd3078>> (accessed 23.07.2020).

... to make and use the [invention].”¹¹² This contrasts to other forms of IP protection, such as trade secrets, which can allow companies to not disclose such information. Critically, this disclosure serves an important societal purpose. Because the information has been made available, a patent in any given field draws on the existing body of scientific knowledge. At the same time, it adds to it in a way that others may use and benefit from in their own research.

Core challenges:

■ **Enforcement:** There needs to be stricter enforcement of existing intellectual property rights in China. While IP protection offers potential for further improvement, some progress has been made on IP legislation in the health sector. Enforcement needs to be tightened, however, and some legal mechanisms need to be strengthened. To prevent intellectual property violations, these include faster injunction procedures and more effective enforcement of claims for damages that have a genuine deterrent effect. The recently published 2020–2021 IP Action Plan and China’s People’s Court Opinion therefore are welcome signs and measures to strengthen IP enforcement. The IP Action Plan from China’s National Intellectual Property Administration (CNIPA) was released on April 20, 2020¹¹³. With its 133 forthcoming measures, it is designed to implement the CPCCC / State Council November 2019 Opinions on Strengthening IPR Protection and to serve as China’s IP implementation plan under the Phase One trade agreement. In addition, the People’s Court Opinion released on April 21, 2020¹¹⁴ called for “comprehensive strengthening of judicial protection of intellectual property rights”, including a call to safeguard the legitimate rights and interests of the rights holders, enhance practical effects and effectiveness of judicial protection, and strengthen trial infrastructure.

■ The current state of IP protection varies across sectors:

– **Examples from the pharmaceutical sector:** The Chinese government is strengthening the incentive system for the pharmaceutical sector and has proposed positive reforms to IPR¹¹⁵, which now need to be implemented and enforced. Patent term extension (PTE), regulatory data protection (RDP), and publication of an Orange Book in particular are generally positive proposals. The Orange Book is a list of drugs that the U.S. Food and Drug Administration (FDA) has approved as both safe and effective. It contains information on patent and regulatory exclusivities pertaining to a product. In addition, discussion of a patent linkage system is a step in the right direction. Meanwhile, ongoing works on Chinese patent law and implementation preparation for the US-China Phase I Agreement, the IP Action plan published in April 2020, foresee 133 concrete measures. These include: revising the patent law to strengthen pharmaceutical patent protection and provide patent term extension; revising the Patent Examination Guidelines to permit applicants and patentees to provide supplemental data (during patent application prosecution as well as during invalidation proceedings), and establishing an early resolution mechanism for pharmaceutical patent disputes by October 2020. From a pharmaceutical perspective, it is important to determine a clear timetable for introducing implementation rules for PTE and RDP, and protection standards. For RDP protection, in particular, China so far has still not fully implemented its prior commitments. For some innovative drug products, it had not provided the six-year protection period of RDP against unfair commercial use for clinical testing and other data that it committed to at its WTO accession in 2001. Another challenging situation is that generic companies are able to obtain marketing authorizations before patent expiry, whereby generic companies launch generics

¹¹² United States Patent and Trademark Office, General Information Concerning Patents, <<http://www.uspto.gov/patents-getting-started/general-information-concerning-patents#heading-12>> (accessed on 17.07.2020).

¹¹³ Chinese National Intellectual Property Administration, Action Plan to Accelerate Building IP Powerhouse, <<http://www.cnipa.gov.cn/zscqgz/1147678.htm>>.

¹¹⁴ People’s Court Opinion on strengthening IP laws from April 21st 2020, <https://mp.weixin.qq.com/s/CNFz2Erj0Q6pGt1XvbgHw>

¹¹⁵ Among those were in May 2017, the former CFDA’s draft document Encourage Innovation of Drugs and Medical Devices, Rights of Innovators (Document No. 55). In October 2017, the Central Committee of the CPC and the State Council jointly published the document Opinions on Deepening the Reform of Evaluation and Approval to Encourage Innovation of Drugs and Medical Devices (Opinions). In April 2018, the State Council called for extending patent protections by a maximum of five years if a manufacturer applies for parallel registration for its innovative drugs in China and abroad. In April 2018, the NMPA published the draft Regulations on Protection of Drug Study Data for public consultation. In January 2019, the NPC released draft amendments to the Patent Law—which includes PTE for invention patents of innovative drugs—for public comment.

at risk, but no effective legal means are at hand for the rights holder, because injunctions are not available on short notice and not provisionally enforceable. They are only enforceable when the second instance has passed its sentence.

- **Examples from the MedTech sector:** Major challenges remain in other sectors, such as medical devices, with a lack of proper enforcement of existing intellectual property rights. Counterfeit medical devices still violate the IPR of many medical device manufacturers, stifle innovation, and prevent provision of high-quality health care.
- **Implementation and consultation:** To ensure the practicability of new measures, proposed IPR should be implemented swiftly and in consultation with industry partners.
- **Future-proof IPR:** Intellectual property rights in China should be updated to reflect the requirements of new technologies such as AI, Big Data, and biometrics. As China has announced the amendments to Patent Examination Guidelines related to AI inventions, effective as of February 1, 2020, health industries should now be given the opportunity to comment on accompanied implementation work. The Chinese government should proactively include the health industry to ensure that all relevant technological development in the health sector is sufficiently considered.
- **Forced technology transfer:** De facto forced technology transfers often happen through joint-venture requirements, licensing, or approval processes. With increasing digitization, China's restrictive cyber security regulations are of particular concern in this respect. China's new foreign investment law (2019) specifically bans forced technology transfer (Article 22). However, the provisions in the law are not specific, and

article 57 of the draft bio security law¹¹⁶ opens the door to a forced technology transfer. The Chinese government should devise detailed regulations in order to prevent forced technology transfers.

Evaluation

The health care industry is encouraged by recent policies that incentivize innovation and strengthen IPR protection. Establishing a truly innovation-friendly environment, however, requires a functioning multi-level protection mechanism that enforces existing IPR.

Recommendations on Intellectual Property Rights:

Elaborate clear IPR implementation rules, for example for PTE and RDP, and refine standards to match EU standards on RDP (8+1+1); establish that patent infringing products are not traded on the market, for example through an effective patent linkage system.

Enforce existing IPR more consistently and strictly and strengthen specific rule of law mechanisms such as injunction procedures.

Review policies that indirectly cause forced technology transfer and ensure that they reflect rapid technological advances.

Increase opportunities for industry to participate in the policy making process and contribute to formulating and implementing IP protection laws and regulations.

¹¹⁶ Chinalawtranslate, Biosecurity Law (Draft) (Second Deliberation Draft), <<https://www.chinalawtranslate.com/en/biosecurity-law-draft-2/>> (accessed on 17.07.2020).

Cooperate on regulatory policies

Ensure internationally harmonized, smoothly functioning approval procedures

In the highly regulated health care sector, national regulatory approval procedures ensure the quality of products on the market. They play a critical role in determining if an innovative medical product able to improve diagnosis and treatment will become available to patients. Harmonized quality and approval procedures can facilitate simultaneous product development programs worldwide and ensure quicker availability of products across markets. In addition, smart regulation, well-staffed regulatory authorities, and well-trained personnel help prevent delays in approving much needed new medical products. Better regulatory approval is at the heart of the Chinese government's reforms.

Core challenges:

- **Building capacity:** In addition to enormous capacity building efforts, the Chinese government and the National Medical Products Administration (NMPA) have taken a number of positive, much needed steps toward creating a more smoothly functioning regulatory process. This includes the Opinion on Deepening the Reform of the Review and Approval System

and Encouraging the Innovation of Drugs and Medical Devices¹¹⁷.

- **MedTech:** The NMPA is moving forward with generally positive reforms to medical device supervision by announcing amendments to Order No. 680. Under the NMPA predecessor, testing institutes in 2017 nevertheless "... received insufficient funding, causing serious delays to the registration of medical devices."¹¹⁸ The amendment allowed for use of alternative testing facilities or self-testing reports, a measure that was warmly welcomed as help for remedying this serious industry concern. However, further clarification of the concepts set out in the amendment is required, e.g., which "qualified" testing institutes are recognized and the criteria that self-testing reports need to meet. Furthermore, implementation of the amendment is not yet complete.
- **Pharma:** Initial achievements include an impressive reduction in the former China Food & Drug Administration's (CFDA's) drug application

¹¹⁷ State Council, Opinion on Deepening the Reform of the Review and Approval System and Encouraging the Innovation of Drugs and Medical Devices, www.gov.cn/gongbao/content/2017/content_5232362 (accessed on 17.07.2020).

¹¹⁸ European Union Chamber of Commerce in China (2018), Healthcare Equipment Working Group, pp. 240, https://www.europeanchamber.com.cn/en/publications-archive/727/Healthcare_Equipment_Working_Group_Position_Paper_2019_2020. (accessed 29.5.2019).



backlog by the end of 2017. The NMPA and the European Medical Authority (EMA) have also started a structural exchange that should help to train more personnel, accelerating approval procedures. The new Drug Administration Law from December 2019 finally codified many initiatives from the major health care reform dating back to 2015, with measures to continuously encourage innovation in the pharmaceutical industry¹¹⁹.

- **Digital:** Big Data promises to improve patient care, but digital health technology regulations have not yet been fully elaborated. This jeopardizes smooth application procedures and a clear vision for the use of patient data. There is a need to accelerate implementation of initiated policies to allow alternative testing methods for medical products.
- **Circular economy:** It is still not possible to sell imported refurbished medical devices in China¹²⁰, though remanufacturing is possible within certain parameters. Refurbished products, however, are crucial for a sustainable society, and China should be encouraged to play its part to create a global refurbished economy. The Chinese regulatory framework therefore should be improved.¹²¹
- **Clinical trials:** There are several positive developments in the attempts to harmonize the Chinese regulatory environment with the EU's, however there are multiple areas that still require improvement and cooperation.
- **Pharma:** China improved clinical trial approval timelines via IND scheme, introduced and encouraged multi-national companies joining in a multi-regional clinical trial (MRTC) from the early development phase. The reforms introduced serve, for example, to streamline the new drug application (NDA) review procedure, parallelizing some time-consuming processes with the aim of improving review and approval efficiency, and achieving faster approval for drugs for urgent treatment of medical needs that have not been met and for

orphan diseases. The recently published draft registration guidelines and other documents released by the NMPA and the Center for Drug Evaluation (CDE) that seem to track the Regulations on Human Genetic Resources (HGR regulations) propose new rules for handling human genetic resources¹²². While data protection and privacy are an important aspect of conducting clinical trials, the HGR regulations seem to hinder multi-regional research and clinical trials. This is because they currently require a multi-layer, NMPA and hospitals' ethics counsel approval before applicants for an international collaboration may submit an HGR application to commence their study. This applies particularly to instances where foreign companies are involved. During the process, questions on data storage and transfer and on IP rights related to ownership and patent rights are negotiated. Also, ownership of patent rights may not be decided purely between Chinese and foreign companies under the current HGR regulations. Instead, Article 24 of the HGR regulations requires that parties jointly patent inventions arising from their collaboration. And the Office of Human Genetic Resource Administration (OHGRA) will not approve a clinical trial unless it agrees with the intellectual property agreement between the parties.

- **MedTech:** The Chinese Good Clinical Practice (GCP) and requirements for clinical evaluation reports (CER) are still not fully harmonized with international regulations, delaying market access in China and making international multi-center studies difficult. Although there are few technical differences between GCP and ISO-GCP, the clinical trial could still take five to six months longer than an equivalent clinical trial in the United States or the EU. This is mainly because of the government's administrative processes and requirements on ethics committee approval, the custom clearance of trialed devices, and clinical trial filing in the Ministry of Science and Technology. In a recent positive development, the NMPA released the guidance on acceptance of overseas clinical trial data. Among further positive developments, the NMPA treated CER with more urgency than the EU according

¹¹⁹ China Law Insight, Major Changes in the Newly Revised Drug Administration Law, <<https://www.chinalawinsight.com/2019/08/articles/healthcare/major-changes-in-the-newly-revised-drug-administration-law/>> (accessed on 17.07.2020).

¹²⁰ Article 48 of the amendment to Order No. 680.

¹²¹ Ibid, pp. 243.

¹²² Human Genetic Resource Regulation: <http://english.www.gov.cn/policies/latest_releases/2019/06/10/content_281476708945462.htm>.

to the current CER guidance. And the MDR will formally enforce CER from May 2020. Finally, the establishment of a clinical trial and static team in June 2019 at the NMPA has enabled knowledge-sharing on CER and clinical trials with qualified manufacturers of medical devices.

- **Harmonization:** The Chinese government has accorded high priority to membership and harmonization endeavors in some international organizations. There are, however, important differences between sectors:

- **MedTech:** Within the framework of the International Medical Device Regulators Forum (IMDRF)—the highest international regulatory body—the Center for Medical Device Evaluation (CMDE) (as a part of NMPA) has started a series of international initiatives and hosted the IMDRF in 2018 to distribute CER experience and harmonize CER requirements with the EU and the FDA. Streamlining mandatory standards is also the aim of the standardization law that took effect in January 2018¹²³. Engineering and health standards are exempted, however, and product registration with the CMDE still requires separate approval from the China Center for Disease Control and Prevention (CDC) e.g., for X-ray machines and CT scanners, though there are large overlaps with international standards.¹²⁴ Conversely, some requirements are contradictory, as updated international standards are translated into national standards too slowly. In addition, adoption of international standards is still slow, and the CMDE is not yet participating in all organizations that are developing international standards in this field.¹²⁵

- **Pharma:** China has joined the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), was elected to the ICH Management Committee, and is striving to gain membership in the Pharmaceutical

Inspection Co-operation Scheme (PIC/S)¹²⁶. This clearly indicates China's efforts to achieve harmonization in areas such as clinical trials, regulatory approval, and standards for Good Manufacturing Practice (GMP) for medicinal products for human or veterinary use.

- **Quality and safety standards for generics and products:**

- **Pharma:** The Center for Drug Evaluation (CDE) has continuously advanced and pushed the generic drugs quality consistency evaluation (GQCE) to improve generic quality. We need equal treatment: There are approval processes that can discriminate against foreign companies. In the past, product lists favoring local producers have prevented installation or guarantees of a level playing field for all competitors. Such policies should be discontinued to allow fair competition, which will ultimately benefit Chinese patients.

- **MedTech:** Assistive technologies such as prosthetics components are not classified as medical devices, leading to a highly unregulated sector jeopardizing patient safety.

Evaluation:

The health care industry welcomes and supports the Chinese government's goal of implementing faster, more transparent regulatory approval processes. Examples include the IND scheme introduction into China and faster clinical trial assessment and approval for essential drugs and other much needed products for diseases such as heart disease.¹²⁷ Further reforms now need to be ensured through stringent implementation and by enhancing capacity building. To align with international standards, the Chinese government should also seek to expand the harmonization process, including in the medical devices industry.

¹²³ Standardisation Law, NPC, 2017, www.npc.gov.cn/npc/xinwen/2017-11/content_2031446

¹²⁴ European Union Chamber of Commerce in China (2018), Healthcare Equipment Working Group, p. 243, <https://www.europeanchamber.com.cn/en/publications-archive/727/Healthcare_Equipment_Working_Group_Position_Paper_2019_2020> (accessed 29.5.2019).

¹²⁵ Ibid.

¹²⁶ "A New Direction for China's Pharmaceutical Management Model", in Eurobiz Online, 01.12.2017, <<https://www.eurobiz.com.cn/a-new-direction-for-chinas-pharmaceutical-management-model/>> (accessed on 17.07.2020).

¹²⁷ MedTechIntelligence, Heart Disease a Growing Threat in China, <<https://www.medtechintelligence.com/column/heart-disease-a-growing-threat-in-china/>> April 25, 2019.

Recommendations Regulatory Policies:

Continue the process of simplifying approval procedures: Further accelerate standard approval procedures and broaden the range of fast-track approval processes for medical products that are urgently needed. Continue implementation of reforms in order to ensure timely access and treatment for Chinese patients. International standards should be translated into national Chinese standards quickly and consistently. Clarify and implement the amendments to the supervision of medical devices. Deepen reforms for introducing innovative modes of supervision in order to regulate digital health technology.

Enable data use: Enable secondary use of data for health and research purposes. Promote harmonization and strengthen the quality of real world data to better inform regulatory and health technology assessments decision-making.

Further enhance capacity building in organizations such as the CDE and NMPA, including through twinning and structural exchanges with the European Medicines Agency (EMA).

Promote precision medicines: Biomarkers analysis and patients' self-tracking via Intelligent Operating System Apps (IOs) should be given the same treatment as orphan drugs and rare diseases, because patient populations are small and there is a need that has not been met.

Promote globally harmonized standards and transparent, predictable, consistent science-based rules in all health care sectors to improve product registration and regulatory approval, including, for example, harmonization of GCP with international standards.

Enable transition to a circular economy: To enable efficient use of resources, import and sale of refurbished medical devices should be allowed.

No discriminatory criteria: Multinational medical device companies face discriminatory approval criteria compared to Chinese companies, even in the case of Chinese subsidiaries. This includes a requirement for approval in the manufacturer's home country, even though most innovative medical devices no longer require market approval in their home countries.¹²⁸ No Chinese drug approval prioritization for first approval in China.

¹²⁸ European Union Chamber of Commerce in China (2018), Healthcare Equipment Working Group, pp. 242, <https://www.europeanchamber.com.cn/en/publications-archive/727/Healthcare_Equipment_Working_Group_Position_Paper_2019_2020> (accessed 29.05.2019).

Conduct reimbursement and health technology assessments (HTA)

Endorse a reimbursement policy that guarantees up-to-date treatment and care

The Chinese government has decided that the key to achieving health equity in the country and ensuring harmony in society is to provide broader service and increase financial coverage for treatments. Healthy China 2030 also expressly aims to provide better prevention, screening, diagnosis, treatment and care.¹²⁹ The Chinese government has therefore started to review its reimbursement models. For innovative German and EU health care companies, this creates new opportunities. Their innovative products now have a chance to be reimbursed and be made available to more patients in China, unless price pressure increases to an extent that innovation is no longer valued or unless local preference rules are introduced that threaten to prioritize Chinese origin, as recently found in e.g., the draft administrative measures for the National Reimbursement Drug List¹³⁰. The Health Technology Assessment (HTA) refers to the process of using evidence to evaluate the clinical efficacy/effectiveness, cost-effectiveness, and broader impact of health technologies on patients and the health care system. The evaluation of a technology's value should seek

to incorporate the interests of patients, health care professionals, payers, and policy makers and manufacturers. In this respect, HTA is a means to improve patient care, aid physician decision-making, and enhance the functioning of the health care system as a whole.

While countries differ in their use of HTA, industry believes that the HTA process must be scientifically sound, transparent, consistent, and of practical use in both policy-making and clinical practice. An HTA system has not been implemented in China to date¹³¹. Since 2019, however, the Chinese government has been preparing to table a legislative proposal for drug evaluation.

Core challenges:

■ Valuing innovation and guaranteeing differentiation:

For medical products, it is important that patients have access to the latest innovations with the highest potential for improving health outcomes. Innovation must be valued in both the reimbursement and HTA system. In the past, this has not always been the case.

¹²⁹ National Health Commission of the People's Republic of China, Development of China's Public Health as an Essential Element of Human Rights, <http://en.nhc.gov.cn/2019-04/29/c_75161.htm> (accessed on 17.07.2020).

¹³⁰ National Healthcare Security Administration, http://www.nhsa.gov.cn/art/2020/4/29/art_48_3059.html Apr 29, 2019

¹³¹ International Decision Support Initiative, The evolution of Health Technology Assessment in China, 05.2018, <https://www.idsihealth.org/wp-content/uploads/2018/05/ICL_case_study_China_PRINT2-003.pdf>.



– **Pharma:** In the last three years, major progress has been made in offering innovative medicines to patients and increasing access. Before 2017, most innovative drugs were not reimbursed by the public health care system and thus were not accessible for most patients on the Chinese market. The emphasis in the previous update of the National Reimbursement Drug List (NRDL) in 2009 had been on me-too, biosimilar, and biobetter products. Since 2017, however, there has been rapid progress on market access. Over a two-year period, the NRDL has been updated three times with dozens of new active ingredients, including one list with 17 oncology drugs¹³² to support the national oncology strategy. The 2018 guidelines on the Reimbursement Standard Payment Policy introduced systemic changes to the process for listing drugs and negotiating the inclusion of drugs on the NRDL. The recently published draft on the administrative measures for the NRDL seek to clarify the important value assessment process, however, for the time being they still lack clarity and innovation-access friendliness in some points. For example, despite the provision that NHSA will establish scope and specific conditions for the current year's NRDL update, there are no provisions yet to enable companies to apply for reimbursement once a new medicine has received marketing authorization from NMPA or to allow contracts to be renegotiated to include new indications. Also, the draft measures suggest that during the two-year NRDL contract renewal period, local medical institutions can conduct secondary negotiations to achieve prices below the nationally negotiated reimbursement payment standard (RPS) and that health care security departments shall adjust the RPS at the end of the contract period. Those practices would break with the 2019 NRDL policy. They also could lead to important price erosion, reduce predictability in the market, and risk undermining China's goals of fostering an innovative biopharmaceutical industry and becoming an early launch destination for innovation that benefits Chinese patients. Preparatory work has finally started on setting up HTA in

China for the first time. Chinese think tanks and government authorities are therefore looking for input and information from other HTA experiences abroad. It is not yet clear whether this will enable truly innovation-friendly assessments, or if precision medicines in particular will be appropriately valued by the new reimbursement systems. It is also unclear whether industry input is well considered early on in the design and consultation phases of HTA, even though this is key to ensuring solid insights into current and future scientific development.

– **MedTech:** Single patient-use implantables may be listed for reimbursement, but reimbursement differs greatly between provinces. In addition, single patient genetic tests for selecting targeted tumor therapies are not yet reimbursed by the public health care system. This is essential for enabling patients to access modern precision medicine, however, and for determining which treatments are appropriate for them. Furthermore, challenges remain as innovative specialized medical products are often not priced differently even though their different qualities should be reflected in their prices. There is, for example, no price differentiation for diagnostic reagents, even though they vary greatly in quality, making price differentiation essential¹³³. Finally, the data sets generated can also help in further developing and optimizing treatments.

■ **No local preferences:** The proposed administrative measures currently suggest that qualified innovative products with “independent intellectual property” should be prioritized for inclusion in the NRDL. “Independent intellectual property” has been defined by the Ministry of Science and Technology as that developed and owned by a Chinese legal entity or Chinese national. We seek clarity on this statement given that country-of-origin preferences would be inconsistent with fair and non-discriminatory reimbursement listing policies.

Evaluation:

¹³² RASLSS, The Changing Face of Regulations and Market Access in China, <<https://www.raslss.com/changing-face-regulations-market-access-china/>> (accessed on 17.07.2020).

¹³³ European Chamber of Commerce in China (EUCCC), “Healthcare Equipment Working Group”, European Business in China Position Paper 2018/2019, pp. 248, <https://www.europeanchamber.com.cn/en/publications-archive/727/Healthcare_Equipment_Working_Group_Position_Paper_2019_2020> (accessed 29.5.2019):

The health care industry welcomes the Chinese government's efforts to improve access through broader reimbursement, including increasing the frequency of updates to the NRDL, and national negotiation of reimbursement for innovative drugs. It is now crucial to ensure that the system is predictable, evidence-based, and adapts quickly to scientific change by means of flexible reimbursement processes. The health care industry also welcomes the Chinese government's efforts to set up an HTA system, as this can systemize and improve the transparency of national reimbursement decisions. However, the extent to which it values innovative medical products depends on the design of the system.

Recommendations on Health Technology Assessments:

Value innovative medical products by opting for national payers' regular reimbursement to make new treatments available to patients. Additionally, rapid endorsement of the legislative proposal on NRDL updates to promote evidence-based criteria and improve the transparency of the reimbursement process are needed. To ensure that new treatments reach the market quickly, ensure that reimbursement assessments can be triggered by industry. Ensure that no price erosion unfriendly to innovation is triggered by multiple negotiation rounds and that no unpredictability for innovation reward is provoked. Industry therefore requests clarity and opportunities for dialog with NHSA on these proposed processes, methodologies, and timelines for adjusting prices.

Avoid mandatory localization by means of reimbursement regulations linked to the origin of the IP right of the medicines or medicinal products.

Promote precision medicine: To improve the efficacy of treatment and make more efficient use of health insurance funds, use modern diagnostics and add genetic testing for guiding targeted tumor therapy to health insurance coverage.

Ensure patient-centric endpoints and patient-centric systems that value innovative medical and assistive products, including incremental advances.

Strengthen good governance: Consult patients and industry experts at early stages of the research and legislative processes to respond to patients' unmet needs and mirror scientific development.

Install future proof HTA policies that allow innovative medical products to be assessed holistically and smoothly and create a strong link between clinical benefit and price. Additionally, medical devices different in quality should be consequently priced differently and reimbursed according to their innovative properties. The currently discussed joint clinical assessment of EU Member States (Euro HTA) should be considered as a basis for further cooperation and twinning programs of EU Member States and China, while both need to be optimized alongside scientific development in order to value innovative medicines and products. Consulting with industries and patients in regular and transparent processes is therefore key. Twinning programs allow administrative officers from different countries' institutions to work and learn from one another. Cooperation and setting up twinning programs could ensure more globally harmonized standards and actions.

09

Open markets for public procurement

Value Innovation Equal Access Quality

Value quality and do not limit treatment or diagnostic options

Public procurement allows purchasing processes that use transparent, predictable rules and can promote healthy competition. It also allows shared purchasing and provides the Chinese government with an important tool for controlling prices over volume, as well as ensuring transparency of anti-corruption efforts. Recent criticism of Chinese purchasing practices, however, has centered on the suggestion that procedures are too price-oriented and pay insufficient attention to quality criteria. Additionally, there have been allegations of localization and discriminatory practices.

Core challenges:

- **Localization:** The use of product lists and restrictions on buying imported goods may favor domestic companies in public tendering processes.

- **MedTech:** Despite the Working Plan 2017/2018 to abolish anti-competition policies, some provinces are issuing administrative notices that restrict the use of imported high-value medical devices¹³⁴. Additionally, the process of localizing highly innovative medical technologies to decrease costs and support local manufacturers is supported at the highest level of the Chinese government. The National Health Commission (NHC) uses product lists, which list a selection of medical products that health care institutions should purchase from local manufacturers.¹³⁵ Domestic market share targets for Chinese companies in the medical device sector,

¹³⁴ Urgent notice on strengthening accountability and strictly controlling unreasonable growth of medical expenses, Sichuan HFPC, see tieba.baidu.com/p/5449562416?redtag=1912952024. Chinese source?

¹³⁵ European Chamber of Commerce in China (EUCCC), "Healthcare Equipment Working Group", European Business in China Position Paper 2018/2019, pp. 248, <https://www.europeanchamber.com.cn/en/publications-archive/727/Healthcare_Equipment_Working_Group_Position_Paper_2019_2020> (accessed 29.05.2019).

as set out in China Manufacturing 2025, are a further challenge. Given such problematic practices, the German health care industry calls for elimination of localization requirements, which lead to discrimination against foreign bidders. More clarification and official guidance from the Chinese government are also necessary.

- **Emphasis on price and volume over quality and innovation:** A number of sectors face the challenge of aggressive price negotiation practices that fail to value highly innovative products and tend to exclude them from the procurement process.

- **Pharma:** The Chinese government has overhauled municipal and provincial procurement regulations with price and volume-based pooled procurement (VBP) pilots for drug purchasing. The government has applied VBP nationwide since September 2019. Specifically, in March 2019 the government started implementation of the 4+7 Cities pilot program. This is a VBP that targets off patent originators and generics that have passed the Generic Quality Consistency Evaluation (GQCE) and centralizes procurement procedures previously conducted by individual hospitals. The 4+7 Cities pilot¹³⁶ uses a “winner takes nearly all” approach, where a 70 percent market share goes to the single bidder offering the lowest price for an active substance. The remaining 30 percent market share is awarded to competitors who set prices in a race to the bottom. Overall prices for the first wave of molecules selected for the pilot program dropped by 52 percent, with some dropping by as much as 96 percent. In September 2019, the Chinese government conducted VBP tender for the 25 active substances of the 4+7 Cities pilot also for the rest of the market, and extended VBP nationwide. In January 2020, the Chinese government conducted VBP tender for 33 new active substance with adjusted rules for the nationwide market. While the introduction of VBP clearly addresses budget savings within an off-patent environment, it may limit innovation within the later part of a product’s lifecycle as there is no incentive, for example, to pursue

indication extensions within a year or two prior to patent expiration. Also, the selection parameters for VBP inclusion are not transparent and may not fully provide an innovation-friendly environment.

- **MedTech and diagnostics:** Innovative medical devices and assistive technology such as prosthetics and orthotics often require individual configuration and commissioning. Manufacturing, assembling, and delivering the product to the customer require additional logistics and service processes. Tendering processes do not consider these costs, however, and tend to favor lower prices¹³⁷.
- **Diagnostics:** Some provincial health authorities in China do not differentiate the price of diagnostics according to their quality and method. This is a barrier to the clinical use of modern diagnostic tests, and it prevents patients from receiving the most appropriate, reliable diagnostic results, potentially leading to increased treatment expenses and shorter survival. This includes, for example, cancer patients who could benefit from modern precision medicine in the form of targeted therapy or immunotherapy. This is true for patients with non-small cell lung cancer. Some of these patients can be treated with modern tyrosine kinase inhibitors or specialized immune drugs (checkpoint inhibitors), resulting in significantly longer overall survival, to name just one example.
- **Precision medicine** will change diagnostics, enable earlier diagnosis, and provide patients with better, more personalized treatment. However, developing and using precision medicines requires a better understanding of biomarkers or analysis of the patient or tumor genome prior to treatment. Enabling access to targeted genetic sequencing and/or immunological testing are therefore key issues. Genetic testing, genome sequencing, and immune analysis are not properly reimbursed at this time and are therefore not available to most patients.

¹³⁶ Bayer Pharmaceuticals, Healthy China 2030: Pressure on Prices Under Pooled Procurement, <https://pharma.bayer.com/healthy-china-2030-pressure-prices-under-pooled-procurement> (accessed on 22.07.2020); DecisionResourceGroup, In China 4+7 equals quality generic medicines at affordable costs, <https://decisionresourcesgroup.com/blog/china-47-equals-quality-generic-medicines-affordable-costs/> (accessed on 21.07.2020).

¹³⁷ European Chamber of Commerce in China (EUCCC), “Healthcare Equipment Working Group”, European Business in China Position Paper 2018/2019, pp. 248; <https://www.europeanchamber.com.cn/en/publications-archive/727/Healthcare_Equipment_Working_Group_Position_Paper_2019_2020> (accessed 29.5.2019).

Evaluation:

The health care industry recognizes and supports the wish to broaden access to diagnostic procedures and treatment. It is to some extent understandable that a volume-based approach has been chosen with the aim of reducing prices. High-quality, innovative, patient-centric medical and assistive products are, however, resource-intensive to develop and produce, and therefore come at a higher price. Ultimately, however, quality should not be compromised to the extent that patients are unable to access high-quality or innovative solutions.

Recommendations on Public Procurement:

Value quality and innovation: Guarantee fair, open tendering procedures that place the maximum possible emphasis on the quality, efficacy, and innovative value of medical products. Before issuing new calls for tenders, conduct comprehensive tender evaluation and avoid selecting winners based purely on the lowest price.

Promote use of the most economically advantageous tender (MEAT), e.g., as foreseen by the European Procurement Directive, in order to award contracts on the best value for money and promote a value-based care approach.

Support fast finalization of negotiations on the International Procurement Instrument (IPI), which aims at improving conditions under which EU businesses can compete for public contracts (public procurement) in third countries. The IPI would enable the European Commission to start a dialogue and negotiations—possibly resulting in charging a price penalty on bids from third country companies in case market access to their home market remains restricted for European companies.

Differentiate where necessary: Separate biosimilar from generic products and do not apply generics regulation to bio products as they are more complex. Differentiate between different diagnostic methods during procurement and pricing. Innovative diagnostics should be valued if they enable earlier or better treatment of patients. Ideally, there should be a nationwide guideline, which would ensure that provinces adapt their procurement and pricing negotiation standards accordingly.

Do not exclude customer-fit or patient-fit solutions:

Design tendering processes that consider essential configuration, services, and logistics. The same tender processes should also not hinder patient-fit treatments and not overly reduce the variety of treatment options for doctors and patients. Allow hospitals and other service providers to purchase products according to the needs of patients, and to adjust and allocate procurement volumes accordingly. Rescind the requirement for individual hospitals and service providers to conduct second-round price negotiations. Similarly, promote precision medicine, through reimbursement by public insurance for genome sequencing and immune analysis. Provinces should aim for genomic testing to be available in a large number of the hospitals, with analysis carried out in specialist hospitals or central laboratories.

Guarantee equal access: We recognize the positive legislative change under the newly enforced PRC Foreign Investment Law and its implementation rules as of January 1, 2020, which aim to ensure national treatment and equal access to foreign invested enterprises in China. It is more important, however, to ensure strict enforcement of these regulations and avoid discriminatory practices.

Eliminate regulations that prevent access to local markets and fair and equal competition. These include product lists and domestic market share targets for local manufacturers of medical devices, both of which currently present an obstacle to a competitive market environment.

Apply fair competition principles: Instead of gradual price reductions or setting price limits to non-winning products that participate in VBP bidding.

Cooperation in commercial medical insurance

The Chinese health care system currently provides public health care coverage to over 95 percent of the population.¹³⁸ Under its Healthy China 2030 plan, the Chinese government has significantly increased public reimbursement, including for innovative drugs and new treatment options over the last two years. Gaps in coverage remain, however, and commercial health insurance is therefore currently purchased to cover deductibles, co-payments, and other cost-sharing, as well as gaps in the coverage offered by the publicly financed health insurance system. This insurance is largely provided by for-profit commercial insurance companies and is at present purchased primarily by higher-income individuals and by employers for their workers¹³⁹.

Private insurance such as life insurance and health insurance often enables people to receive better quality of care and higher levels of reimbursement, since some health services are very expensive or not covered by public insurance. The main health insurance products currently available are personal critical illness insurance and medical insurance. Despite the aging demographic, insurance covering social care needs is underdeveloped¹⁴⁰. Epidemic risk insurance policies are now available for the first time, including policies offered by German insurers¹⁴¹. There is great investor interest in China, as these policies protect clients and their balance sheets from the consequences of an epidemic. They cover items such as delays in operations, business interruptions, and extraction of the workforce as a result of infectious diseases.

Improving service and financial health coverage for 1.4 billion people without overburdening public health care funding is a challenge for the Chinese government. The government therefore recognizes that commercial insurers perform a valuable function, and under its Healthy China 2030 plan it is promoting expansion of

the private insurance sector. It has, for example, created tax incentives for employers and employees by making costs for eligible health insurance plans tax-deductible. While China's new Foreign Investment Law (FIL) already is improving equal access and treatment for foreign investors (since January 1, 2020)¹⁴², restrictions in the life insurance sector will not phase out until 2021. Until then the negative lists' restrictions will remain. However, the opening signal is important, and implementation must then soon follow suit¹⁴³.

Megatrend: an aging society and rising middle class creating greater demand

An aging demographic and rising middle class are increasing demand for commercial health products. Forecasts suggest that China will have 329 million people aged 65 or older by 2050, including 120 million people over 80¹⁴⁴. Better prevention, diagnosis, and care, including precision medicine, will be needed to tackle the growing burden of NCDs. Additionally, a burgeoning middle class is demanding up-to-date treatments and is willing to make larger out-of-pocket (OOP) payments. Rather than risking unexpected one-off payments, however, many would prefer to better manage their risk by taking out commercial insurance policies.¹⁴⁵ The potential demand is clear from the figures. In 2017 individual OOP health expenditures reached RMB 1.49 trillion, representing 28 percent of all health expenditures¹⁴⁶. OOP expenditures are likely to increase with the growth in middle income families, which by some is forecasted to grow from 37 percent of families in 2017 to 50 percent of families by 2025.¹⁴⁷ From the perspective of the Chinese government, to relax pressure on public funds and improve overall health security it would therefore be

¹³⁸ Ulrike Reisach, *Das Gesundheitswesen in China*, Berlin 2017, p. 20.

¹³⁹ EY, White Paper on China Commercial Health Insurance, 2018, <[https://www.ey.com/Publication/vwLUAssets/ey-white-paper-on-china-commercial-health-insurance/\\$File/ey-white-paper-on-china-commercial-health-insurance.pdf](https://www.ey.com/Publication/vwLUAssets/ey-white-paper-on-china-commercial-health-insurance/$File/ey-white-paper-on-china-commercial-health-insurance.pdf)>.

¹⁴⁰ Ibid.

¹⁴¹ Allianz China Ltd. Allianz launches fully-owned insurance holding firm in China, <https://www.insurancebusinessmag.com/asia/news/breaking-news/allianz-launches-fullyowned-insurance-holding-firm-in-china-210603.aspx> (accessed 22.07.2020)

¹⁴² Ministry of Commerce of the People's Republic of China, Foreign Investment Law of the People's Republic of China - Order of the President of the People's Republic of China No. 26, <http://www.fdi.gov.cn/1800000121_39_4872_0_7.html> (accessed on 17.07.2020).

¹⁴³ Latham & Watkins, China Introduces New Foreign Investment Law, Negative Lists, and Encouraged Industries Catalogue, 02.08.2019, <<https://www.lw.com/thoughtLeadership/china-introduces-new-foreign-investment-law-negative-lists-and-encouraged-industries-catalogue>>.

¹⁴⁴ EY, White Paper on China's Commercial Health Insurance, 2018, p. 7, <[https://www.ey.com/Publication/vwLUAssets/ey-white-paper-on-china-commercial-health-insurance/\\$File/ey-white-paper-on-china-commercial-health-insurance.pdf](https://www.ey.com/Publication/vwLUAssets/ey-white-paper-on-china-commercial-health-insurance/$File/ey-white-paper-on-china-commercial-health-insurance.pdf)>.

¹⁴⁵ Ibid.

¹⁴⁶ Ibid, p.7 (as sourced from: Statistical Bulletin on China Healthcare Industry Development Issued by the National Health Commission).

¹⁴⁷ Ibid, p.7 (as sourced from Chinese Academy of Social Sciences, Social Blue Book 2017).

beneficial to accelerate development of commercial supplemental health insurance.

Evaluation

The health care industry welcomes the Chinese government's approach to combining public and commercial coverage, and recent steps to encourage commercial insurance in general. The health care industry also believes that facilitating the purchase of commercial health insurance requires the right incentives, and that private insurers should be able to respond to the demand for additional insurance products from Chinese consumers. The country of origin of the insurer should not be a criterion for market access. Up to now, foreign-funded companies have generally been subject to regulatory restrictions concerning their business location and have been unable to reach all potential policy holders. The improvements resulting from the Foreign Investment Law (FIL) and the upcoming changes in the negative lists mean that foreign insurance companies will soon be able to carry out commercial insurance activities in a previously highly restricted Chinese insurance market. It is encouraging that some German insurers have now received approval to establish Chinese subsidiaries. To meet the needs of an aging society, the health care industry therefore advocates steps to further encourage the commercial health insurance sector, particularly for products that improve preventive diagnosis, treatment, and care of patients with NCDs.

Recommendations for Promotion of Private Insurance:

Incentivize private insurers and industry: Make it easier for insurance companies to enter the market and register irrespective of their country of origin and provide tax incentives to both insurers and partner pharmaceutical companies. Thereby, it is particularly important to incentivize private insurance covering NCDs, such as cardiovascular or cancer care, to prudently prepare for the rising health cost pressure on the aging population.

Incentivize potential insurance policy holders: Grant further tax credits or reductions to insurance policy holders and to employers who provide their employees with supplemental insurance.

Organize insurance pilots: Organize medical insurance payment and tax credit pilots for treatment of chronic diseases such as cancer, hypertension, and diabetes in designated pharmacies. In particular, tax credits should be available for insurance packages enabling diagnosis and treatment with precision medicines.

Cooperation in the digitalization of health

As outlined in the first section of this position paper, digitization and digitalization in the health care sector are already strongly encouraged by the Chinese government and various provincial and municipal entities. China's New Generation Artificial Intelligence Development Plan¹⁴⁸ states that AI should help establish intelligent medical care in areas such as smart hospital construction and development of man-machine coordination in surgical robots. In addition, China's VR master plan 2025 identifies education and health care as key industries, creating a firm foundation for foreign companies wishing to use VR technology to enter the health care e-learning market¹⁴⁹. This enables the German health industry to seek out areas where collaboration in services and combined products offers value for both sides. More encouragement is needed in areas such as e-learning and virtual reality learning.

Current challenges and opportunities:

- **Digitalization in patient and service provider management:** Digital health and patient pathway records can significantly improve care delivery in areas such as oncology. In addition, digital health records can enable advanced care management, including better self-management and organization of health services by the patient, and e-learning programs can help optimize hospital and care management.
- **Digitalization in diagnostics:** To promote patient-centered care, precision medicines rely on large, high-quality data sets and analysis of genome sequencing data. This data is currently often not available, and many patients do not have access as tests are not reimbursed. Improving identification and understanding of biomarkers, better data and digitalization of processes would help alleviate the burden of a number of diseases, including cancer, rheumatism, diabetes etc. In particular for difficult cancer cases, a precise diagnosis is the crucial basis of an adequate treatment. Fully digitized data including images of X-rays, ultra-sound,

and histology slides, etc. should be exchanged between German, EU, and Chinese experts, organized as an interdisciplinary telemedicine network.

- **Digitalization in improving R&D productivity:** By combining expertise in biologics, pharmacology, biochemistry, engineering, and data science, we now have a real opportunity to bring new medicines to patients faster and more efficiently. We are leveraging Big Data and advanced analytics to accelerate drug discovery and improve drug development productivity. This includes both pre-approval and post-approval data, as well as real world evidence. Clinical trial timelines and approval procedures, however, have not yet been optimized.
- **Digitalization in training health professionals:** Combined digitalized medical products and health-related services like e-learning and virtual reality can be highly useful in areas such as improving education and life-long learning for doctors and nurses. Technologies such as e-learning, simulation, and extended reality will change the way we learn. They are smart additional education options for treatment and care. Currently, in part because of China's aging demographic, some parts of the country face shortages of sufficiently skilled medical staff. On average, for example, there are just 1.9 doctors¹⁵⁰ and 2.7 nurses¹⁵¹ per 1,000 people in China, compared to 4.1 doctors¹⁵² and 12.9 nurses¹⁵³ per 1,000 people in Germany. Cultivating specialization by doctors is still a challenge in some parts of the Chinese education system. In 2014, 48 percent of doctors and assistant doctors had a bachelor's degree or above, while 31 percent had a vocational diploma¹⁵⁴ and 21 percent a secondary vocational diploma. Similarly, a shortage of

¹⁴⁸ Foundation for Law & International Affairs, China's New Generation of Artificial Intelligence Development Plan, <<https://flia.org/notice-state-council-issuing-new-generation-artificial-intelligence-development-plan/>> (accessed on 17.07.2020)

¹⁴⁹ Chinese Ministry of Industry & Information Technology, Guiding Opinions of the Ministry of Industry and Information Technology on Accelerating the Advancement of the Development of the Virtual Reality Industry, <<http://en.pkulaw.cn/display.aspx?cgid=83f1361ce6b20a68bdfb&lib=law>> (accessed on 17.07.2020).

¹⁵⁰ World Health Organization, Global Health Observatory data repository – medical doctors, <https://apps.who.int/gho/data/node.main.HWFGRP_0020?lang=en> (accessed on 17.07.2020).

¹⁵¹ World Health Organization, Global Health Observatory data repository – Nursing and midwifery personnel, <https://apps.who.int/gho/data/node.main.HWFGRP_0040?lang=en> (accessed on 17.07.2020).

¹⁵² Statista, Number of practicing doctors in Germany between 1991 and 2017, <<https://www.statista.com/statistics/236511/practicing-doctors-per-thousand-inhabitants-in-germany-since-1991/>> (accessed on 22.07.2020).

¹⁵³ Statista, Number of practicing nurses in selected countries as of 2017, <<http://www.statista.com/statistics/283124/selected-countries-nurses-per-1-000-inhabitants/>> (accessed on 17.07.2020).

¹⁵⁴ Researchgate, China's doctors and assistant doctors by education level, 2002-2014, <https://www.researchgate.net/figure/Chinas-doctors-and-assistant-doctors-by-education-level-2002-2014-Sources-Health_fig1_333642222> (accessed on 22.07.2020).

well-trained nurses is a widespread problem in China, particularly for elderly care.

■ **Digitalization in occupational safety and health:**

Evaluating statistics and e-learning can be helpful for promoting occupational safety. They can also facilitate health in medical and geriatric institutions as well as in elderly care outside institutions. Work-related accidents, injuries, and diseases have an impact on not only the lives of individual employees and their families but also on the productivity and profitability of employers and ultimately on the welfare of society. Government, employers, and employees in China are strengthening efforts to prevent workplace accidents and diseases resulting from inappropriate working conditions. Improving occupational safety and health particularly in small and medium-sized enterprises (SMEs), which employ many young and migrant workers, is a major challenge¹⁵⁵. E-learning could be an effective educational option.

■ **Digitalization in therapy or remote service:** Sending online data from therapy or diagnostic screening devices (e.g. ventilators, retinal cameras, optical coherence tomographers) to remote specialists can facilitate inclusion of expert advice in medical therapies. It can also quickly ensure medical engineers' support for identifying and fixing failure sources in medical devices. The rural-urban divide in health

infrastructure can thus be better bridged in therapy delivery. Additionally, medical device downtimes can be reduced to ensure infrastructure readiness.

■ **Digitalization for population health management:**

To reduce health care costs in the health care system, it is important to promote broad health care systems analysis that can collect, analyze, and identify cost drivers and cost cutters in the health care system in order to make evidence-based decisions on interventions and related budget allocation. Currently, health care costs are administered based on limited data for long-term cost and health development trends in different parts of the population. However, real-time health data and cost data on regional and even local (neighborhood) levels is important for developing information and strategies to prevent unnecessary morbidity, and to reduce excessive cost increases and the burden of disease for the population. The German health care industry provides solutions ranging from data-warehousing and data-analysis to developing insights and strategies with regard to focused interventions in primary health care, thus avoiding more expensive secondary hospital care. Regional German health care pilots are renowned worldwide for their business cases, forms of management, and patient-focused results¹⁵⁶. When relying on such tools, governments can better identify and set up more effective education, prevention, and

¹⁵⁵ International Labour Organization, Safety and health at work in China and Mongolia, <<https://www.ilo.org/beijing/areas-of-work/safety-and-health-at-work/lang-en/index.htm>> (accessed on 17.07.2020).

¹⁵⁶ Medtronic, An integrated approach to value-based healthcare: Germany's Gesundes Kinzigtal, 2018, <https://www.medtronic.com/content/dam/medtronic-com/transforming-healthcare/documents/germany_case_eiu_av_corpmark.pdf>.

rehabilitation policies that contribute to health preservation or quick rehabilitation. In addition, other economic factors can be better considered through AI and digitization. These include economic gains through quicker return to work, less absenteeism from work due to illness, reductions in the need for nursing, hospital, and elderly care, and improving the overall health status of the population.

Recommendations on Cooperation on Digital Health:

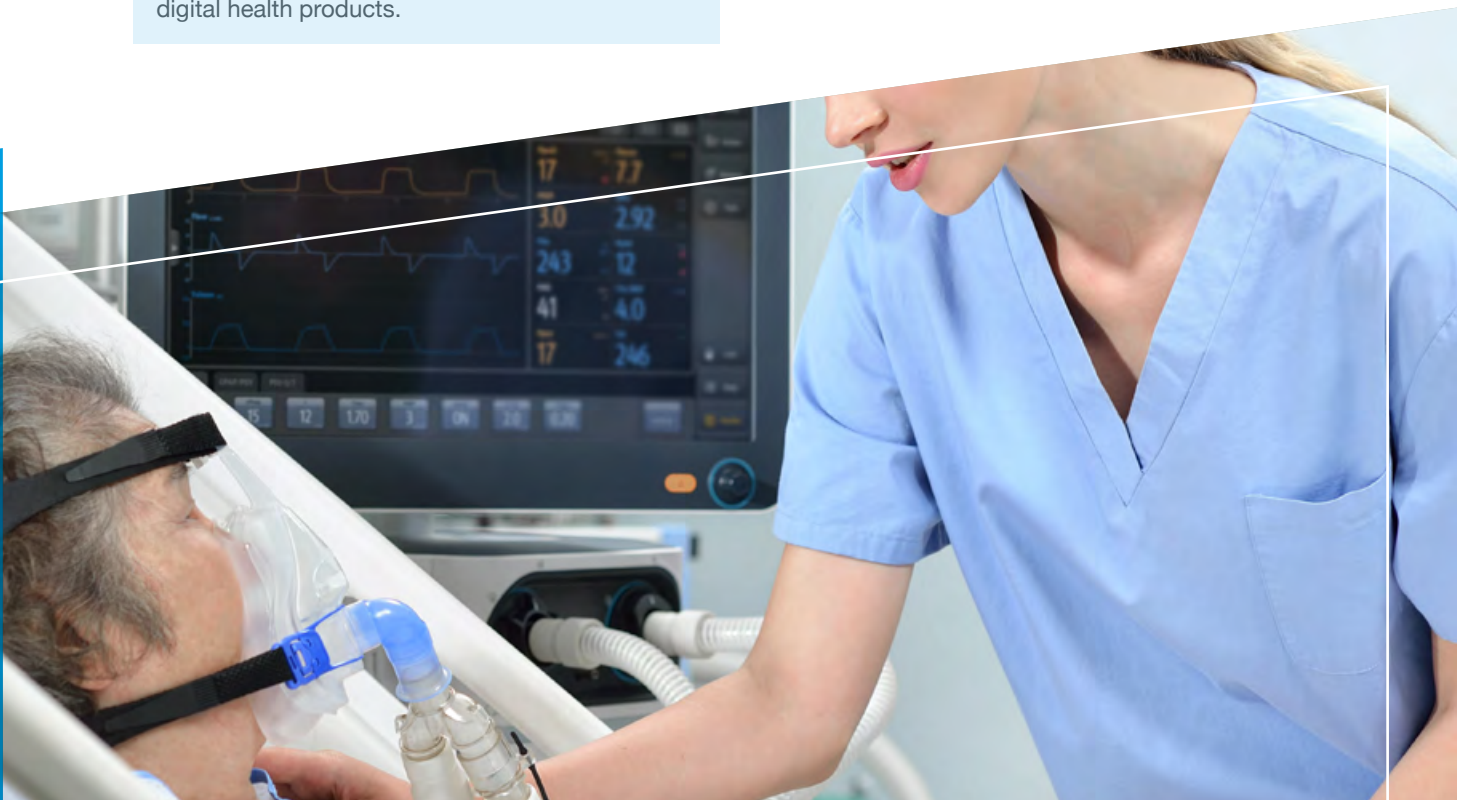
Establish and promote Sino-German collaboration on digitalization in areas of shared interest, such as education, occupational safety, patient and service provider management, interdisciplinary and transdisciplinary knowledge exchange (for example to secure second opinions regarding difficult cases), and precision medicine.

Address the issue of data security and data transfer with Chinese authorities. With the adoption of Cyber Security Law (CSL) of 2017, the integrity of company data is challenged. The international transfer and exchange of data generated in China is curtailed by the CSL, which in turn greatly hampers the prospects for cooperation and joint development of digital health products.

Ensure equal market access for digitalization products and services in health facilities in China.

Facilitate cooperation between Chinese and German companies of all sizes, including SMEs and start-ups, and encourage better mutual understanding.

Enable and promote genetic testing and genome sequencing, particularly for cancer research and treatment, through better reimbursement and facilitating digitized procedures.



Imprint

Publisher

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Publishing Company

Industrie-Förderung GmbH, Berlin

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Date and Number

August 2020
BDI-Publications-Nr. 0105

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