MARYLAND TECH COUNCIL
ADVANCING LIFE SCIENCES AND TECHNOLOGY

May 2, 2023

Sent via Email: *comments.pdab@maryland.gov*

Maryland Prescription Affordability Board
16900 Science Drive
Suite 112-114
Bowie, MD 20715

RE: COMAR 14.01.01.01 – General Provisions (Definitions)
COMAR 14.01.01.02 – Rules of Construction
COMAR 14.01.01.04 – Confidential, Trade-Secret, and Proprietary Information
COMAR 14.01.02.02 – Prescription Drug Affordability Fund (Fee Assessment, Exemption, Waiver, and Collection) Amendments
COMAR 14.01.03.01-05 – Cost Review Process
COMAR 14.01.04.01 – Public Information Act

On behalf of the Maryland Tech Council (the "Tech Council"), thank you for the opportunity to comment on the above draft regulations proposed by the Prescription Drug Affordability (the "PDAB" or "Board"). The Tech Council is the State's largest association of technology companies with over 700 member companies across multiple technology sectors including life sciences, biotechnology, and others. The Tech Council's vision is to propel Maryland to become the number one innovation economy for life sciences and technology in the country. We bring the technology community to together into a single, united organization that empowers our members to achieve their business goals through advocacy, networking, and education. We are writing on behalf of our members in the life sciences and biotech industries to express our concerns about the impact of the proposed regulations on these critical sectors of the Maryland economy.

Throughout the current regulation adoption process, the Tech Council urges the PDAB to consider the potential impacts the regulations would have on the environment for innovation and competitiveness for life sciences and biotech in Maryland. Maryland is one of the leading states in the nation for the concentration of life sciences companies and jobs. We are rich in assets in the life sciences and biopharma space – Maryland is home to more than 54,000 life sciences jobs, world class universities, government agencies, and leading biopharma companies. Despite these assets, growth in Maryland continues to be challenged by states making strategic and significant investments to foster continued expansion of this industry. In addition to alignment of key assets and a talented workforce, companies must consider the regulatory environment when determining whether to locate or expand.

Regulations that are vague or unpredictable contribute to a negative regulatory environment that could be a limiting factor for continued growth and innovation. We are concerned that aspects of these proposed regulations are vague, and thus subject to interpretation and unpredictable outcomes. For example, the term "affordability" that is used throughout the draft regulations is vague and without a definition. This could lead to a great deal of latitude among regulators on what is considered affordable and thus subject to price controls contemplated by the Board.

The Tech Council is also concerned that "All insulins marketed in the State in the most recently available calendar year" are specifically called out as drug eligible for selection for a cost review. It is unclear why this drug, and no others, was individually deemed eligible for a review independent of the metrics intended to be used for other drugs. Although insulin is a widely prescribed and essential medication for many people, absent a compelling stated reason otherwise, this drug should be evaluated through the same metrics as all other drugs. We therefore request that this section be removed.

In addition to the general points raised above, the following are some specific concerns raised by Tech Council members in the life sciences sector.

- The definition of "exclusivity" may conflate different concepts and fails to capture important types of

exclusivity, such as that granted under the Orphan Drug Act of 1983 or under section 505A of the of the Federal Food, Drug, and Cosmetic Act (i.e., pediatric exclusivity). For instance, market exclusivity may prevent a competitor from entering a specific market, while data exclusivity simply prevents the FDA from approving a competitor's product by relying on the innovator's data. Pediatric and orphan exclusivity, furthermore, may still allow for competitors to enter a market outside of those indications for which exclusivity was granted.

- For these reasons, we recommend the definition of "exclusivity" be tailored to reflect the varying types of exclusivity. The broad regulatory exclusivity defined in the proposed regulations should be specified as such:

  Regulatory exclusivity means a period during which FDA may not approve a generic or biosimilar version of an FDA-approved drug or biologic.

- This definition, however, either should be qualified with language accounting for the indication-specific types of exclusivity previously referenced or separate definitions should be provided. Citations to federal law may also be helpful to ensuring clarity.

- Second, for reasons of consistency and alignment with federal law, we strongly recommend that the definition of "interchangeable biosimilar" cite federal law as follows:

  "Interchangeable biosimilar" means a biosimilar biological product, as defined in 42 USC 262(i)(3), that the FDA has found to meet the standard for interchangeability, as defined in 42 USC 262(k)(4).

- This helps to avoid any potential differences in interpretation and helps to preserve the integrity of interchangeable status for a biological product, for which the FDA has set a high bar.

- Finally, we recommend a number of changes to aid in clarity and in alignment with Federal law:

  1. Definition of "active ingredient": *"Active ingredient" means the ingredient in a drug that provides pharmacological activity or prevention of disease, or affects the structure or any function of the body, as defined in 21 CFR §314.3*.
  2. Definition of "Food and Drug Administration (FDA)": Add the word "certain" to condition the reference to "other consumer products." The language currently may be read to imply broader authority over consumer products than is held by the FDA, as the Consumer Product Safety Commission regulates most consumer products.
  3. Definition of "therapeutic alternative": We recommend "active ingredient," which is a defined term, be substituted for "therapeutic agent."
  4. Definition of "therapeutic class": Because this term is not defined by the FDA, we recommend a more targeted, fit-for-purpose definition be considered. For instance, if Maryland will rely on a specific data source, the definition should be consistent with the classifications in that dataset (e.g., United States Pharmacopeia Drug Classification (USP DC)). Depending on the data source and its use, the category associated with a drug may also be important.

Finally, the Tech Council is aware that the Biotechnology Innovation Organization (BIO) and the Pharmaceutical Research and Manufacturers of America (PhRMA) have submitted comments on these regulations as well. The Tech Council has reviewed BIO's and PhRMA's comments and is fully supportive of their comments and recommendations.

Thank you for the opportunity to comment on these draft proposed regulations prior to their formal publication for public comment. We look forward to continuing to work productively with the Board as it continues its work to ensure that prescription drugs are affordable and accessible to Marylanders. Please do not hesitate to contact me at kelly@mdtechcouncil.com or (240) 243-4026 to discuss these matters in greater detail.

Sincerely,

Kelly Schulz, CEO
Maryland Tech Council