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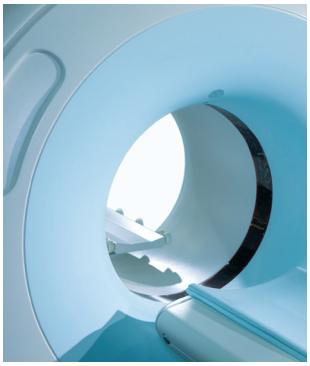
Regulatory Excellence



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Regulatory Excellence

Achieving Public Health Impact Through Distinctive Regulatory Management Systems

Taking a holistic approach to agency management can help regulators meet the complexities inherent in their public health missions. We propose taking such an approach, one that spans strategy, operations, and organizational considerations and constitutes what we call a "distinctive regulatory-management system."

The mission to protect public health is what unites drug and medical device regulatory authorities around the world. However, that mission is difficult to attain in the face of today's many pressures—among them the introduction of new and innovative products, increasingly global supply chains, the emergence of new risks, and mounting budget pressures.

To address these complexities and help regulators achieve their missions, we propose a holistic approach to the management of regulatory authorities—an approach that we call a "distinctive regulatory management system." This system spans strategy, operations, and organizational considerations. This compendium is devoted to ideas and practices that can help implement this holistic approach.

Regulator impact in the healthcare ecosystem

At the highest level, drug and medical device regulators are charged with a fundamental mission to protect public health. Ultimately, the success of that mission is measured through improved health outcomes, such as preventing deaths and illnesses, or enhancing the quality of life.

However, shaping the broader healthcare ecosystem so it improves healthcare outcomes is an important intermediate step. There are many ways to do this, including fostering greater public confidence in regulated products, improving access to medical products with an appropriate benefit/risk profile, and creating environments that are conducive to innovation. Each of these paths requires interaction between regulators and stakeholders throughout the healthcare ecosystem.

One way to frame the roles of regulatory authorities in the ecosystem is through the lens of the product lifecycle—from initial concepts to marketed products used by consumers and/or healthcare professionals. At each stage of the lifecycle—innovation, access, decision making, and appropriate product use—regulators play key roles through their interactions with healthcare stakeholders (See Exhibit 1). Public health impact

Exhibit 1 | Points of regulatory impact along a product's lifecycle

Role of regulators in having public health impact—a product lifecycle view

is possible when regulator roles are coordinated with these stakeholders across the lifecycle of a single product as well as across the entire portfolio of available products.

The need for a new approach

But the standard for what constitutes regulatory excellence keeps rising. It is being pushed higher by a host of factors—from the industry's ongoing development of innovative products that require fresh assessments of their benefits and risks to the rapid rise of new threats, including the proliferation of economically motivated adulteration and counterfeits. On top of it all, governments everywhere are calling on regulatory agencies to do more with less as they cope with budget pressures.

In the past, regulators followed two typical paths to meet their challenges. The first was to create new regulatory programs and sometimes to expand the scope of existing programs, which required increased funding and resources. The second path aimed for a technocratic culture that relied heavily on subject matter experts to generate scientific insights and to shape the management decision-making process. Given the press of new challenges, these approaches need to be modified—and soon. McKinsey proposes an alternative approach that we call a distinctive regulatory management system.

Distinctive regulatory management system

A distinctive regulatory management system is based on three tenets: a clear articulation of strategy and overall agency direction; a well-defined operating model based on efficient

and effective processes and systems; and an organizational culture that harnesses the unique talents of employees and steers those talents toward achieving the agency's mission. Strong capabilities in all three components are critical and must be consistent and reinforce each other.

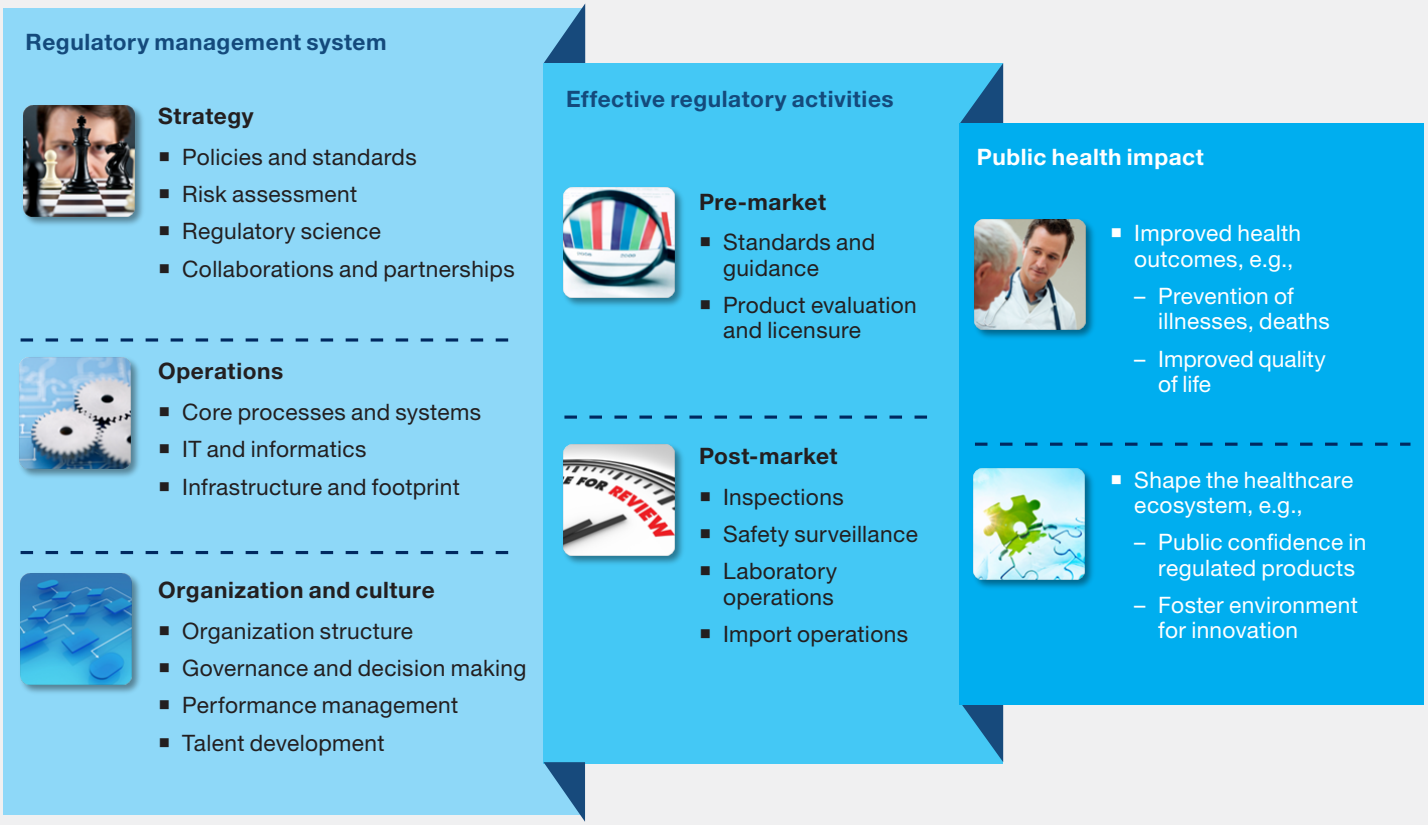
Taking a holistic approach to agency management can help regulators meet the complexities inherent in their public health missions. As shown in Exhibit 2, a distinctive regulatory management system is the foundation of efficient and effective regulatory programs. Each of the three tenets of this system merits a closer look:

Strategy

For drug and medical device regulatory authorities, the essence of strategy is the explicit choices made about how the agency will achieve its desired public health impact. For example, a strategy designed to prevent illness or death might entail prioritizing potential risks and articulating the regulatory activities that mitigate them. Strategy should also account for practical constraints, such as laws and regulations, budgets and resource levels, and the organization's skills and capabilities.

In this compendium we explore several examples of distinctive strategic choices, including:

Exhibit 2 | Distinctive regulatory management systems are the foundation for public health impact



- Improving product approval decisions by incorporating targeted external expertise in advisory committees or similar bodies

- Partnering with industry to shift its compliance mind-set toward a holistic view of improving product quality

- Supporting the safe use of new drugs in children through industry incentives and critical clinical data

Operations

Once the strategy has been created, regulatory agencies can develop and deploy the processes and systems for its execution. Operations focus on underlying business processes (for example, budgeting, strategic planning, regulation development, and HR). However, they also address systems specific to a regulatory program, such as inspection procedures and review guidelines. Recently, information technology and informatics are taking on greater roles in improving these systems.

In this compendium, we look at several applications of distinctive operating systems, including:

- Achieving operational efficiency through new risk-based resource allocation tools and global collaboration

- Bolstering the effectiveness of inspection programs with the systematic collection and use of data throughout the inspection process

- Unlocking new sources on innovation and efficiencies by using Big Data in pharmaceutical R&D

Organization and culture

Ultimately, a regulatory agency can achieve its desired impact on public health only if it maximizes the unique talent and capabilities of its people. Clear organization structures, roles, and responsibilities are necessary, but not sufficient, to become a high-performance regulatory organization. Governance and decision making can also be addressed and streamlined. In a science-driven organization such as a regulatory authority, it is often hard to resist the scientific instinct to reach full consensus on decisions. Leaders must be comfortable making informed decisions that may not represent a full consensus, but at the same time are sufficient to move the organization forward. In addition, best practices suggest that the organization embrace performance management in order to develop existing talent and build the next generation of leaders.

In this compendium, we offer several examples of organization and culture, including:

- Increasing the organization's existing capabilities by tailoring a proven talent development framework and system to regulatory authority settings

- Driving transformational change by building change management capabilities within the organization

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We believe that in the medium and long term, the protection of public health will become increasingly linked to regulatory agencies' ability to develop and apply distinctive regulatory management systems. In this compendium, we illustrate these systems using case examples, observations of the regulatory sector's practices, analyses of publicly available regulatory data, and the perspectives of other healthcare stakeholders. Because of the complex nature of the topic, we can't be comprehensive. However, we hope that by illustrating the broad contours of the concept, we can further the discussion and amplify the flow of ideas that are essential to regulatory excellence—and thus to maintaining public health.

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