

Date: February 16, 2007

Subject: DRC Recommendations to DCC and DHS

To: DHHS, DCC, Dean's Office

From: Henry F. Simmons, Jr., MD, Ph.D. Chairman DRC

At its 02/15/07 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of selected inhaled beta 2 agonists.

Long acting inhaled beta2 agonists [LABAs]

Formoterol (Foradil Aerolizer)

Salmeterol (Servent Diskus)

Short- acting Inhaled beta2 agonists [SABAs]

Albuterol (Ventolin, Proventil)

Levalbuterol (Xopenex)

Pirbuterol (Exirel, Maxair)

Metaproterenol (Alupent)

Indications

Asthma, exercise-induced asthma, exercise induced asthma prophylaxis, and chronic obstructive pulmonary disease in adults in outpatient settings

Asthma, exercise induced asthma, and exercise induced asthma prophylaxis in children in outpatient settings

Discussion

The Committee reached the following conclusions unanimously based upon its perception of the bulk of the best available evidence:

Safety Adverse Events

1. Neither of the LABAs listed above is associated with a greater risk of either adverse events or lesser safety when used to treat adults in the outpatient setting with the captioned indications.
2. None of the SABAs listed above are associated with a greater risk of either adverse events or lesser safety when used to treat adults in the outpatient setting with the captioned indications?
3. Neither of the LABAs listed above is associated with a greater risk of either adverse events or lesser safety when used to treat children in the outpatient setting with the captioned indications.

4. None of the SABAs listed above is associated with a greater risk of either adverse events or lesser safety when used to treat children in the outpatient setting with the captioned indications.

Efficacy/Effectiveness

5. Neither of the LABAs listed above is superior to the other in either efficacy or effectiveness for treating adults in the outpatient setting with the captioned indications.

6. None of the SABAs listed above is superior to the others in either efficacy or effectiveness for treating adults in the outpatient setting with the captioned indications.

7. Neither of the LABAs listed above is superior to the others in either efficacy or effectiveness for treating children in the outpatient setting with the captioned indications.

8. None of the SABAs listed above are superior to the others in either efficacy or effectiveness for treating children in the outpatient setting with the captioned indications.

Demographics

9. Neither of the LABAs listed above when used to treat the captioned indications is likely to be more efficacious, more effective, or associated with fewer adverse events on the basis of a patient's age, race, gender, concomitant medications, comorbidities or pregnancy status than the other.

10. None of the SABAs listed above when used to treat the captioned indications are likely to be more efficacious, more effective, or associated with fewer adverse events on the basis of a patient's age, race, gender, concomitant medications, comorbidities or pregnancy status than the others. However, if pirbuterol is the only SABA chosen, then an alternative should be available for children less than 12 years of age.