Regulators and Manufacturers

- For regulations, PROs were included in the product label for all of the six products reviewed in the clinical development program. For the manufacture of the PROs data generated label claims and many publications that allowed extensive public dissemination of PROs data were developed.

- PRO label claims were generated by the FDA for Atopica, Botox, pimecrolimus, tacrolimus, and ustekinumab. The type of PROs claims that the FDA received were as follows:

  - Symptom (e.g., itching, burning, pain) (n = 4); Atopiclair (FDA), ustekinumab (FDA and EMA), tacrolimus (EMA), and pimecrolimus (EMA).

  - Functional (e.g., daily activities, sleep) (n = 4); tacrolimus (EMA), Botox (FDA and EMA), and ustekinumab (FDA and EMA).

  - Global (n = 4); Botox (FDA) and ustekinumab (EMA).

- Treatment satisfaction (n = 7); Botox (EMA).

  - Global subject assessment (n = 3); pimecrolimus (EMA).

  - Change in pruritus Score-10 (n = 4); Atopiclair (FDA).

- The types of PROs claim that the FDA received were as follows:

  - Symptom (e.g., itching, burning, pain) (n = 4); Atopiclair (FDA), ustekinumab (FDA and EMA), tacrolimus (EMA), and pimecrolimus (EMA).

  - Global (n = 4); Botox (FDA) and ustekinumab (EMA).

- Payers

  - For payer, utility values based on PROs were used in cost-effectiveness evaluations for two of the six products.

  - Treatment satisfaction was considered a criterion for reimbursement.

  - Treatment satisfaction was considered as a criterion for reimbursement.

  - Payers considered the PROs in the treatment development of moderate-to-severe dermatologic conditions.

  - Payers considered the PROs in the treatment development of moderate-to-severe dermatologic conditions.

Table 1: Summary of PRO Label Claims for Approved Dermatology Drugs in the US and EU

<table>
<thead>
<tr>
<th>Product</th>
<th>Label Indicator</th>
<th>EU Approval Date/PRO Label Claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atopiclair®</td>
<td>Improves specific dermatologic symptoms</td>
<td>Not applicable. Global assessment (n = 3); pimecrolimus (EMA).</td>
</tr>
<tr>
<td>Botox*</td>
<td>Improves specific dermatologic symptoms</td>
<td>Not applicable. Global assessment (n = 3); pimecrolimus (EMA).</td>
</tr>
<tr>
<td>pimecrolimus</td>
<td>Improves specific dermatologic symptoms</td>
<td>Not applicable. Global assessment (n = 3); pimecrolimus (EMA).</td>
</tr>
<tr>
<td>tacrolimus</td>
<td>Improves specific dermatologic symptoms</td>
<td>Not applicable. Global assessment (n = 3); pimecrolimus (EMA).</td>
</tr>
<tr>
<td>ustekinumab</td>
<td>Improves specific dermatologic symptoms</td>
<td>Not applicable. Global assessment (n = 3); pimecrolimus (EMA).</td>
</tr>
<tr>
<td>Ustekinumab</td>
<td>Improves specific dermatologic symptoms</td>
<td>Not applicable. Global assessment (n = 3); pimecrolimus (EMA).</td>
</tr>
</tbody>
</table>

REFERENCES


CONCLUSION

- Including patient-reported assessment of the treatment impact on disease activity, the clinical value of dermatology PROs has many benefits for all stakeholders.

- The PROs used as a measure for clinical development of dermatology drugs has many benefits for all stakeholders.

CONTACT INFORMATION

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DISCUSSION

- For the dermatology drugs reviewed, include of PROs in the clinical development program provided evidence of treatment benefits to patients, prescribers, regulators, manufacturers, and payers.

  - Drug manufacturers of developmental drugs for atopic dermatitis, psoriasis, and primary hyperhidrosis in their marketing labels and summaries of product characteristics.

  - The inclusion of PROs in marketing labels and summaries of product characteristics has been shown to improve patient outcomes and satisfaction.

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