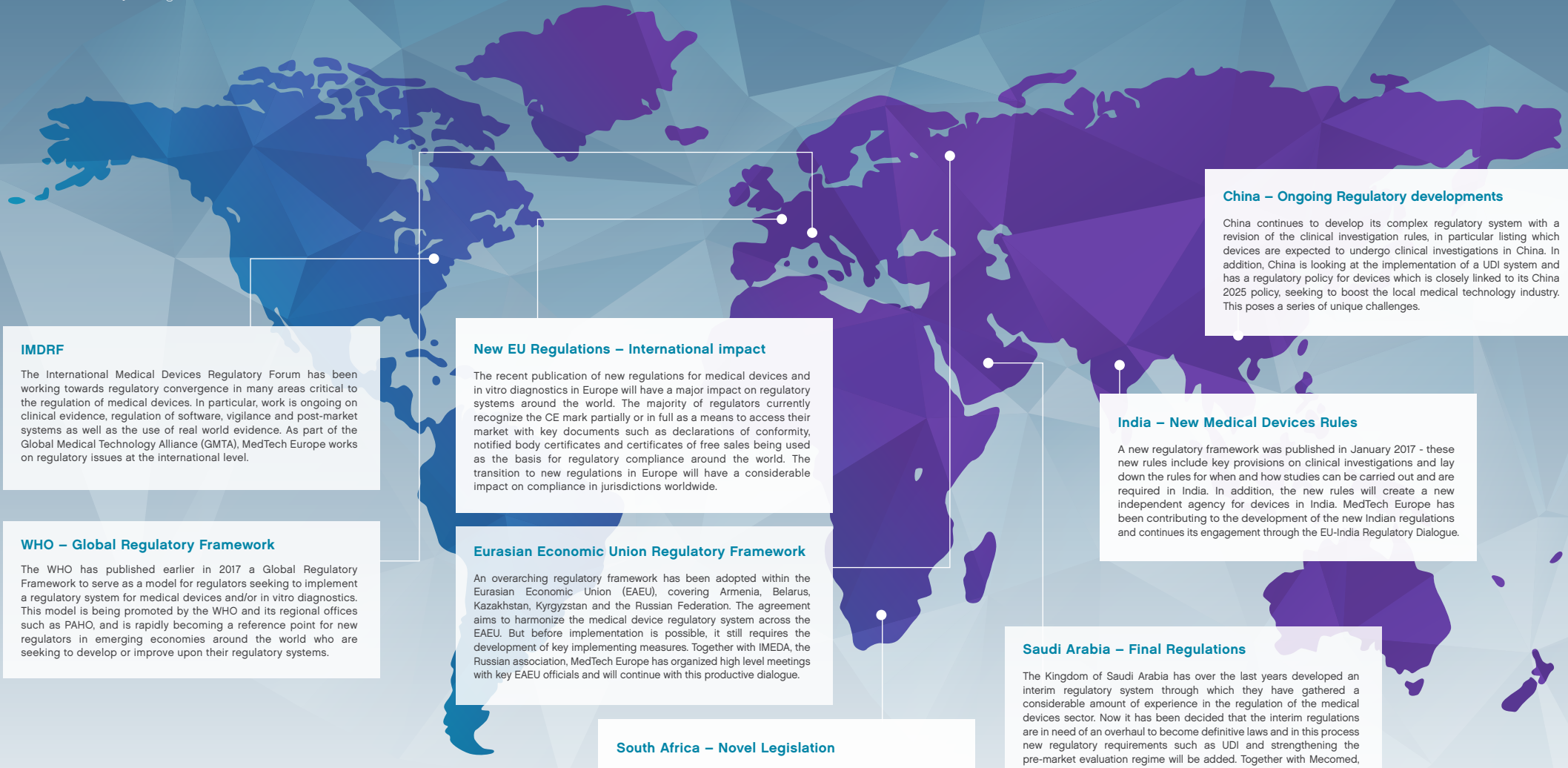
International Regulatory Developments

Regulatory requirements have been increasing globally in the last years as new jurisdictions develop their own regulatory systems. In such an environment, facilitating regulatory convergence and ensuring that the requirements being deployed around the world are in line with regulatory best practices is an essential part of the activities of MedTech Europe.

The trend where we see more and more jurisdictions and oversight stepping in to regulate medical technologies is likely to continue as the importance and value of medical technologies to health systems as a whole becomes widely recognized.



IMDRF

The International Medical Devices Regulatory Forum has been working towards regulatory convergence in many areas critical to the regulation of medical devices. In particular, work is ongoing on clinical evidence, regulation of software, vigilance and post-market systems as well as the use of real world evidence. As part of the Global Medical Technology Alliance (GMTA), MedTech Europe works on regulatory issues at the international level.

WHO – Global Regulatory Framework

The WHO has published earlier in 2017 a Global Regulatory Framework to serve as a model for regulators seeking to implement a regulatory system for medical devices and/or in vitro diagnostics. This model is being promoted by the WHO and its regional offices such as PAHO, and is rapidly becoming a reference point for new regulators in emerging economies around the world who are seeking to develop or improve upon their regulatory systems.

New EU Regulations – International impact

The recent publication of new regulations for medical devices and in vitro diagnostics in Europe will have a major impact on regulatory systems around the world. The majority of regulators currently recognize the CE mark partially or in full as a means to access their market with key documents such as declarations of conformity, notified body certificates and certificates of free sales being used as the basis for regulatory compliance around the world. The transition to new regulations in Europe will have a considerable impact on compliance in jurisdictions worldwide.

Eurasian Economic Union Regulatory Framework

An overarching regulatory framework has been adopted within the Eurasian Economic Union (EAEU), covering Armenia, Belarus, Kazakhstan, Kyrgyzstan and the Russian Federation. The agreement aims to harmonize the medical device regulatory system across the EAEU. But before implementation is possible, it still requires the development of key implementing measures. Together with IMEDA, the Russian association, MedTech Europe has organized high level meetings with key EAEU officials and will continue with this productive dialogue.

South Africa – Novel Legislation

New legislation has been introduced in South Africa in December 2016. Implementation of the new legislation will take time, though a key deadline is the 23rd August 2017 by which point all manufacturers will need to have applied for an establishment license. Ongoing work on the implementation and overcoming the challenges posed by the ambitious legislation continues together with SAMED – the sister association of MedTech Europe in South Africa.

China – Ongoing Regulatory developments

China continues to develop its complex regulatory system with a revision of the clinical investigation rules, in particular listing which devices are expected to undergo clinical investigations in China. In addition, China is looking at the implementation of a UDI system and has a regulatory policy for devices which is closely linked to its China 2025 policy, seeking to boost the local medical technology industry. This poses a series of unique challenges.

India – New Medical Devices Rules

A new regulatory framework was published in January 2017 - these new rules include key provisions on clinical investigations and lay down the rules for when and how studies can be carried out and are required in India. In addition, the new rules will create a new independent agency for devices in India. MedTech Europe has been contributing to the development of the new Indian regulations and continues its engagement through the EU-India Regulatory Dialogue.

Saudi Arabia – Final Regulations

The Kingdom of Saudi Arabia has over the last years developed an interim regulatory system through which they have gathered a considerable amount of experience in the regulation of the medical devices sector. Now it has been decided that the interim regulations are in need of an overhaul to become definitive laws and in this process new regulatory requirements such as UDI and strengthening the pre-market evaluation regime will be added. Together with Mecomed, MedTech Europe maintains an ongoing engagement and dialogue with Saudi regulators.

MedTech Europe
from diagnosis to cure