



November 5, 2009

Ms. Wendy Morgan  
Office of the Attorney General  
109 State Street  
Montpelier, VT 05609

**RE: Advisability of Requiring Disclosure of Free Samples of Prescribed Products Given to Vermont Healthcare Professionals**

Dear Ms. Morgan:

Thank you for the opportunity to comment on Vermont's consideration of requiring the disclosure of free samples of prescribed products to healthcare professionals (HCP). AstraZeneca offers life-sustaining and life-enhancing pharmaceuticals to enable patients and physicians to optimally manage diseases of the gastrointestinal, cardiovascular, respiratory and central nervous systems. AstraZeneca provides free drug samples to Vermont HCPs. Drug samples enable HCPs to provide trial courses of therapy to determine tolerability and effectiveness for an individual patient prior to filling an entire prescription and allow patients to gain access to a particular drug without delay. HCPs determine whether providing a drug sample is the most appropriate course of action for a patient.

There are no financial incentives or economic benefits for HCPs to receive and provide a particular drug sample. AstraZeneca samples are provided free of charge to HCP offices for the exclusive use of patients; samples are not gifts or inducements to HCPs and are not provided to HCPs for their personal use. Therefore, the value of samples to the HCP is zero.

AstraZeneca does not support state-by-state disclosure and reporting of drug samples. Such requirements are unnecessary given the Federal laws and regulations that are currently in place. Additionally, publicly disclosing where drug samples are distributed could create a venue for criminals who seek to steal particular product samples, potentially putting employees, patients and providers at risk. There is no clear patient benefit to disclosing information about drug samples; establishing requirements would only create an economic burden on the state with no resulting benefit and possible detriment to Vermont residents.

AstraZeneca has policies and protocols in place to ensure our company and representatives follow the Federal laws. As requested in the Notice of Public Hearing, we have outlined below the type of information that we are required to capture and the processes we have in place for providing samples to HCPs upon their request.

AstraZeneca distributes free drug samples to Vermont HCPs through a common carrier in response to a written request by the HCP. The request includes the following information; all of which is required by Federal law:

- HCPs name (first, last)
- Professional designation (MD, DO, NP, PA)
- HCPs address
- State license number
- The name and strength of the product sample
- Manufacturer
- Quantity of product sample requested
- Date of the request
- HCP's signature

AstraZeneca collects this information from HCPs through three different methods: sales representative office calls, sample request fax programs, and electronic-sampling programs. AstraZeneca only samples HCPs who are licensed or authorized to prescribe by the state in which they practice and whose practice is appropriate for the on-label use of the product sampled. AstraZeneca complies with federal law which requires manufacturers to keep copies of the sample requests and receipts for a minimum of 3 years.

Each sample must be clearly labeled as a **“Professional Sample: Not to be Sold,”** to ensure that all individuals within the healthcare setting can easily distinguish the sample package. Sample packages must also contain a lot or control number to permit tracking of the sample to the HCP. This is critical information for the purposes of product recalls. If at any point AstraZeneca believes that anyone is diverting product samples or falsifying any records relating to the distribution of drug samples, the suspicion must be reported to the FDA within 5 days and AstraZeneca must conduct an investigation.

As noted above, AstraZeneca has strict policies in place to ensure that all authorized company representative adhere to the Federal requirements and act in an ethical manner when engaging with HCPs. AstraZeneca sales representatives must not sell, purchase, trade or offer to sell, purchase or trade samples, or advise or suggest that HCPs or their agents bill patients and/or third party payers for samples. AstraZeneca sales representatives are trained on these requirements and must report employees and/or HCPs known or suspected of selling samples to the AstraZeneca Code of Conduct HelpLine.

In conclusion, AstraZeneca strongly urges Vermont to refrain from imposing disclosure requirements for distribution of free drug samples. The provision of samples allows HCPs to determine whether a particular drug may be effective and tolerated by a patient; allows patients to gain access to a drug without delay; and permits doctors to determine the appropriate dosage of a drug without causing the

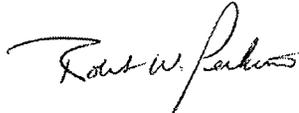
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patient to have to purchase a 30-day supply of the drug. Mandatory state disclosure requirements inappropriately characterize samples as a "gift" to HCPs and may deter an HCP from requesting products to the detriment of patient health, even though samples have no value to the HCP and provide no economic benefit to the HCP.

AstraZeneca would also like to encourage the state to review the Pharmaceutical Researcher and Manufacturers of America (PhRMA) public testimony and supporting submissions for additional information and insight. AstraZeneca supports the position and points provided by PhRMA.

Thank you for your time and consideration. Please feel free to contact me at 302-885-2698 if you have any questions regarding our comments and recommendations.

Sincerely,

A handwritten signature in cursive script that reads "Robert W. Perkins". The signature is written in black ink and is positioned above the typed name.

Robert W. Perkins  
Vice President, Policy & Promotional Affairs  
AstraZeneca Pharmaceuticals

cc: David Anderson, Director, State Government Affairs, AstraZeneca