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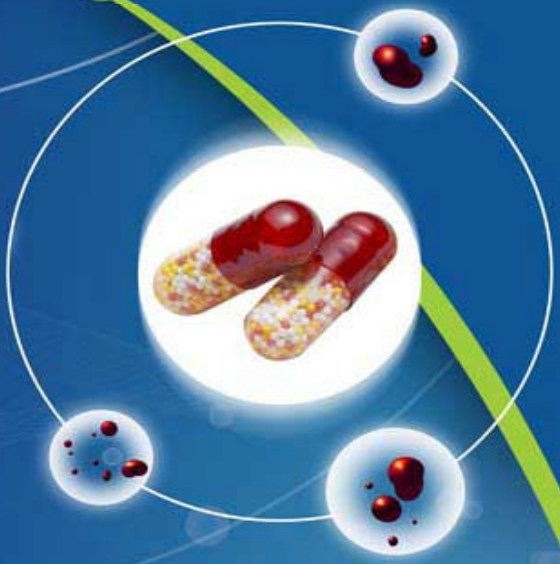

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Short Communication

REGULATORY INTELLIGENCE - NEED OF THE HOUR

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ABSTRACT

The pharma industry is characterized by a long R&D cycle with an acute need for speed to market. Regulatory agencies have increased scrutiny leading to fewer innovative drugs & increased costs in clinical trials. Considering the current dynamic regulatory landscape along with other challenges, Regulatory Intelligence (RI) has become a key function in the industry. Regulatory professionals have to deal with abundant data from varied sources, analyze and evaluate the required necessary information from that. The analyses and evaluation of all the available information has to be interpreted to buildup future regulatory strategies. The objectives of RI are to identify competitive advantages in the sectors of Regulatory Affairs, Business development, Sales and Marketing, CMC, Manufacturing, Toxicology, Preclinical phases, Drug development stages and many more. Successful RI drives successful global business. Importance and advantages of RI have been articulated here to demonstrate the needof the hour for the industry to focus on Regulatory Intelligence.

Key Words: *Pharma industry, Regulatory agencies, Regulatory Affairs, Regulatory Intelligence*

TEXT

Regulatory Intelligence (RI) is defined in different ways like "RI is act of gathering and analyzing publicly available regulatory information. This includes communicating the implications of that information, and monitoring the current regulatory environment for opportunities to shape future regulations, guidance, policy, and legislation."Whereas RI is also defined as "The act of processing targeted Information and data from multiple sources, analyzing the data in its relevant context and generating a meaningful output-e.g. outlining risks and opportunities – to the regulatory strategy. The process is driven by needs and linked to the decisions and action."

The process of Regulatory Intelligence and its potential impact on Regulatory Strategy can be summarized as follows:

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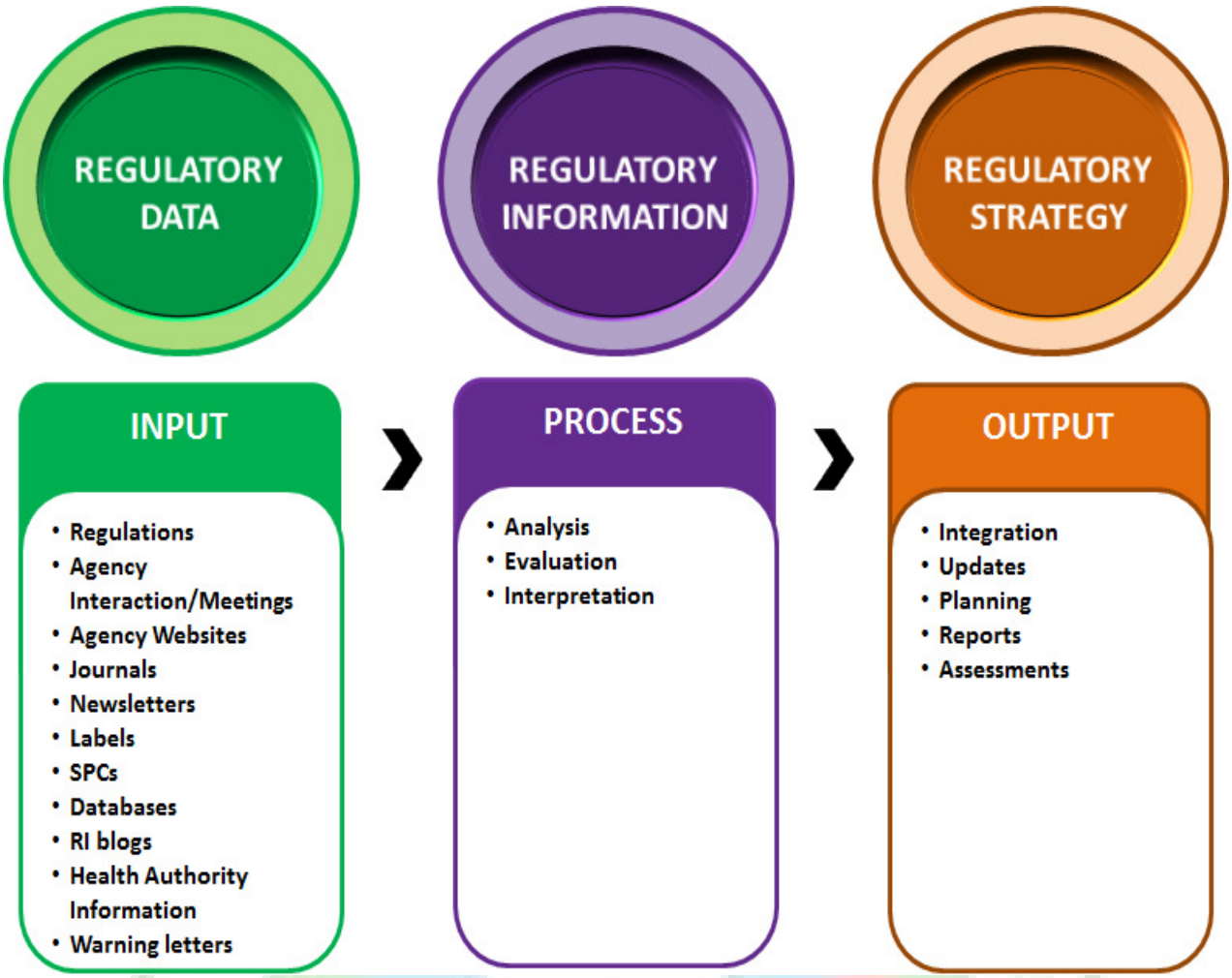


The internet is the most common source to gather regulatory data. Other important commonly used RI sources have been indicated in the figure above. This need not only be limited to published data. Other forms include oral, written, competitor details, networking etc. A complete and systematic search or gathering is focused on the most apt or relevant piece of data from the heap of data available at multiple sources. Also the data types and sources differ as per product type – drugs, devices, biologics, vaccines etc.

Knowledge of different regulations and documentation is thus the first step in the process. The next step is to process this data into useful information gathered with a definite purpose. The processing involves detailed analyses and evaluation of the same. Ability to gain insights and draw inferences (interpretations) after analyzing and evaluating the information is of utmost importance.

This information can then be utilized to update various reports or SOPs, study impact of different factors, make assessments etc. It can be used to understand guidance and procedures for submission to agencies and review agency recommendations about previous approval/rejection of products. RI can help in building metrics reports on product approvals. It can help companies frame responses to queries from health authorities.

It can be used to formulate drug development programs and assess market position of a product by analyzing competitor information. It can help companies identify opportunities for instance an indication for existing product. Simultaneously it can help identify challenges or risks like issues related to compliance, alterations in audit requirements etc.

Following examples illustrate how to gather information from publicly available sources to get answer to specific questions:

Q1: "What is the difference between US and EU approval process for Medical Devices?"

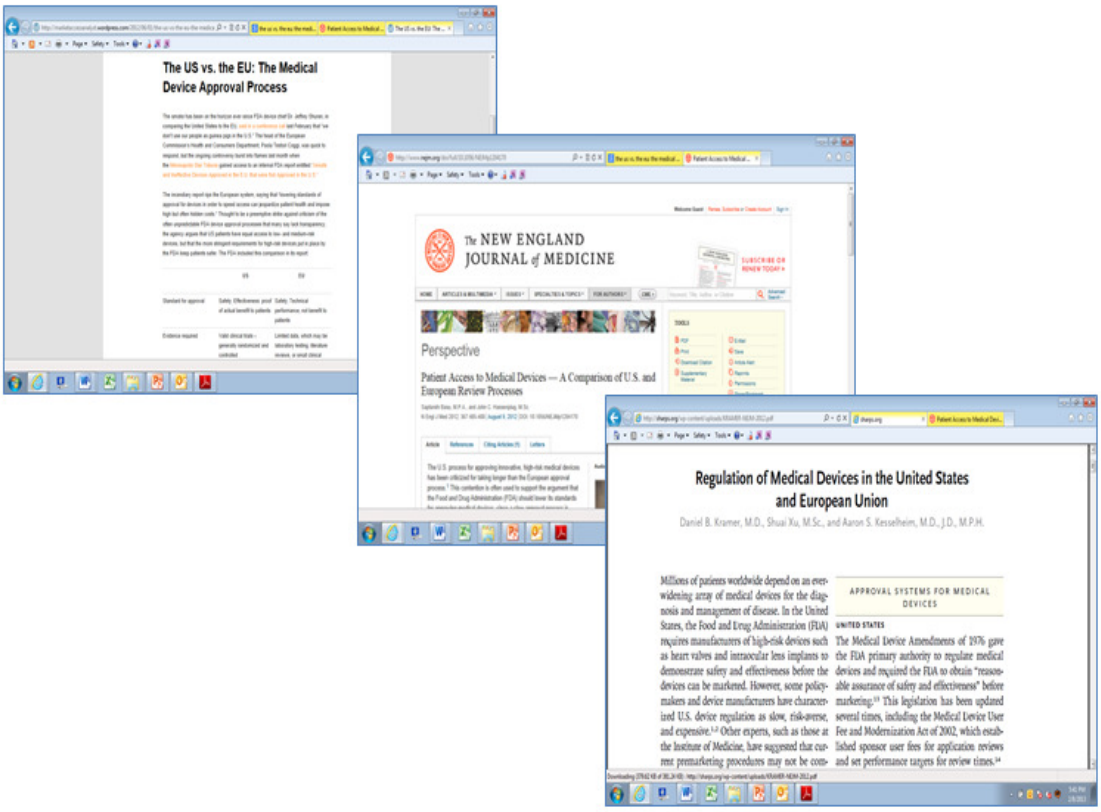
Q2: "What do we know about the competitor product(s)?"

Q3: "Does our product qualify for orphan? How would we get orphan designation and what are the differences between the US and the EU?"

Example 1

Q1: ***"What is the difference between US and EU approval process for Medical Devices?"***

Solution:



Example 2

Q2: "What do we know about the competitor product(s)?"

Solution:

- Essential info gathered on competitor products
- Trade and INN name(s) in all countries
- Drug class
- Submission and approval dates in all countries
- Non-approval?
- Route of administration; presentations
- Pivotal clinical studies
- Label/SPC
- Submission info: standard/priority review, fast track, accelerated review? EU: centralized, decentralized or mutual recognition procedure?

Additional useful RI information

- Overview of current regulatory landscape for that type of product and in the markets identified for product distribution
- Status of competitor products under development

RI Report

- Generate RI report including executive summary reviewing competitor products on the market and under development, the current regulatory landscape and submission routes used by competitor products

Example 3

Q3: "Does our product qualify for orphan? How would we get orphan designation and what are the differences between the US and the EU?"

Solution

- Research regulations, guidance's, Agency websites, previous orphan designations for related products and other relevant websites

Summarized findings for the US and the EU such as

- Definition of orphan designation
- Regulatory requirements for orphan drug product
- Benefits for orphan drugs (tax breaks, grant programs, reduced/waived fees etc.)
- Estimated costs/timeframe for orphan designation request

Highlight differences between the US and the EU regulations

- Whether or not the product might qualify for orphan designation
- Whether to apply in the US, the EU, or both
- Implications of orphan designation on overall development plan

Business decisions are taken based on rational interpretations. RI helpscommunicate the implications and design the implementation plan. It also helps to understand the risks involved and plan for possible mitigations.RI effectively helps in meeting compliance standards, cycle time reduction for product approvals; cost savings in drug development process and increased market reach. Thus effective RI enables an organization to build successful regulatory strategies and development programs. Intelligence failures are always appalling and without effective RI, there will be longer R&D and regulatory cycle with increased time to market.

CONCLUSION

Methodical approaches to gain insights into the spectrum of regulatory data, its evaluation & interpretation and using it to

drive business decisions is the power that RI holds. Regulatory Intelligence is an indispensable contributor to forming of Regulatory Strategy and Regulatory Strategy is a vital component for drug's approval in the drug development process. Thus RI is undoubtedly a key driver to global success of an organization and critical for its survival in the ever dynamic & challenging marketplace. At the same time, it is imperative to understand where to look and how to utilize the consolidated information.

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