**BACKGROUND**

This multi-country study was conducted in the USA, France, Germany, Brazil and South Korea, with 57 healthcare professionals (HCPS) and 30 patients/caregivers participating, in total.

**OBJECTIVES**

The objectives of this study were to evaluate the performance of the new pen device in terms of its ease of use, appearance and functionality amongst potential users and caregivers, in addition to HCPS who will be involved in recommending it and/or training patients in its use.

**METHODS**

The study was initiated in the US (5 sites) in December 2015 and in France (3 sites), Germany (4 sites), Brazil (2 sites) and South Korea (1 site) in March 2016. The US study was completed in January 2016 and all others in April 2016.

Semi-structured 60-minute qualitative interviews were conducted at each site with HCPS and caregivers responsible for administering GH to children (PGHD) as well as adults with Growth Hormone Deficiency (AGHD). HCPS were selected from Endocrinologists, Nurses, Growth Hormone Coordinators (GHCs) and Medical Assistants (MA).

Criteria for selection of HCPS included senior grade with personal responsibility either for initiating treatment in patients with GHD or training individuals on how to administer hGH.

Criteria for selection of caregivers of children with PGHD/AGHD were having personal responsibility either for injecting or supervising the injection of hGH with a pen or other device for at least 6 months. In Brazil and South Korea syringe and vial users were also eligible for the study.

The participants in the study were provided with a prototype Saizen pen and a Quick Reference Guide leaflet that explained the handling of the prototype pen. The tested pen was red in the US (Figure 1) and silver in the other countries.

Trained observers recorded comments made by the study participants, observed and recorded how they interacted with the device and assessed and recorded how well they had comprehended and implemented the Quick Reference Guide.

**RESULTS**

- **A total of 57 HCPS and 30 patients/caregivers participated in the study in the 5 countries involved. (Table 1)**

**CONCLUSIONS**

- The trained observers noted that 95% of patients/caregivers dialed the dose accurately the first time they handled the pen. Nevertheless, a few patients/caregivers had some minor reservations about the dose window.

- In addition, a few mentioned the dose selection knob being slightly stiff to turn, the absence of an audible signal (‘click’) to indicate completion of dose delivery and the need to calculate any partial doses when the current cartridge did not contain enough hGH to provide the full dose required.

- **Moreover, global HCP ratings of the new Saizen pen in comparison with the current market leaders in disposable and reusable devices were positive. The new pen was perceived as easier to use than the leading reusable device. Its sleek, distinctive appearance, combined with its ease of preparation/injection, was felt to enhance the overall user experience and to differentiate this device from other reusable pens.**

- In addition, HCP ratings of the new pen’s ease of preparation/injection were almost as high as the leading disposable device (Figure 3).

- From the patient/caregiver’s perspective, the pen was seen as easy to prepare and use making it suitable for both children and adults to self-administer.

- Patients/caregivers rated the device higher than their current devices in terms of ease of learning, preparation and administration and ease of handling/use (Table 2).

- **The majority of HCPS claimed that they were likely to recommend the new Saizen pen to patients, with likelihood highest in Brazil and the USA.**

- **Dose window showing relative frequency of words used to describe the new pen device**

- **Table 2. Global patient/caregiver rating for performance of Saizen® pen device vs their current devices (mean scores on a 1–7 scale (1=not at all easy, 7=very easy)**

- **Figure 4. Global HCP likelihood of recommendation of the new pen device**

- **Similary, around half of the caregivers and patients stated that they would request the new device from their HCP when it became available to replace the device they currently use.**

**DISCUSSIONS**

MS is an employee of Merck KGaA, Darmstadt, Germany. MRC is an employee of Merck Biopharma. At the time this work was carried out

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