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a System of Contrasts



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Management system qualification? A necessity in any business

What is the success of a company? Although this answer cannot be simplified to one thing, the truth is that the success and proper functioning of a company depends on several factors that, integrated, are an almost guaranteed formula for good results. Among these factors, the management systems stand out. When reviewing the statistics, there has been a considerable increase in the adoption of management systems certifications in the last several years. Businesses are today struggling to meet customer expectations, experiencing reduced business opportunities, poor internal culture, and high staff turnover. Those results reflect uncertain times but are also encouraging in their demonstration of action shown by businesses to stabilize and secure their future.

Implementing Management System Standards (ISO) provides a modern and robust framework to adapt to the ever-changing business environment. A business management system is a work system, a key tool that helps to streamline your business processes and build-in efficiency. Implementation of the appropriate management system improves business performance and embeds safe and sustainable practices into your operations. On a practical level, it demonstrates your ability to meet your customers' needs. A company focusing on

its customers is estimated to be up to 60% more profitable than those that do not. An effective management system looks at managing and optimizing time, risks, and money, improving performance and transparency, fueling a culture of continual improvement.

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Federal presidential representative and democratic republic, governed by the Constitution of 1917

Mexico, officially named the United Mexican States, has 31 federal entities and the capital Mexico City, as separate entity, not formally a state, seat of federal government

11th most populous country in the world, with over 128.5 million residents, 77% living in urban areas

Approximately 15 million people identify as Indigenous (12% of total pop.), speaking 68 languages and living often in small, isolated communities

Upper middle-income economy, with one of the highest per capita incomes in Latin America, second largest economy in Latin America

Highly integrated with the U.S. via trade and nearshore manufacturing, low unemployment, inflation gradually decreasing

State intervention in energy sector and public infrastructure projects, challenges from income inequality, corruption, and cartel-based violence

Mexican Healthcare, a System of Contrasts

Although committing to a universal health care system, the necessary resources have not yet been made available, and a wholesale reform of the system remains pending.

🕒 11'
Reading time

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Editorial Director
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As the second most populated country (after Brazil) in Latin America and the Caribbean, Mexico has one of the largest healthcare markets in the Americas and, in a country as economically unequal as Mexico, where 40% of wealth is held by 1% of the population, effective public healthcare can help act as an equalizer, bridging the gap in access to basic services, including those guaranteed by the Mexican constitution. In fact,

since the Mexican Social Security Institute (IMSS) was established in 1943, the Mexican public healthcare system has evolved and expanded to incorporate more members of the population and provide coverage for wide a range of services from disease screening and prevention to the treatment of catastrophic diseases and conditions.

Mexican healthcare system is characterized by the coexistence and overlapping of various private and public health schemes. The public sector covers most of the population and is divided into two main categories: (i) while contributors to social security are cared for by different institutions according to the type of organization they work for, (ii) the government offers basic medical services in local clinics to anyone who is not inscribed in a particular health program. Overall, Mexican healthcare system is considered of good standards, affordable and especially large cities have excellent hospitals and clinics, staffed by highly trained and often English-speaking doctors. Many Mexican doctors go to medical school or do extra training in the United States or Europe and many still perform house visits, a rarity in modern medicine. However, there is still a high number of people who cannot afford more than the most basic care. As well, the Mexican government has one of the lowest per capita healthcare expenditures of all OECD countries and, despite its public healthcare is used by most Mexican residents, the private healthcare sector has grown considerably and is driven by increasing disposable income, the growth of medical tourism, and a demand for higher quality healthcare services.

Public Healthcare Delivery

Mexico's public healthcare has a complex and elaborate provisioning and delivery system. Public care is provided to all Mexican citizens, as guaranteed by Article 4 of the Constitution and is fully or partially subsidized by the federal government. Coverage eligibility stems from employment status, and the delivery system depends on whether a beneficiary works in the public or private sector, and whether their employment is formal or informal. The sys-

tem is thus segmented across diverse public and private payers and providers consisting of three main components operating in parallel: 1) employment based social insurance schemes, 2) public assistance services for the uninsured supported by a financial protection scheme, and 3) a private sector that includes hospitals, clinics, service providers, insurers, and pharmaceutical and medical device manufacturers and distributors. The social insurance schemes are managed by highly centralized national institutions while coverage for the uninsured is operated by both state and federal authorities and providers.

In most cases, social insurance institutions own their health infrastructure and hire salaried employees, who are mostly unionized through institutional trade unions. These institutions deliver a wide range of promotional, preventive, curative and rehabilitation services, with few exceptions (for example, cosmetic surgery and prosthesis), but there are no defined benefit packages, which vary across the coverage schemes. The largest social insurance institution – the Mexican Social Insurance Institute (IMSS) – is governed by a corporatist arrangement, which reflects the political realities of the 1940s rather than the needs of the 21st century.

The over 96,000,000 Mexicans accessing public healthcare receive medical attention through 5 different avenues.

“ Despite its public healthcare is used by most Mexican residents, the private healthcare sector has grown considerably and is driven by increasing disposable income, the growth of medical tourism, and a demand for higher quality healthcare services.

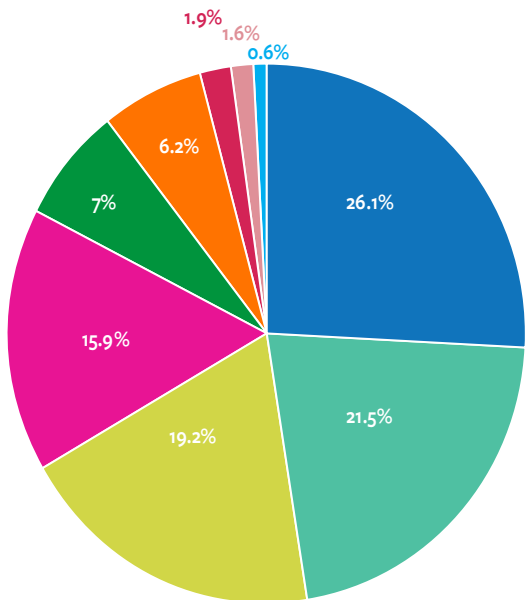
a) According to INEGI (the National Statistics Bureau), over 51% of public health coverage comes from IMSS, the *Instituto Mexicano del Seguro Social* (Mexican Social Security Institute), the system which covers formal employees working in the private sector as well as retirees, the families of all people covered, and a small proportion of people with other forms of employment. The IMSS program is a tripartite system funded equally by the employee, the private employer, and the federal government and currently covers around 68,659,149 people, according to IMSS. Further, within IMSS there exists the *IMSS-Oportunidades*, a program established out of the Program to Combat Poverty, which is specifically targeted towards aiding the poorest individuals in the country in both the health and educational fields. This program is completely funded by the government.

b) The *Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado* (ISSSTE), Institute for Social Security and Services for State Workers, attends to the health and social care needs of government employees at the local, state, and federal levels (as well as their spouses, and underage children), from public officials to public school teachers and police officers. Over 13 million people are covered by the ISSSTE.

Current healthcare spending	90.6 bn USD
Healthcare expenditure as share of GDP (average)	5.4-5.5%
Government's health expenditure per capita, per year	1,181 USD
Per capita out-of-pocket spending on health, per year	522 USD

Note: Healthcare spending is the final consumption of health care goods and services including personal health care and collective services.

Distribution of the Health GDP in Mexico in 2022, by Segment



- Hospital services 26.1%
- Associated goods and services 21.5%
- Outpatient medical services 19.2%
- Unpaid health-related work 15.9%
- Manufacturing of health care goods 7%
- Public health administration 6.2%
- Ancillary health care activities 1.9%
- Taxes 1.6%
- Centers and residences for health care and social assistance 0.6%

Notes: GDP = Gross Domestic Product
Source Statista 2024

c) PEMEX, the State-owned petroleum company, covers its roughly 750,000 employees and family members health services through a separate institution.

d) The Ministry of National Defense (SEDENA) and the Secretariat of the Navy (SEMAR) offer medical attention to service members and their families through the Social Security Institute for the Mexican Armed Forces (ISSFAM), which roughly covers 870,000 people.

e) An additional public healthcare insurance program, called *Seguro Popular*, was

created in 2003 to subsidize individuals not covered by other programs (informal employment, self-employed, unemployed or those out of the labor force). The program originated in a 1983 amendment to Article 4 of the Constitution that read “every person has the right to health protection,” but which for two decades the government struggled to realize. The system behind *Seguro Popular* slowly took shape as evidence accumulated about the economic and medical hardship of the uninsured, who made up nearly half the country. It was an important affirmation of the principle that social protections should

be expanded to all Mexicans, regardless of their work status, and not just those with formal employment. By 2018, *Seguro Popular* covered 42% of the population, however, while coverage for catastrophic diseases and conditions was effective, generating massive improvements in health outcomes, the program was managed at state level and, because of its decentralized nature, was closed in June 2020 as susceptible to corruption, and parts of the system were dismantled. In 2020, the Institute of Health for Welfare (Insabi - Instituto de Salud para el Bienestar) was created to replace *Seguro Popular*. Under this system, public healthcare would be recentralized, and operated by both the Federal, and state governments. Transition to Insabi sought to address medication scarcity and expand access to healthcare, but its inability to do so has led to its elimination in 2022 and to the transition into *IMSS-Bienestar (Instituto Mexicano de Seguro Social y Bienestar)*, an ambitious endeavor meant to assume a crucial role in reshaping Mexico’s healthcare system, by providing healthcare services especially to underserved areas and vulnerable populations. The *IMSS-Bienestar* program, initially founded in 1973 to offer healthcare services to the most vulnerable and marginalized communities, many with no taxpaying capabilities, may offer Mexico the opportunity for significant improvement. It currently covers over 13 million people and will allegedly continue to grow through agreements between the states and the federal government. Since *Seguro*



Public healthcare units (2019) of which:	22,831
Hospitals (124 highly specialized and 3,114 accredited private hospitals)	4,629
No. of medical schools	103

	Mexico	OECD recommended
No. of Doctors, 2021	324,292	
No. of General Medical Practitioners	115,004	
No. of Specialists Medical Practitioners	209,288	
No. of doctors per 100,000 people	2.5	3.2
No. of nursing and midwife personnel	378,974	
No. of nurses per 100,000 people	2.9	8.8
Hospital bed density	1 beds/1,000 population	

Source: WHO – Global Health Workforce Statistics Database/www.cia.gov



Perceptions on the Healthcare System in Mexico 2023

According to a survey conducted in Mexico in 2023, only 40% of respondents said they trusted their country's healthcare system to provide the best health treatment.

Moreover, around 74% of interviewees stated that many people cannot afford good healthcare in Mexico, while seven in every ten said waiting times to get an appointment with doctors are too long.

According to the same survey, approximately 34% of respondents believed that the quality of the Mexican healthcare system is either good or very good.

Popular closure, however, the percentage of the population covered declined sharply (by 16.8% between 2018 and 2020) and improvements in key indicators such as maternal mortality seem to have reversed. Patients are waiting longer to see doctors, paying more out of pocket, and encountering medicines shortages. Funding for certain types of specialized care, such as childhood cancers, has also fallen.

Mexico's private health subsystem, a significant component of the country's healthcare system, is large and growing, as a response to the limitations of the public sector within the context of an increasingly competitive economy and an ageing population. Underfunding and inefficiency have led to government health service shortages, providing the private sector with an opportunity for their fulfilment. Up to 45% of total outpatient consultations and 19.5% of hospital care is supplied by private provid-

ers. Public health care services are preferred for the more costly care while the private sector is often the first choice of care for minor conditions as well as for continued care among the wealthy, particularly those covered by private health insurance. Private providers are also the main source of care for the uninsured. Among the patients covered by social insurance institutions, up to 32% of outpatient care and 14.1% of hospital care is provided by private providers. In the case of the non-insured, up to 33% of total outpatient consultations and 14.8% of hospital care is supplied by private providers.

The private hospital sector offers medical services to individuals who seek premium healthcare outside of the public healthcare system, willing to pay for higher quality facilities, faster access to medical treatments, and a wider range of specialized services. The Mexican private hospital sector has seen steady growth due to increasing demand from middle and high-income individuals

who desire more personalized and efficient healthcare services, as well as from medical tourists attracted to the country's relatively lower costs for certain medical procedures.

Health Challenges

National health spending has grown in recent years (averaging 5.4% of GDP) but is lower than the Latin America and Caribbean average (7.4%) and considerably lower than the OECD average (8.8%). Public spending accounts for 58% of total financing, with private contributions being mostly comprised of out-of-pocket spending. The private sector, while regulated by the government, mostly operates independently.

Health challenges are not only limited to resources and services, the system faces challenges with obesity, diabetes and other chronic diseases, violence, as well as with health inequity, despite the efforts put forward by authorities to diminish inequalities. Recognizing the inequities in access, created by its segmented structure, both civil society and government are calling for greater integration of service delivery across public institutions, although no consensus yet exists as to how to bring this about. Furthermore, although efforts have been made to encourage citizens to follow healthier habits, it will still take large structural efforts from local authorities to create a more preventive culture among the Mexican population.

As revealed by the 2020 census, 70.9% of Mexicans are covered by public healthcare. While this represents significant coverage increases since the 1990s (partially

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spurred by Seguro Popular), entitlement to coverage does not always account for the quality or availability of medical attention, which often pushes people into the private healthcare sector, and leaves the most vulnerable populations with no access at all. Private sector services serve approximately 25-30% of the Mexican population (this includes the overlap between the two systems) and are in high demand given insufficient resources among most public institutions and the lack of voice by the insured to ensure the fulfilment of entitlements. Currently, 2.3% of the population is insured through the private medical and accident insurance while over 32 million Mexicans (26.5%) have no access to any form of healthcare.

Changes in government policies, the creation of new healthcare programs, the overhaul of the medication purchase plan, and the COVID-19 pandemic, have further exacerbated the lack of access to healthcare since 2018. During the pandemic, the country had among the highest levels of excess mortality of any country. Many of the challenges facing Mexican health care date back in time and administrations. For example, Mexico faces an acute shortage of medical professionals. While the Mexican government has proposed the hiring of Cuban doctors and the establishment of

the National Recruitment and Hiring Session for Specialized Physicians to hire 13,765 doctors, especially for rural and marginalized areas, factors such as corruption, lack of security for doctors, and inefficient systems have not yet been addressed.

In a drive to reduce costs and improve healthcare outcomes, there has been a trend towards outsourcing specialized procedures and care. For instance, most dialysis services in Mexico are provided by private sector companies under contract to public healthcare agencies. Many public and private hospitals outsource surgical procedures to companies that offer integral surgery services or surgery centers. Thus, hospitals have been able to avoid big

capital investments in plants and equipment, materials, pharmaceuticals, and instruments, while gaining access to some of the most modern specialized surgical procedures.

Mexico has a well-established regulatory framework and a robust healthcare system, providing a favorable environment for companies to operate. The country's proximity to the US also offers advantageous market access to North America. Nevertheless, approval processes and bureaucratic procedures are burdensome, causing lengthy waits for registration and authorization of pharmaceuticals and medical devices. It has a thriving pharmaceutical industry

“ Transition to Insabi sought to address medication scarcity and expand access to healthcare, but its inability to do so has led to its elimination in 2022 and to the transition into IMSS-Bienestar (Instituto Mexicano de Seguro Social y Bienestar), an ambitious endeavor meant to assume a crucial role in reshaping Mexico's healthcare system, by providing healthcare services especially to underserved areas and vulnerable populations.

that produces a wide range of generic and branded medications. With a large population and increasing healthcare needs, the demand for pharmaceutical products and services is continuously expanding.

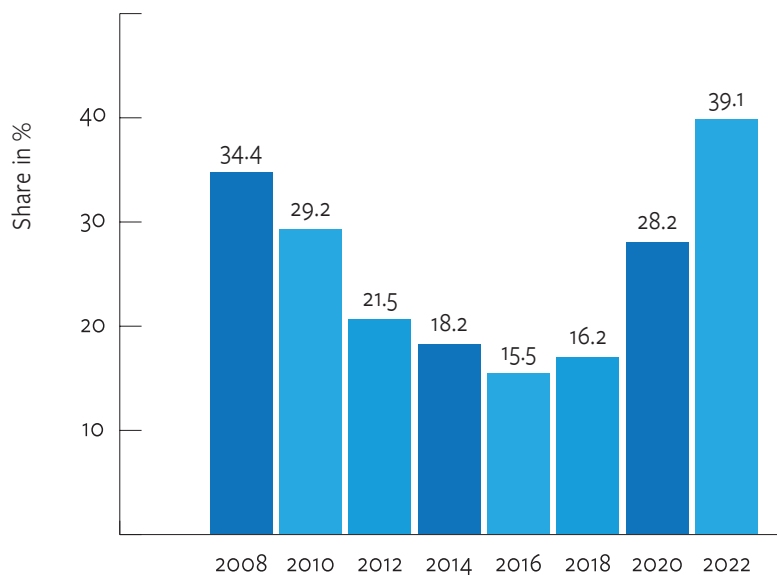
The country's public health system recently underwent a series of changes in the procurement system and distribution structure. Access to medicines has steadily worsened since 2018. While the IMSS (Mexican Social Security Institute) was historically in charge of purchasing medications and other health-related products, in response to alleged corruption in 2019, this responsibility was transferred to the Ministry of Finance and Public Credit. This Ministry lacked experience and was unable to effectively put together a purchase plan. This role was subsequently transferred first to INSABI and then UNOPS, a UN agency (July 2020) and then to the authority of the Mexican Institute of Social Security and Welfare (IMSS Bienestar). The process faced difficulties, and this repeated transfer of responsibility has created uncertainty

in the procurement process for medicines and medical devices. The scarcity of publicly provided medication directly increased out-of-pocket medical expenses by 40% between 2018 and 2020. Additionally, during this period the number of people suffering from some form of healthcare deprivation increased, with vulnerable populations being the most affected, amounting to more than one third of the country's population in 2022 (in that year, it was estimated that 39.1% of the Mexican population suffered vulnerabilities, from 15.5% in 2016). The COVID-19 pandemic reduced access to healthcare as public healthcare usage fell by 11.3% between 2018-2020 and at least 7 out of every 10 Mexicans were forced to rely on private healthcare for their needs.

For anything applied to entering the country, whether a device, instrument, or pharmaceutical, sanitary registration issued by COFEPRIS is mandatory. However, COFEPRIS, the Federal Commission for Pro-

tection against Health Risks (Comisión Federal para la Protección contra Riesgos Sanitarios), is undergoing major restructuring due to alleged corruption concerns, which has caused a significant backlog of registrations, import permits, and Good Manufacturing Practices (GMP) certifications. Part of COFEPRIS' transformation strategy includes plans to digitalize its procedures and go paperless by 2030. In the meantime, companies continue to struggle with delayed response times. COFEPRIS regulates approximately 14% of Mexico's economy, including industries such as food and beverages, health supplies, pharmaceutical drugs, health services, organ transplants, cosmetics, pesticides, plant nutrients, natural emergencies, occupational health, and environmental risks. It is estimated that COFEPRIS regulates 45 cents of every peso spent by Mexican households, primarily goods that fall into the following main categories: food and beverages, health care, personal care, and tobacco.

Share of Vulnerable Population Due to Lack of Access to Health Services in Mexico



Source Statista 2024

Among Main Sources:

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European Antibiotic Awareness Day 2024



Data published by the European Center for Disease and Control in connection with European Antibiotic Awareness Day, on November 18, shows that, despite improvement in some areas, the EU is lapsing in progress towards its 2030 antimicrobial resistance (AMR) targets.

While some Member States have made great progress towards their recommended AMR targets, or even in some instances have already reached the recommended targets, the overall picture shows that more specific, intensified interventions are urgently needed across the EU.

- Each year, over **35,000** people in the European Union (EU), Iceland and Norway, die from infections resistant to antimicrobials – a number that has increased in recent years. The mortality caused by these infections is comparable to that of influenza, tuberculosis and HIV/AIDS combined.*
- Each year, **4.3 million** patients in the European Union/European Economic Area (EU/EEA) acquire at least one healthcare-associated infection during their stay in a hospital and many of these infections are resistant to antimicrobials.**
- On any given day, about 7%, or 1 in 14 patients in hospitals in the EU/EEA have at least one healthcare-associated infection.
- **1 in 3 microorganisms** detected in healthcare-associated infections are bacteria resistant to important antibiotics, thus limiting options for treating infected patients.

Between 2019 and 2023, antibiotic consumption in the EU increased by 1%, moving further away from the 2030 target of a 20% reduction recommended by the Council of the European Union. Although during the same period there have been significant reductions in methicillin-resistant *Staphylococcus aureus* bloodstream infections, the situation in other critical areas, such as carbapenem-resistant *Klebsiella pneumoniae* bloodstream infections, has worsened, with an increase in incidence by almost 60% between 2019 and 2023. This represents a growing threat to patients in hospitals across the EU, particularly since very few therapeutic options remain available to treat patients infected with carbapenem-resistant *K. pneumoniae*.

“Reaching the EU targets by 2030 requires a united, urgent response across the EU to prevent AMR from undermining healthcare. This response is key to protecting patients and sustaining the effectiveness of antibiotics for future generations.” says Dr Pamela Rendi-Wagner, ECDC Director.

To turn the tide in the fight against AMR (Antimicrobial Resistance), the European Center for Disease and Control (ECDC) is calling for accelerated efforts in three main areas: infection prevention and control, prudent use of antimicrobials, and the development of and access to novel antimicrobials.

Healthcare-associated infections account for 70% of the AMR-related health burden in the EU. This is why hospitals must prioritise basic, yet critical measures

for infection prevention and control, such as:

- improving hand hygiene and giving easy access to alcohol-based solutions for hand disinfection,
- increasing screening for the carriage of resistant bacteria to curb the growing trend in carbapenem-resistant *Klebsiella pneumoniae*,
- increasing the capacity to isolate positive patients by making sure that there are enough single rooms,
- increasing the number of dedicated infection prevention and control staff and relevant training.

The community sector accounts for 90% of total antibiotic use in humans. Reducing the use of antibiotics requires more information and public awareness campaigns, complemented by social and behavioural interventions to prevent their unnecessary use.

ECDC continues to promote the development of and access to novel antimicrobials, and alternatives to antimicrobials, that are both effective and safe for humans. Antimicrobials of this type are essential for treating patients with infections that are resistant to last-line antibiotics such as carbapenems.

In the absence of stronger and swifter public health action, it is unlikely that the EU will reach all its targets by 2030. The consequence will be an increased number of infections with antimicrobial-resistant bacteria that will be more difficult to treat, leading to increasing challenges for patients and larger numbers of AMR-related deaths.

ECDC is committed to supporting Member States in achieving their 2030 AMR targets and has a range of measures to help them address specific gaps and strengthen national capabilities. These include individual AMR country visits and regular Public Health Emergency Preparedness Assessments for all EU/EEA countries, with antimicrobial resistance and healthcare-associated infections as key focus areas.



Source: The European Centre for Disease Prevention and Control (An agency of the European Union) www.ecdc.europa.eu

Notes:
*35 000 annual deaths from antimicrobial resistance in the EU/EEA

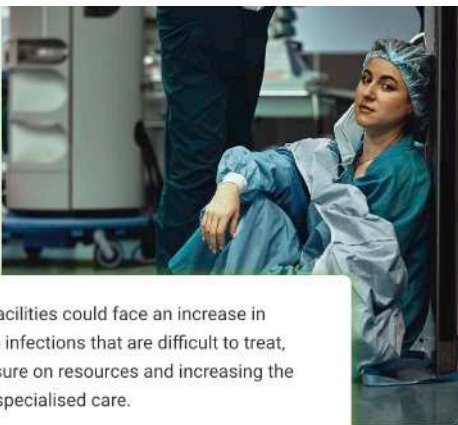
**Point prevalence survey of healthcare-associated infections and antimicrobial use in European acute care hospitals – 2022-2023



Simple infections could become difficult or impossible to treat with antibiotics or other antimicrobials, causing long-lasting sickness.



Simple surgical procedures, organ transplants and cancer treatments would be severely affected, as patients rely on the availability of effective antimicrobials to prevent and treat infections.



Healthcare facilities could face an increase in patients with infections that are difficult to treat, putting pressure on resources and increasing the demand for specialised care.



Prolonged hospital stays, increased healthcare costs and decreased productivity due to illness or premature death could lead to an increased economic impact on individuals, families and societies.

The high cost of inaction to tackle AMR

11.7
billion EUR

This is the annual cost of antimicrobial resistance in the EU and European Economic Area (EEA)

Most of the costs are caused by:



Longer treatment

6.6 billion EUR of the total cost is extra health expenditure from treating resistant infections and their consequences



Reduced workforce participation

5.1 billion EUR is economic losses due to reduced participation in the workforce (e.g. premature loss of life or reduced productivity due to long sick leaves)¹

¹ Organisation for Economic Co-operation and Development (OECD). Fighting antimicrobial resistance in the EU/EEA. Embracing a One Health approach. Paris: OECD, 2023. Available at: <https://doi.org/10.1787/35555555>

What could the future look like?

Without urgent actions to address AMR, severe health, social and economic consequences are foreseen, such as:

Key Considerations for Entering China's Healthcare Market

China's healthcare market is continuously growing and dynamic, making it one of the most attractive in the world. However, the market is heavily regulated, with high compliance requirements and strong competition.

For foreign investors to successfully enter this market, it is crucial to understand the relevant industry policies and compliance requirements and develop a well-tailored strategy.

In this article, we outline some key considerations for entering China's healthcare market and summarize critical success factors.

Is China's healthcare sector open to foreign investment?

When investing in China's healthcare market, one of the first considerations should be whether the specific sector they want to enter allows foreign investment.

Despite China's continuous liberalization of its healthcare industry to allow foreign participation by removing items from the Special Administrative Measures (Negative List) for Foreign Investment Access (hereafter referred to as the "FI Negative List") and adding items to the Catalogue of Encouraged Industries for Foreign Investment (hereafter referred to as the "FI Encouraged Catalogue"), there are still certain sectors that remain off-limits or restricted to foreign investment.

Medical institutions

Foreign investment in medical institutions is restricted to joint venture structures and cooperation with Chinese companies, unless where special approval has been granted. An exemption exists for Hong Kong entities and eligible Hong Kong Service Suppliers, who are eligible to establish wholly foreign-owned medical institutions if they meet the requisite conditions under the *Mainland and Hong Kong Closer Economic Partnership Arrangement (CEPA)*. Additionally, in 2014, wholly foreign-owned hospitals were once allowed in seven cities including Beijing, Tianjin, Shanghai, Jiangsu, Fujian, Guangdong, and Hainan on a pilot basis.

Find Business Support

Sino-foreign joint venture hospitals must comply with the *Interim Measures on the Administration of Sino-Foreign Joint Venture and Cooperative Medical Institutions*, which stipulate that foreign investors' shareholding ratio or equity in the joint venture shall not exceed 70 percent. The total investment must be at least RMB 20 million (Approx. US\$2.9 million), and the joint venture's operation term cannot exceed 20 years.

In practice, some foreign investors have managed to break through these restrictions on foreign ownership

“ Entering China's healthcare market presents an alluring opportunity for global investors, but it is highly regulated and fiercely competitive. To achieve success, businesses must skillfully navigate the evolving regulatory and compliance landscape, strategically plan their approach, and remain proactive and adaptable to maintain their competitive advantage and respond effectively to market trends.

ratio or even gain complete control over domestic medical institutions through historical investment, domestic reinvestment, VIE arrangement, or custody agreement. However, they may face obstacles when changing or renewing their operational qualifications, such as the Practicing License of Medical Institutions. Furthermore, in the case of subsequent shareholding changes, regulatory authorities may review the actual foreign shareholding ratio based on the “look-through approach” (穿透式审查, meaning tracing to the ultimate shareholder by looking through the multiple layers of shareholding structure based on the current effective law at that time), which may require foreign investors to reduce their ownership. Therefore, foreign investors should exercise caution when planning their investment structure.



Human stem cells and genetic technology

Another healthcare sector that is restricted to foreign investment is human stem cell and genetic technology. According to the latest FI Negative List, foreign investors are currently not allowed to directly invest in the development and application of human stem cells and gene diagnosis and treatment technologies.

However, foreign investors are encouraged to invest in the manufacturing of high-throughput gene sequencing systems, according to the latest FI Encouraged Catalogue. Foreign investors are also generally not restricted from engaging in the import and export, production, sales, and research and development of genetic testing equipment.

On the other hand, in accordance with the *Regulations of the People's Republic of China on the Administration of Human Genetic Resources*, foreign investors can cooperate with domestic institutions in scientific research related to stem cell and/or genetic diagnosis and treatment, provided that certain requirements are met, and regulatory approvals are obtained. They can also grant licenses to domestic institutions for the technological development and sale of genetic diagnostics and/or stem cell products owned by them.

Although there are established pathways for foreign investment in the sector, foreign investors may still encounter challenges. For instance, it can be challenging to clearly distinguish between the development of genetic testing equipment and the research and development of genetic testing technology in practice. Consequently, some activities of genetic testing equipment research and development enterprises may be classified as the application of genetic diagnosis and treatment technology, thereby prohibiting foreign investment. To avoid such complications, foreign investors are advised to communicate with relevant authorities in advance.

Traditional Chinese medicine

Foreign investors are prohibited from investing in the application of steaming, frying, moxibustion, calcination, and other processing techniques of traditional Chinese medicine (TCM) decoction pieces, as well as the production of confidential prescription products of proprietary Chinese medicines. However, such restrictions do not exist in China's 21 free trade zones.

Beyond these three sectors – medical institutions, human stem cell and genetic diagnosis and treatment technology, and TCM – other healthcare sectors are mostly open to foreign investment in China.

In fact, foreign investment is actively encouraged in many healthcare areas, such as the manufacturing of new compound drugs or drugs with active ingredients, researching and developing (R&D) and manufacturing of cell therapy drugs (excluding areas where foreign investment is prohibited), manufacturing of dental implant systems for implant repair in patients with bone loss, post-partum maternal and child services in maternity centers, and rehabilitation institutes for autistic children, to name a few. Foreign investors with expertise and a strong presence in a particular area should confirm whether their business falls within these encouraged sectors to benefit from corresponding investment facilitations and receive preferential land and tax incentives.

Approval and licensing Find Business Support

The healthcare sector has always been subject to stringent regulations as the quality of medical services



and healthcare products directly impact the safety and well-being of individuals. Recent efforts have been made to simplify and streamline administrative procedures in the healthcare industry, as part of medical reforms aimed at encouraging social capital, including foreign investment, to participate in providing diversified healthcare services. However, relevant market players still need to obtain various qualifications and fulfill registration and approval procedures to demonstrate their technical capabilities and ensure compliance with regulations.

Pharmaceutical approval and licensing

In the pharmaceutical area, depending on their specific business scope and business type, different certifications and qualifications are required:

- For businesses engaging in pharmaceutical R&D, they will need to obtain a Good Laboratory Practices for Nonclinical Drug Research (GLP) certificate issued by the National Medical Products Administration (NMPA) for doing preclinical trial; a record-filing with local health bureau for the use of pathogenic microbiology and an approval from



local department of science and technology for use of experimental animals in laboratories; a Radiation Safety Permit from local environmental protection bureau if the drug R&D process involving radiative materials; and import-export related licensing and approvals if the drug R&D involves in imported raw materials.

- For businesses engaging in pharmaceutical manufacturing, they will need to apply for a Drug Manufacturing License from provincial NMPA and then comply with the Good Manufacturing Practices (GMP) standards. They also need to obtain a Work Safety License for the production activities, and relevant import-export licenses if needed.
- For businesses engaging in drug supplying and trading, they will need to apply for a Drug Trading License and comply with the pharmaceutical Good Supply Practice (GSP) standards.

Medical devices approval and licensing

Medical devices in China are subject to classified management: medical devices are divided into three classes based on the level of risk they present to patients or users. Class I is the lowest risk class and is subject to record-filing management, which is comparatively easier, and Class II and Class III are the higher risk classes and are subject to product registration management, which involves a longer and more rigorous process.

Upon registration, the business will obtain a Medical Device Registration Certificate for relevant Class II and Class III medical devices. Also, businesses will need to file

a record with local NMPAs for trading Class II medical devices while they need to obtain an approval for trading Class III medical devices.

Approval and licensing of medical institutions

As for setting up medical institutions, foreign investors will need to obtain an Approval for the Establishment of Medical Institutions and a Practicing License of Medical Institutions from local health authorities.

Medical institutions will additionally need to obtain multiple licenses based on their business scope, such as the license for radiological diagnosis and treatment, license for maternal and infant health technical service institutions, license for occupational health examination and diagnosis institutions, and license for purchase and use of narcotic drugs and category I psychotropic drugs.

However, under the “many-in-one” reform, most of these post-establishment licenses, except the Large Medical Equipment Configuration License, have been integrated into the Practicing License of Medical Institutions. That is to say, upon getting approval for relevant applications, the authority in charge will affix relevant information on the Practicing License of Medical Institutions, rather than issuing separate licenses.

Foreign investors engaging in relevant sectors are suggested to have a thorough understanding of the qualification, certificates, and approval requirements in advance and consult with experience local agencies to estimate the time and cost.

Two-invoice system

The “two-invoice system” means that during the distribution process from drug manufacturer to hospital, only two value-added tax invoices (or fapiao) may be issued. The manufacturer issues a first invoice to the distributor, while the distributor issues a second invoice to the hospital or medical service provider. Unlike the previous system where drug distribution chains were typically comprised of manufacturers and multiple levels of distributors, the two-invoice system allows only one level of commissioned distributor in the procurement chain.

Find Business Support

First piloted in selected provinces in 2016, this program was expanded nationwide in 2017 and 2018 for drug distribution. The two-invoice system has also been expanded to cover certain categories of medical devices since 2018, such as the “high-value medical consumables”.

The “two invoices system” is designed to streamline pharmaceutical distribution channels, reduce the cost of pharmaceuticals, and prevent corruption. But in practice, the system has changed the way manufacturers (importers), distributors, sales, and compliance teams in the pharma industry work from both business and tax perspectives.

To ensure compliance and enhance competitiveness in this evolving system, relevant businesses must transition from a hierarchical to a flat structure in the distribution channels of pharmaceutical products and integrate the supply chain. This not only challenges enterprises to effectively collaborate and manage upstream and downstream business partners but also increases the complexity of internal operational management. In light

of this, enterprises are advised to seek professional assistance in advance and implement appropriate supply chain management systems and tools.

Further, under the two-invoice system, pharmaceutical distributors will face higher financial pressure as they have to deal with the long payback period of hospital and medical institutions alone, rather than sharing with other distributors. Companies are advised to make plans for cash flow management as early as possible.

In addition, pharmaceutical companies must be mindful of their pricing strategies, as the difference in pricing between the hospital purchase price and the manufacturer’s (or importer’s) ex-factory price not only affects the manufacturer’s (or importer’s) margins but also impacts their VAT payable.

Medical advertising

Medical advertisements have become increasingly important in boosting the sales of related medical products in China, given the highly competitive market and rapid growth of the platform economy. However, due to the close connection between medical products and services and consumer health, medical advertising is subject to higher compliance requirements and scrutiny compared to general advertising.

In April 2021, market supervision administrations across the country launched special campaigns to target illegal advertising practices in medical treatment, drugs, health food, and medical beauty, including unauthorized medical advertising, exaggerated claims, and false advertisements.

Furthermore, China has revised several laws and regulations related to medical advertising, such as the *Advertisement Law* and the *Regulations on the Supervision and Administration of Medical Devices*, which have established stricter compliance standards, increased penalties



for non-compliance, and thereby increased the costs of non-compliance for relevant enterprises.

As crackdowns on illegal medical advertising are likely to persist in the near future, it is important for investors to consider medical advertising regulations when developing their overall compliance system. This may include implementing qualified professional services, providing proper training, establishing a well-developed internal control system, and conducting regular compliance audits to avoid potential penalties and reputational harm to the business.

Crackdown on corruption in the healthcare sector

Businesses operating in the healthcare industry should also pay attention to anti-corruption management, as China sees corruption in the medical fields as the one of the main factors that undermine the reliability and efficiency of the country's medical system. The government has taken a strong stance against anti-competitive behaviors and corruption in the medical field, leading to increased scrutiny and low tolerance for such actions.

In August 2020, the Central Supervision Commission (CSC) issued a notice emphasizing the importance of strict anti-corruption investigations in the medical field. In October of the same year, the CSC issued another statement calling for the investigation of power-money transactions, the establishment of a list of dishonest individuals, and the cutting off of the benefit chain of medical bribery.

Companies in the healthcare sector are thus at a higher risk of being implicated in commercial bribery and subject to administrative or even criminal penalties. Therefore, it is crucial for relevant enterprises to include anti-corruption measures as an essential part of their overall compliance system. They should also continuously monitor the authenticity, rationality, and verifiability of their employees' behavior in subsequent marketing processes.

Key takeaways

China's healthcare sector is highly regulated and competitive and is among the most promising markets in the global healthcare sector. To succeed in this market, foreign investors must be proactive and agile, planning strategically, acting quickly, and working diligently.

In addition to the considerations mentioned above, foreign investors should stay abreast of the latest policies, not only those related to the administration and compliance of the healthcare sector but also those outlining the government's industry priorities. They should adjust their strategy and operations accordingly.

Furthermore, innovation is a key advantage for foreign investors, especially those with expertise in a particular area, but smaller in size. It is wise to capitalize on their creativity by customizing their products to meet the needs of the Chinese market and addressing existing challenges. They should also develop a comprehensive intellectual property strategy early on to maintain their competitive edge.

Finally, foreign investors who are unfamiliar with the Chinese market are advised to partner with local companies and hire professional agencies to facilitate market entry and compliance management. However, they should conduct due diligence to verify the reliability and qualifications of potential local partners and professional agencies.



ABOUT US

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MEDICA 2024 and COMPAMED 2024: medical technology industry uses global reach to compete for innovation leadership



17–20 Nov. 2025

International networking, a wide range of innovations and a forward-looking programme

“Meet Health. Future. People.” is MEDICA’s campaign motto for the future in the new trade fair year 2025. The aptness of the motto was confirmed by the success of MEDICA 2024 and its concurrently held number 1 supplier trade fair, COMPAMED 2024. “The best options for global networking were on offer, along with an incredible variety of cutting-edge innovations and top-level programme highlights. MEDICA is unique in its global reach”, says Marius Berlemann, Chief Operating Officer of Messe Düsseldorf, clearly impressed by all that happened at the exhibition booths and on the programme stages. From 11 to 14 November, a total of 5,800 exhibiting com-

panies from 72 nations presented their expertise to some 80,000 trade visitors (from 165 countries) and provided an impressive overview of modern healthcare solutions for inpatient and outpatient care. The trade fair is one of a kind worldwide for its inclusion of the entire medical technology value chain, which also comprises technically sophisticated supplier products. With a high proportion of decision-makers and high satisfaction ratings, both events were perfectly in line with the excellent results of previous years.

More than 90 percent of the visiting professionals who travelled to the event have decision-making authority, and more than 90 percent of visiting professionals were satisfied with their participation in the event.

“This boosts our exhibitors’ business. Overall, the trade fair’s success shows us that the international competition for leadership in medical technology innovation is gaining momentum and, as in other industries, companies from Asia are also heavily involved. In addition to the German companies participating, other national and regional businesses from Europe, China, South Korea, India and, of course, Japan and Taiwan were particularly well represented with top innovations. We are particularly pleased with the large number of exhibitors from the United States, which once again made up almost 10 percent of all exhibitors, with their variety of joint booths, including those representing multiple US states”, explains Christian Grosser, Director Health & Medical Technologies at Messe Düsseldorf.



The special show ‘Hospital of the Future’ also presented digital innovations from South Korea in cooperation with the Korea Medical Device Association (© Constanze Tillmann/ Messe Düsseldorf).



Strong international visitor attendance at MEDICA 2024 and COMPAMED 2024 (© Messe Düsseldorf).

In particular, the high level of internationality among exhibitors and visitors once again proved a decisive success factor for the many newcomers participating in MEDICA and COMPAMED, for small and medium-sized companies and for players operating in highly specialised niches in their search for partnerships for development, contract manufacturing or distribution. “MEDICA brings together thousands of industry experts from around the world every year. It is the ideal stage to discover the latest advances and developments in the healthcare sector and to forge valuable contacts”, Maxine Wang, Managing Director of Bricon GmbH, describes the inspiring global exchange during the trade fair. Her company specialises in the development, manufacture and worldwide distribution of spinal implants.

Hospital Conference provides powerful impetus for the trade fair business

For more than half a century, MEDICA has been characterised by its ability to surprise with innovations, with programme updates that keep pace with the times and that, ideally, bridge the gap between knowledge transfer, professional discussion and the relevant exhibitor innovations.

One important new feature this year was the themed hall space allocation in the MEDICA spheres “Med Tech & Devices” and “Digital Health” (Halls 12 and 13) with a new location for the accompanying German Hospital Conference. For the first time, the leading event for the top man-

agement of German hospitals was held at the very centre of the trade fair in Hall 12. The much-anticipated opening of the **47th German Hospital Conference saw German Federal Minister of Health Professor Karl Lauterbach (via livestream) and North Rhine-Westphalian Minister of Health Karl-Josef Laumann**, among others, address the delegates, focusing in particular on the changes in the German hospital landscape as a result of the impending hospital reform.

Particularly relevant exhibitors presented hospital decision-makers with innovations for clinical equipment and operating theatres around the event area. This resulted in a perfect match and a powerful impetus for the trade fair business, and not only for the company LINAK. Together with TENTE, LINAK presented a new type of drive system that can be integrated into most hospital beds. This works according to the e-bike principle and noticeably relieves burdens on hospital staff when transporting patients. “MEDICA was an excellent opportunity to present our new product, which will revolutionise the care sector. We were able to address medical personnel, hospital management, developers and health politicians alike”, explains LINAK’s Managing Director Christoph Messing.

Exciting sessions and special events

In the neighbouring MEDICA world of experience “Digital Health”, the range of exhibitors was complemented by a packed **stage programme** (MEDICA HEALTH

IT FORUM, MEDICA ECON FORUM and MEDICA INNOVATION FORUM) as well as **special events** such as the MEDICA START-UP PARK (with a record number of 60 start-ups) and the Wearable Technologies Show, all of which ensured excitement and attracted a great deal of attention. The **Hospital of the Future** is a relatively new addition to the MEDICA programme. The special exhibition started last year and is now being continued with a focus on digital networking and cooperation via telemedicine in hospital networks. The Korea Medical Device Association (KMDA) agreed to a collaboration and presented digital innovations for rapid patient diagnostics in hospitals in a dedicated zone, which also used AI-based software.

In addition to the popular start-up competitions, the **Women Leaders in Healthcare** session at the MEDICA INNOVATION FORUM, which is now tailored to the entire spectrum of digital innovations, was one of the absolute highlights on the second day. The session featured, for example, Hadas Bitran from Microsoft, **Ayelén Fernández** from HP, **Audrey Sherman** from Solventum and **Nina Wöss** from Female Founders. They provided insights into how they achieved success and attained management positions, and how they are playing a decisive role in shaping innovation and digital transformation in the still mainly male-dominated medical technology and health IT business.

In the final of the 13th MEDICA START-UP COMPETITION, Robeauté from France



was the winning pitch team on the forum stage with a newly developed micro-robot for use in neurosurgical procedures. This year's Healthcare Innovation World Cup was won by the Samphire Neuroscience team from the United Kingdom with a headset that acts on the neural networks of the brain to help alleviate menstrual pain and the symptoms of premenstrual syndrome (PMS).

News about the year's hot topics

With programme sessions at the forums and conferences and with exhibitor presentations in the five trade fair spheres, MEDICA 2024 shone a spotlight on all the year's hot topics driving the healthcare sector against the backdrop of its digital transformation, such as the growing **importance of interconnected models of care**. The focus was also on **AI-supported systems, robotic solutions** and concepts for dealing with the urgent **shortage of skilled workers**. Among the innovations presented at the trade fair were robotic applications to assist with highly complex neurosurgical procedures or orthopaedic operations (including hip replacements). Also new was an AI-based tool for the automatic documentation of medical consultations, a whole range of rapid tests for point-of-care diagnosis of a wide variety of infectious diseases (e.g., gonorrhoea or

the mpox virus including the problematic clade 1b mutation) and a medically certified smartwatch (Huawei) for easy blood pressure measurement at the wrist.

The special **"Automotive Health"** activity area (in Hall 12), which was designed in cooperation with the Innovation Institute from Frankfurt, also attracted a lot of attention and a high visitor frequency on all days of the trade fair. Nowadays, a number of sensors and functions can be built into cars to enable safe and healthy driving. Fatigue detection systems, which are already commonplace, are just one example. In future, many more functionalities will be able to automatically detect risks of emergencies based on the measurement of drivers' vital data, thus possibly avoiding serious accidents. The Innovation Institute demonstrated its development expertise in this field by exhibiting vehicles such as the VW ID.4 and also made the technology tangible in a racing simulator.

COMPAMED: a platform for "enablers"

In Halls 8a and 8b, 750 supplier companies participating in COMPAMED 2024 impressively demonstrated their expertise in key technologies for use by the medical technology industry – from a wide range of high-tech components and microfluidic applications to special packaging solutions

(taking cleanroom requirements into account). Two accompanying forums offered a packed programme on all days of the fair, covering the latest hot topics in the supplier sector, such as AI, robotics and automation, microtechnology developments and material innovations.

With a view to the growth markets in Asia, Messe Düsseldorf started marketing its health fairs in Singapore, Thailand, China and India, which have been successful for years, under the uniform umbrella brand MEDICARE ASIA from a central location in Singapore a few weeks ago.

**MEDICA in Düsseldorf:
17–20 November 2025**
**COMPAMED in Düsseldorf:
17–20 November 2025**

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TRADE SHOWS CALENDAR

JANUARY 2025



■ 27-30 / 01

Arab Health 2025

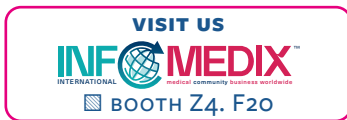
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United Arab Emirates

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► www.arabhealthonline.com



JANUARY 2025



■ 31 / 01 - 02 / 02

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Exhibition & Conference

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► www.messe-stuttgart.de

FEBRUARY 2025



■ 24-25 / 02

RMD Europe 2025

9th EAAR Annual Conference

■ **BRUSSELS, BELGIUM**

Organised by: BioEvents UK
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rosemarie@bioevents-congress.com
Website: www.bioevents.net

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► www.rmd2025.com



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FEBRUARY 2025



■ 26-28 / 02

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2025**

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Venue: Tokyo Big Sight
 East Halls
 Tokyo
 Japan

▶ www.this.ne.jp/en

FEBRUARY 2025



■ 26 / 02 - 02 / 03

**ECR
2025**

European Congress of Radiology

■ **VIENNA, AUSTRIA**

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▶ www.myesr.org/congress

MARCH 2025



■ 05-07 / 03

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 Osaka
 Japan

▶ www.medical-jpn.jp/hub/en-gb.html

MARCH 2025



■ 10-14 / 03

**AAOS
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American Academy of Orthopaedic Surgeons Annual Meeting

■ **SAN DIEGO, CA, USA**

AAOS - American Academy of Orthopaedic Surgeons
9400 West Higgins Road
Rosemont, IL 60018
Phone: +1 847 823 7186
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E-mail: exhibits@aaos.org, meeting@aaos.org
Website: www.aaos.org

Venue: San Diego Convention Center
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USA

► www.aaos.org/annual

MARCH 2025



■ 14-15 / 03

**ACE
2025**

Aesthetics Conference & Exhibition

■ **LONDON, UK**

Contact:
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Email: contact@aestheticsjournal.com

Venue: Business Design Centre
London
UK

► www.aestheticsconference.com

MARCH 2025



■ 17-19 / 03

**Bio Europe
Spring 2025**

Annual International Partnering Conference

■ **MILAN, ITALY**

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► www.informaconnect.com/bioeurope-spring/

MARCH 2025



■ 27-29 / 03

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APRIL 2025



■ 08-11 / 04

**CMEF 2025
ICMD 2025**

Spring Edition

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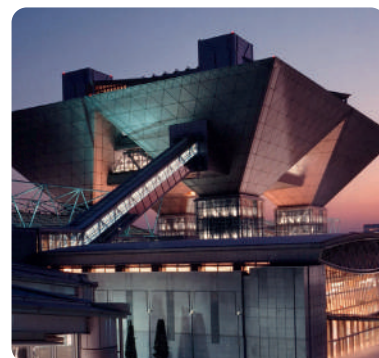
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APRIL 2025



■ 09-11/04

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APRIL 2025



14-16 / 04

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APRIL 2025



23-25 / 04

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▶ www.sea-healthcare.com

APRIL 2025



24-26 / 04

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▶ www.austropharm.at

UNICEF on World AIDS Day, in 2023 90 thousand children and adolescents have died from AIDS-related causes

unicef 
for every child

On **World AIDS Day**, on 1 December, UNICEF recalls that in 2023, **every day 330 children aged between 0 and 14 years contracted HIV**. Last year, more than 90,000 children and adolescents died from AIDS-related causes - equivalent to 250 lives a day - 73% of them children under the age of 10.

While 77% of adults contracting HIV have access to antiretroviral therapy (ART), only 57% of children aged 0-14, and 65% of adolescents aged 15-19 can access.

In 2023, there were **250,000 new HIV cases in the 0-19 age group**, bringing the total number of children and adolescents infected with HIV globally to 2.4 million.

Globally, **96,000 girls and 41,000 boys aged 15 to 19 contracted HIV in 2023**, meaning seven in 10 new adolescent infections occurred among girls. In sub-Saharan Africa, 9 out of 10 new HIV infections among young people aged 15-19 involve girls.



Everyday,
208 children,
0-14 years, dies from AIDS-related causes



AIDS remains the
leading cause of death
among adolescents
in sub-Saharan Africa

Although there has been a notable decline in new HIV infections among children and adolescents globally, over the last decade, according to the latest available estimates, adolescent girls still struggle to access prevention and support services.

Urgent Action

In view of the world day to combat AIDS, UNICEF warns that without urgent action to address the disproportionate impact of HIV on girls and young women - particularly in sub-Saharan Africa - the hard-won gains may be lost in the fight against HIV.

*“Many countries have made great strides to end AIDS,” said **Anurita Bains**, UNICEF Associate Director for HIV/AIDS. “However, children and adolescents are not fully reaping the benefits of broad-based access to treatment and prevention services. Children living with HIV must be prioritized when it comes to investing resources and efforts to increase care for all, including through the expansion of innovative testing technologies.”*

- ▶ www.unicef.it
- ▶ www.unicef.org



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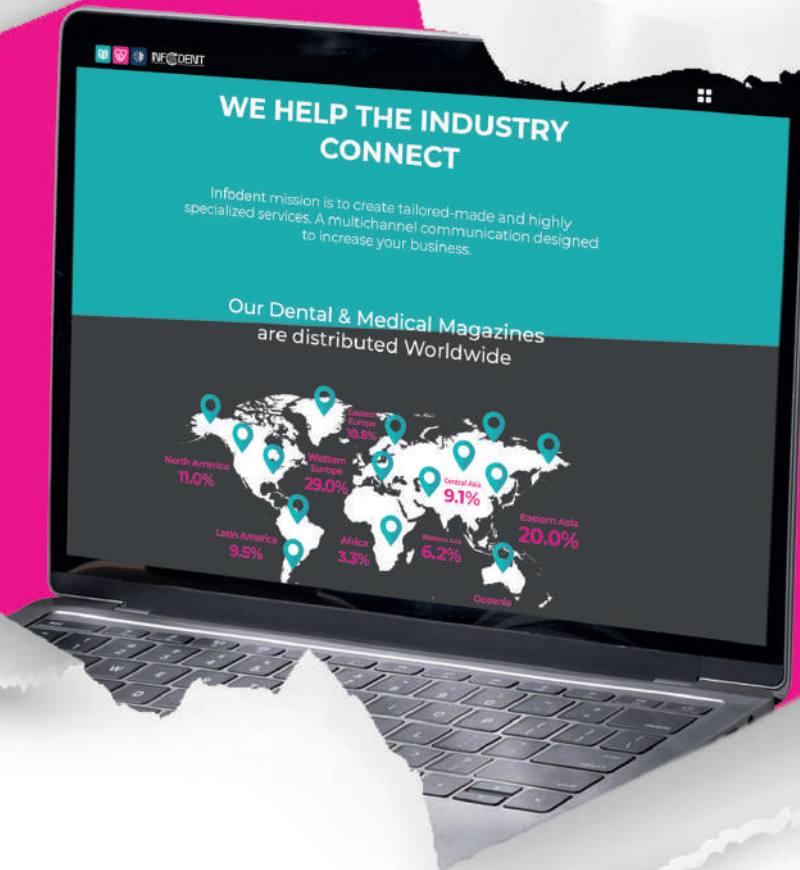
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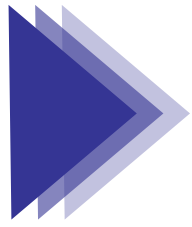
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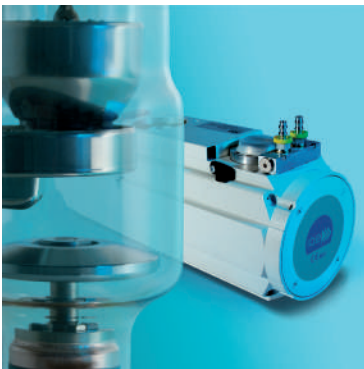


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