Poster No. P2-670

A New Reusable Manual Pen Device for Injection of Human Growth Hormone (GH): Results of a Convenience and Functionality Evaluation Study

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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.
- The new Saizen® manual pen device consists of a reusable aluminium body and cap, with a multi-use cartridge system, viewing window, dose-display window, dose-selection knob and injection button. (**Figure 1**) The pen device was designed to improve on the ease of use, appearance and functionality of existing devices for administering injections of recombinant human growth hormone (r-hGH) to patients with growth hormone deficiency (GHD).

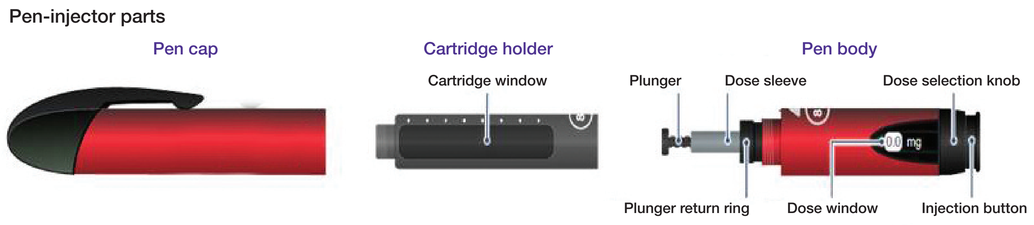
OBJECTIVES

- 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 with 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 r-hGH.
- Criteria for selection of caregivers of children with PGHD/GHD patients were having personal responsibility either for injecting or supervising the injection of r-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 of the 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.

Figure 1. Pen injector components



RESULTS

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

Table 1. Study participants by type in each country

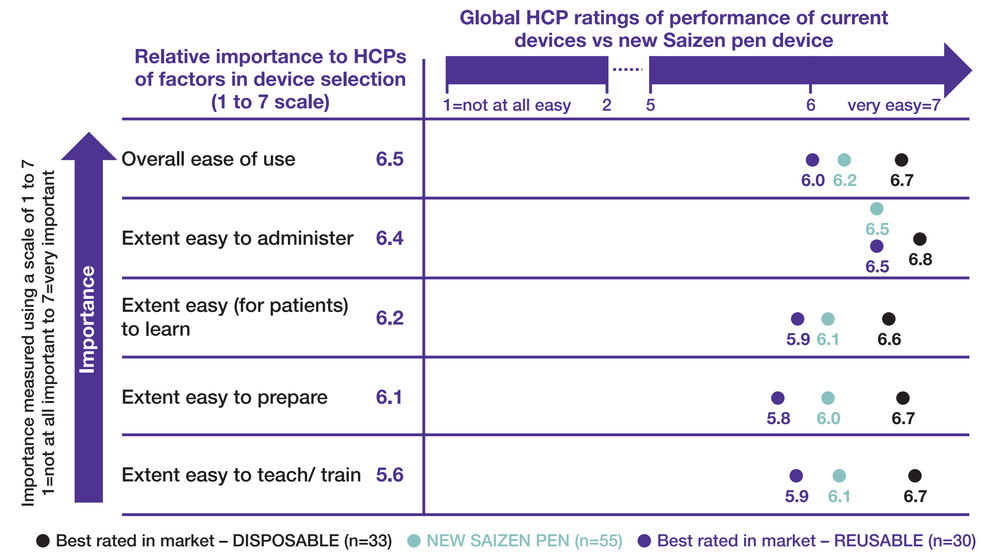
HCPs	22	7	8	12	8
Caregivers, AGHD patients	5	7	6	6	6

- 65% of HCPs described the new pen device as ‘simple’ or ‘easy’, 39% used the words ‘accurate’ or ‘reliable’, with 26% choosing the adjective ‘sleek’ to summarise its appearance. ‘Modern’ and ‘simple’ were the words most commonly chosen by caregivers/patients to describe the new pen. The relative frequency of words used to describe the new device is represented visually in the word cloud. The larger the word, the more frequently it was used (**Figure 2**).

Figure 2. Word cloud showing relative frequency of words used to describe the new pen device

- The pen device was perceived as comfortable to hold and operate. 70% of patients/caregivers spontaneously mentioned both its weight and size as positive features and claimed the metal pen and cap felt sturdy and robust.
- 62% of all respondents spontaneously mentioned the look and feel of the device as positive. The aluminium body was considered particularly attractive, providing a high quality finish vs. devices made of plastic.
- The injection button was considered smooth, firm and easy to press – so easy a child could use it – with a reassuring click. Less pressure was required to carry out the injection compared with other devices so the whole injection process felt controlled. Moreover the speed of injection was perceived to be neither too slow nor too abrupt.
- 60% of all participants spontaneously mentioned the process involved in setting the dose as a positive feature of the pen. The ability to dial back the dose, if incorrectly set, was seen as a key benefit.
- Patients/caregivers appreciated seeing the plunger as it moved through the cartridge window. The accompanying dose countdown to 0.0 during the injection process was highlighted as a benefit by all respondent types as it satisfied them that the correct dose had been delivered.
- The inability to dial a dose greater than that remaining in the cartridge was also perceived as an additional safety feature and the dose display using increments of 0.1 mg permitted accurate dose selection.
- Although inserting or changing a cartridge meant an additional step for disposable device users, the reusable nature of the new pen device was overall seen to positively reduce waste. It was also considered easy to insert or change the cartridge and to view the quantity of r-hGH remaining.
- The trained observers noted that 90% of patients/caregivers dialled the dose accurately the first time they handled the pen. Nevertheless, a few HCPs and 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 r-hGH to provide the full dose required.
- However, the positive features of the pen far outweighed any reservations, and these minor concerns would not be barriers to full adoption of the device.
- Among HCPs in all countries, overall ease of use was seen as the most important factor in device selection (**Figure 3**) and the new pen device was considered to perform successfully in terms of being both easy to prepare and easy to learn/use.

Figure 3. Global HCP assessment of relative importance of factors in device selection and comparative ratings of device performance



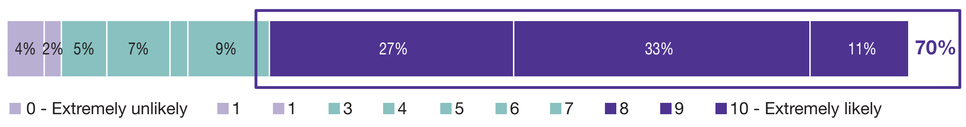
- Moreover, global HCP ratings of the new Saizen pen in comparison with the current market leaders in disposable and reusable devices were positive. The new pen was perceived as easier to use than the leading reusable device. Its sleek, distinctive appearance, combined with its ease of preparation/injection, 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, administration and ease of handling/use. (**Table 2**)

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)

	Easy to learn	Easy to prepare	Easy to administer	Overall ease of use
New Saizen® pen device (n=29)	5.8	6.1	6.3	6.0
All current devices (n=34)	5.8	5.2	5.5	5.8

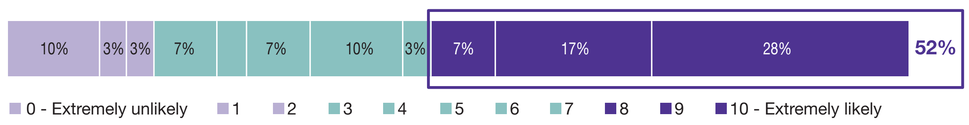
- The majority of HCPs claimed that they were likely to recommend the new Saizen® pen to patients, with likelihood highest in Brazil and the USA. (**Figure 4**)

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



- Similarly, 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. (**Figure 5**)

Figure 5. Caregiver/patient likelihood of requesting the new pen device from their HCP



CONCLUSIONS

- **The new pen device successfully met its design objectives and was well accepted by HCPs and patients/caregivers for ease of use, appearance and functionality.**
- **The ease of use of this new pen device was considered superior to that of currently available reusable pens and was almost comparable with the ease of use of the leading disposable pen.**

DISCLOSURES

MS is an employee of Merck KGaA, Darmstadt, Germany.
M-NC was an employee of Merck Biopharma at the time this work was carried out

ACKNOWLEDGEMENTS

The study was sponsored by Merck KGaA, Darmstadt, Germany. The authors would like to thank patients, caregivers and HCPs for their participation, and also thank Carole Abbotts, Pharmaceutical Market Research Consultant, London, UK and Shazada Ali at Double Helix Discovery, London, UK. Medical writing assistance was provided by David Candlish, inScience Communications, Tattenhall, UK and funded by Merck KGaA, Darmstadt, Germany.

To view the e-Poster, scan the QR code or go to http://medpub-poster.merckgroup.com/ESPE2016_P2.670.pdf

Presented at ESPE, Paris, 10-12 September, 2016

55ESPE 670--P2

Growth

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DOI: 10.3252/pso.eu.55ESPE.2016

Poster presented at: ESPE 2016 PARIS

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