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One of the key challenges lies in keeping pace with rapid technological advancements while ensuring regulatory compliance

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Rami Rajab, CEO of the medical devices trade association, MECOMED, walks us through the organization's current priorities, including its focus on Saudi Arabia in light of the kingdom's ongoing transformation, and the creation of the UAE Regulatory Authority for Medical Devices (EDE). In addition, he reviews the challenges surrounding digital health and the association's role in helping members navigate complex regulatory landscapes in that realm, and the adoption of Health Technology Assessment (HTA) policies in the Middle East and Africa.

What are the key priorities for Mecomed and strategic objectives for 2024?

At Mecomed, we are proud of the progress we have made since our inception 17 years ago, evolving from four companies to a diverse association of 60 manufacturers across North America, Western Europe, and Japan as well as local distributors and manufacturers. Despite the challenges posed by COVID-19, our membership has grown by more than 50 percent since 2018, reflecting our commitment to transferring knowledge and solutions to the Middle East and Africa while adhering to strict regulatory standards. Simultaneously, we emphasize the importance of ethical conduct in our interactions with healthcare professionals (HCPs) and other stakeholders. To formalize this commitment, we developed a comprehensive code of conduct. This code serves as a guideline for our members, outlining the ethical standards expected in their interactions with HCPs and the broader healthcare community. Importantly, this code has been widely adopted and adapted by countries across the Middle East and Africa, underscoring our collective dedication to upholding

ethical behaviour and ensuring the best possible outcomes for patients.

During our recent board meeting, we took stock of our achievements in 2023 and set our sights on key objectives for 2024. As CEO, I presented our geographical and strategic imperatives for the year ahead. One of our primary focuses remains on Saudi Arabia, the largest market in our region, where we have witnessed significant transformations and steps towards encouraging continued investment and business growth.

Additionally, we are closely monitoring the progress in the UAE, particularly the establishment of the UAE Regulatory Authority for Medical Devices (EDE). Our presence in the region has been instrumental in attracting more companies and garnering attention from local authorities, reinforcing our commitment to supporting the region's healthcare ecosystem.

Our board meeting also featured presentations from various working groups, including regulatory, compliance, legal, human capital, market access, and digital health. Notably, our Saudi chapter that has transitioned from conceptualization to reality, further enhancing our local presence and engagement.

Looking ahead, we are prioritizing initiatives to support digitization and AI integration, particularly in medical devices, in vitro diagnostics, and imaging. The deployment of digital health technologies is becoming increasingly prevalent among our member companies, with dedicated Chief Digital Officers leading the charge.

Moreover, sustainability is emerging as a key focus area, encompassing environmental impact, diversity, inclusion, and governance (ESG). While environmental considerations are essential, our emphasis on diversity, equity, and governance within our companies and board structures reflects our commitment to responsible corporate practices.

In conclusion, our board meeting underscored our dedication to advancing healthcare standards in the Middle East and Africa through collaborative efforts, regulatory compliance, and technological innovation. We remain open to adapting to evolving dynamics and look forward to driving positive change in the region's healthcare landscape. One aspect of our support is our participation in public consultations.

Could you provide further insights into Saudi Arabia's current healthcare landscape and the significant advancements the country has made in recent years, particularly within the context of Vision 2030?

Saudi Arabia's healthcare landscape has undergone significant transformation, aligned with the ambitious goals outlined in Vision 2030. At the heart of this transformation is a strong focus on enhancing the well-being of citizens and building local capacities within the healthcare sector. This emphasis on capacity building is evident in various initiatives aimed at strengthening the country's healthcare infrastructure and capabilities and more importantly the local human resources.

One of the notable trends we have observed is Saudi Arabia's commitment to fostering a conducive environment for investment and business growth, particularly in the medical devices, diagnostics, and imaging sectors. The introduction of initiatives such as the RHQ by the Ministry of Investment underscores the government's efforts to incentivize companies to establish regional headquarters in the country. Moreover, the emphasis on attracting top talent and facilitating visa processes for expatriates demonstrates a proactive approach to talent acquisition and retention.

Education also plays a pivotal role in Saudi Arabia's healthcare transformation journey. The government's focus on enhancing educational opportunities, both for locals and expatriates, reflects a commitment to nurturing a skilled workforce capable of driving innovation and excellence in healthcare delivery. The alignment of educational programs with the demands of the digital age underscores Saudi Arabia's forward-looking approach to preparing its workforce for the future.

Furthermore, Saudi Arabia's emphasis on continuous education mirrors the evolving nature of healthcare and the need for professionals to adapt to emerging trends and technologies continually. This commitment to lifelong learning is crucial in ensuring that healthcare practitioners and regulators remain abreast of the latest advancements and best practices in their respective fields.

Overall, Saudi Arabia's healthcare transformation journey is characterized by comprehensive efforts to build local capacities, attract investment, enhance educational opportunities, and foster innovation. These initiatives align closely with the objectives outlined in Vision 2030 and underscore the country's commitment to achieving sustainable progress and prosperity in the healthcare sector.

Given the association's diverse membership base, could you elaborate on the most pressing challenges or needs that your members are currently expressing, and how Mecomed is addressing them?

The value we provide to our members stems from our role as the collective voice of the industry, advocating for their interests and addressing common challenges. In the realm of digital health, for instance, there are multifaceted issues that require attention, ranging from regulatory compliance to privacy laws and encryption standards. Our members often seek guidance on navigating these complex regulatory landscapes while ensuring adherence to ethical practices.

One of the key challenges lies in keeping pace with rapid technological advancements while ensuring regulatory compliance. Regulatory bodies, though knowledgeable, may require support and capacity-building to adapt to the evolving digital health landscape. To bridge this gap, Mecomed facilitates dialogue and collaboration between industry stakeholders and regulatory authorities. We engage in initiatives like sandboxing, where we demonstrate emerging technologies to regulators, ensuring a mutual understanding of their potential and regulatory implications.

Moreover, the lifecycle of medical devices, typically around 24 months, necessitates swift approvals and deployment to maximize their impact. Mecomed strives to create an enabling ecosystem that fosters dialogue among manufacturers, healthcare providers, insurers, and other stakeholders. By facilitating these conversations, we ensure that technological innovations reach patients and healthcare professionals in a timely and effective manner, driving positive outcomes in healthcare delivery.

Can you elaborate on the significance of Health Technology Assessment (HTA) policies and value-based healthcare in the context of the Middle East and Africa region?

The adoption of Health Technology Assessment (HTA) policies and value-based healthcare represents a crucial shift in healthcare delivery, particularly in regions like the Middle East and Africa where healthcare budgets are finite and non-communicable diseases pose significant challenges. HTA and value-based healthcare emphasize the importance of prioritizing interventions and investments based on their cost-effectiveness and impact on patient outcomes.

By investing in prevention and early intervention strategies, healthcare systems can reduce the long-term burden of diseases such as diabetes, heart disease, and cancer, thereby optimizing resource allocation and budget planning. This proactive approach not only improves patient outcomes but also enhances the overall efficiency of healthcare delivery.

Value-based healthcare goes beyond traditional models of healthcare procurement by focusing on achieving desirable patient outcomes rather than simply purchasing healthcare services. This shift towards value-based procurement incentivizes providers to deliver high-quality care that is aligned with patient needs and preferences.

As an organization, we are committed to facilitating the adoption of best practices in HTA and value-based healthcare within the region. Through collaboration with regulatory bodies and healthcare institutions, we aim to adapt international standards to the unique healthcare landscape of the Middle East and Africa. By leveraging the expertise of organizations like the FDA and working closely with local stakeholders, we can ensure that healthcare technologies and interventions are tailored to the specific needs and challenges of our region.

Digitalization is a significant topic, especially regarding healthcare, and you have mentioned advancements in Saudi Arabia, particularly in electronic health records and data-driven decision-making. Can you provide an overview of these advancements and share your impressions?

The strides we are witnessing in digitalization, especially within healthcare, are truly remarkable. The initiatives undertaken by the Ministry of Health in Saudi Arabia, such as the implementation of electronic health records and the establishment of data centres, are pivotal in fostering data-driven decision-making and enhancing overall healthcare delivery. These efforts are instrumental in streamlining processes, improving patient care, and optimizing resource allocation.

From our perspective, while we celebrate these advancements, there are key areas where our members require support and where we must focus our efforts moving forward. Firstly, ensuring the timely regulation of new digital health products is paramount. Our members are at the forefront of innovation, developing cutting-edge technologies that have the potential to revolutionize healthcare delivery. However, the pace of regulatory approval must align with the rapid pace of technological advancements to facilitate timely market entry and adoption. We are collaborating with various regional authorities to address the new requirements associated with the introduction of AI with various innovative solutions to ensure safe and efficient introduction of these solutions.

Secondly, data privacy and security remain critical considerations in the digital health landscape. As we embrace technologies like AI and remote monitoring, it is imperative to uphold patient confidentiality and data integrity. Collaborating with regulatory authorities to establish robust

frameworks for data protection will be essential in fostering trust and confidence in digital health solutions.

Moreover, personalized healthcare is emerging as a dominant paradigm, fuelled by advancements in genomics, AI, and data analytics. Empowering patients to take control of their health and tailoring interventions to individual needs are pivotal in driving better health outcomes. Supporting our members in navigating this shift towards personalized medicine and harnessing the full potential of digital health technologies will be a priority. Healthcare delivery is changing and with digital health, Telemedicine and video consultations we are seeing a shift in the role of the hospitals and a better reach to remote areas.

In essence, while we celebrate the progress made in digitalizing healthcare, our focus remains on ensuring that these advancements translate into tangible benefits for patients and healthcare providers alike. By addressing regulatory challenges, safeguarding data privacy, and embracing personalized healthcare, we can unlock the full potential of digitalization to transform healthcare delivery in Saudi Arabia and beyond.

Is there any final message you would like to convey directly to our international readers?

I would like to emphasize the immense potential and attractiveness of the Middle East and Africa region, particularly in the realm of healthcare. Saudi Arabia is emerging as a hub for cutting-edge technologies and healthcare investments, thanks to the establishment of new regulations and facilitative policies. We see a strategic shift towards local manufacturing and greater industry participation, including from local manufacturers and distributors, all adhering to the same high standards of ethical conduct. At Mecomed, we are committed to supporting our members in navigating this dynamic landscape and fostering a healthier and more robust healthcare ecosystem for the region.

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