

## The Importance of Data-Driven Information Sharing with Health Care Professionals and Payers

In the era of data-driven medicine, fostering informed communications among all stakeholders are critical. Today, the wealth of information about medicines is more comprehensive and complex than ever before. Scientific knowledge and new findings go beyond clinical trial data and may be outside the scope of regulations established by the U.S. Food and Drug Administration (FDA). This often results in the FDA-approved labeling being outdated.

Biopharmaceutical companies generate and collect important data and analyses on an ongoing basis that can benefit patient care and enhance the efficiency of our health care system. Patients would benefit if biopharmaceutical research companies could provide prompt access to the newest information about innovative medicines. When treating patients, health care professionals must understand the full range of treatment options, including both established and emerging information about available medications. Biopharmaceutical companies are uniquely positioned to help health care professionals achieve the best outcomes for patients, because they maintain timely, accurate and comprehensive information about approved and unapproved uses of the medications they research, develop and bring to patients.

Private payers and other stakeholders are requiring more evidence than ever before about the value of innovative medicines. In recent years, payers have expressed a need for greater predictability and certainty regarding the biopharmaceutical pipeline as they often set premiums and formularies 18 months in advance. Further, once a medicine is approved, patients and other stakeholders can benefit from more timely dissemination of important new safety, value or efficacy information that is not already included in the product's labeling. Yet, regulations designed for an earlier era often slow the diffusion of evidence about new medicines and make it more difficult for private payers to plan ahead. By addressing barriers to effective communication, we can help the private market realize the value of medicines and support patients in getting the right medicine at the right time.

**Biopharmaceutical companies currently are inhibited from sharing science-based information with health care professionals and payers**



**BIOPHARMACEUTICAL COMPANIES**



**REGULATORY BARRIERS**



**PAYERS/PROVIDERS**



**To ensure that science-based data are communicated effectively,** we need to modernize the FDA and improve patient care by allowing biopharmaceutical companies to share accurate, science-based information with health care professionals and payers about medicines.

## Principles on Responsible Sharing of Truthful and Non-Misleading Information about Medicines with Health Care Professionals and Payers

In order to support the best use of scientific information for patient care, PhRMA and our member companies have endorsed Principles on Responsible Sharing of Truthful and Non-Misleading Information About Medicines with Health Care Professionals and Payers. These principles are intended to form the basis for defining new and clear regulatory standards governing responsible, truthful and non-misleading communications to inform health care professionals and payers about the safe and effective use of medicines. The principles pertain primarily to data and information outside of FDA-approved labeling, and are intended to establish responsible, science-based parameters for accurate and trusted information sharing.

### Key Concepts of PhRMA Principles:



#### **Commitment to Science-based Communication**

Communications should be based on analyses using scientifically and statistically-sound methodologies. There are many types of data and analyses that are scientifically and statistically-sound, and thus can support truthful and non-misleading communication about medicines. These include analyses that can improve patient care based on methodologically sound real-world evidence, analyses that focus on specific sub-populations and pharmacoeconomic analysis.



#### **Commitment to Provide Appropriate Context about Data**

Communications should clearly disclose appropriate contextual information about the data presented, including information about limitations of the data and the analyses conducted to prevent health care professionals from reaching inaccurate conclusions or forming misimpressions about the efficacy or safety of a medicine.



#### **Commitment to Tailoring Communications to the Intended Audience**

Communications should take into account the sophistication of the intended audience so that they can accurately incorporate the new information into existing body of knowledge and expertise.