

## **Direct Healthcare Professional Communication (DHPC)**

**17 August 2023**

### **The importance of specifying a clear treatment description in the prescription of Dry Powder Inhalers (DPI); considerations on potential risk of medication errors**

Dear Healthcare Professional,

AstraZeneca (UK) LTD.CO, TSSO, in agreement with Saudi Food and Drug Authority (SFDA), would like to notify you that essential differences in design and function of Dry Powder Inhalers (DPI) may constitute a risk of medication errors in relation to unspecified prescription with subsequent switching of device without proper patient instruction and follow-up.

#### **Summary**

- Dry powder inhalers are drug-device combination products where the complexity of the formulation, its functionality, the ability of patients to utilize the device, and potential user error risks play essential roles in the drug delivery since each DPI device can have a unique design and administration procedure (Mohan et al 2022).
- Standard DPI in-use errors are related to:
  - Storage temperature, shelf-life, and in-use lifetime in humid atmosphere.
  - Under/overdosing due to handling errors and inhalation technique that differs between inhalers.
- As per the SFDA's general recommendations for substituting registered medicines (version 1 issued January 2021), inhalers are among the listed medications requiring additional consideration before substitution, to ensure the patient's safety and treatment effectiveness. Health practitioners must be more cautious and closely monitor the patient during the inhaler substitution to ensure they have achieved their treatment objectives.
- It is important to counsel patients on the proper use of DPIs when it's prescribed/dispensed depending on the inhaler type, to avoid any adverse effects on patients.

## The SFDA call to action

The SFDA emphasizes the importance of specifying a clear treatment description in the prescriptions of the approved Budesonide/ Formoterol Dry Powder Inhalers, to use both brand and generic names on prescriptions:

- To prevent dispensing errors at the pharmacy level.
- To ensure the proper inhaler selection and device training at the physician's discretion according to the individualized patient's treatment plan.
- To avoid any adverse clinical outcomes driven by unintended inhaler switching due to an unclear prescription.
- To prevent patient confusion and ensure adequate patient device and inhalation technique training to improve adherence for better disease control and outcomes. (Ekberg-Jansson et al 2015, Bjermer L 2014, Thomas et al 2009 for all the above)

## Call for reporting

The prescribing healthcare provider and/or the provider's designee is/are responsible for mandatory reporting of all serious adverse events and medication errors potentially related to a product.

For SYMBICORT TURBUHALER please submit safety concerns using one of the following methods:

- Directly to AstraZeneca Patient Safety:  
Email: [ksa.ae@astrazeneca.com](mailto:ksa.ae@astrazeneca.com) - Phone: +966 11 2249235  
Portal: <https://contactazmedical.astrazeneca.com>
- SFDA reporting information:  
Email: [npc.drug@sfd.gov.sa](mailto:npc.drug@sfd.gov.sa) - Toll-free phone: 19999 - Portal: <https://ade.sfda.gov.sa>

Best Regards,  
Malak Alshammari  
Saudi QPPV

Malak Alshammari  
Malak Alshammari (Aug 28, 2023 18:18 GMT+3)

## References

### **Bjermer L 2014**

Bjermer L. The importance of continuity in inhaler device choice for asthma and chronic obstructive pulmonary disease. *Respiration*. 2014;88(4):346-52.

### **Ekberg-Jansson et al 2015**

Ekberg-Jansson A, Svenningsson I, Rågdell P, Stratelis G, Telg G, Thuresson M, Nilsson F. Budesonide inhaler device switch patterns in an asthma population in Swedish clinical practice (ASSURE). *Int J Clin Pract*. 2015 Oct;69(10):1171-8.

### **Mohan et al 2022**

Mohan AR, Wang Q, Dhapare S, Bielski E, Kaviratna A, Han L, Boc S, Newman B. Advancements in the Design and Development of Dry Powder Inhalers and Potential Implications for Generic Development. *Pharmaceutics*. 2022 Nov 17;14(11):2495.

### **Thomas et al 2009**

Thomas M, Price D, Chrystyn H, Lloyd A, Williams AE, von Ziegenweidt J. Inhaled corticosteroids for asthma: impact of practice level device switching on asthma control. *BMC Pulm Med*. 2009 Jan 2;9:1.





# dhpc-symbicort-17AUG2023-prescription-saudi-arabia

Final Audit Report

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