



Evaluating the Evidence for EMEA Treatment Satisfaction Claims



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Introduction

- Patients' satisfaction with medication is a central part of the success of treatment outcomes and affects:
 - Patient's health-related decisions.
 - Treatment-related behaviours.
- Studies have shown that although a medication can successfully treat a disease area, if aspects of treatment satisfaction are not met:
 - Patients can become non-adherent which can adversely affect health.
 - Patients make medication-related decisions without seeking medical advice (Atkinson et al 2004).
- Some consider the importance of measuring treatment satisfaction in clinical trials as paramount, especially for chronic health condition patients, as this can lead to non-compliance with treatment regimens.

Treatment Satisfaction

A recipient's rating of, or report on, salient aspects of the process and the outcome of his or her treatment experience according to predetermined criteria

- Treatment satisfaction is directly associated with adherence to treatment regimens and indirectly associated with clinical outcomes and health-related quality of life (HRQL) outcomes (Weaver et al 1997).
- Treatment satisfaction are usually best captured as a patient-reported outcome is frequently measured using structured questionnaires.
- Treatment satisfaction measures are either generic [e.g. Treatment Satisfaction Questionnaire for Medication (TSQM), Treatment Satisfaction with Medications Questionnaire (SATMED-Q)] or disease-specific (e.g. Diabetes Treatment Satisfaction Questionnaire (DTSQ), Treatment Satisfaction Questionnaire – GERD (TSQ-G), Insulin Treatment Satisfaction Questionnaire (ITSQ)).
- Treatment satisfaction measurement in clinical trials often relies on single-item measures or instruments which have not been validated (degl' Innocenti et al 2004).

Study Objective

This study sought to document the extent to which treatment satisfaction claims have been approved by the European Medicines Agency (EMA), the extent to which treatment satisfaction evidence is provided, and

to evaluate the quality of evidence provided in support of the label claims.

Methods

- Authors reviewed the Scientific Discussion or Public Assessment Report for each currently authorised medicinal product approved by the EMA (as of December 2009).
- Products were excluded if they had been previously approved but marketing authorisation had been subsequently withdrawn.
- Results were documented in a data extraction table with the following information recorded:
 - Treatment name.
 - Authorisation date.
 - Marketing authorisation holder.
 - International Non-proprietary Name (INN).
 - Pharmacotherapeutic group.
 - Anatomical Therapeutic Chemical Classification System (ATC) Code.
 - Therapeutic indication.
 - PRO utilised to measure treatment satisfaction.
 - PRO measure description provided in documentation.
 - Summary of documented evidence.
 - This evidence was evaluated in order to establish the nature and extent of previous successful claims for treatment satisfaction.

Results

- 508 authorised medical products were reviewed.
- 17 approved products reported measuring patient satisfaction with treatment, with approval dates ranging from July 1998 to July 2008.
- Information on the authorisation date, therapeutic indication, and description or name of the treatment satisfaction measure is provided in Table 1.
- Treatment satisfaction approvals were distributed across a broad range of pharmacotherapeutic groups (see Table 2):
 - Cluster of approvals for insulin analogues for injection, long lasting (n=4).
- 11/17 approvals provided limited reference to the way in which treatment satisfaction had been evaluated e.g. reference to a total satisfaction score without any further details or simply stating 'subject satisfaction was evaluated'.

Results (continued)

- Four treatments had documentation recording a named treatment satisfaction measure:
 - Treatment Satisfaction and Compliance Scale.
 - Diabetes Treatment Satisfaction Questionnaire (DTSQ).
 - Treatment satisfaction dimension of the Seattle Angina Questionnaire.
 - Patient Perceived Quality of Treatment (PPQT).
- 2/17 measured treatment satisfaction using a visual analogue scale (VAS).
- 5/17 provided treatment satisfaction results, yet only two gave any details on the way in which treatment satisfaction was measured.

Table 1. Data extracted from labels with reference to treatment satisfaction

| Treatment | Authorisation date | Therapeutic indication | Treatment Satisfaction Measurement Approach |
|------------|--------------------|---|--|
| Aloxi | 22 March 2005 | Prevention of nausea and vomiting in moderately and/or highly emetogenic cancer chemotherapy | 0-100mm VAS: not at all satisfied to totally satisfied |
| Apidra | 27 September 2004 | Treatment of adults, adolescents and children, 6 years or older with diabetes mellitus, where treatment with insulin is required | Diabetes Treatment Satisfaction Questionnaire, status version (DTSQs) and DTSQc (change version) |
| Emselex | 22 October 2004 | Symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome | Patient Perceived Quality of Treatment (PPQT) |
| EVRA | 22 August 2002 | Female contraception intended for women of fertile age | Reference to 'subject satisfaction' being evaluated |
| Firazyr | 11 July 2008 | Symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults (with C1-esterase-inhibitor deficiency) | Reference to a 'patient satisfaction questionnaire' |
| Insulatard | 07 October 2002 | Treatment of diabetes mellitus | Reference to an overall treatment satisfaction score |
| Ionsys | 24 January 2006 | Management of acute moderate to severe post-operative pain for use in a hospital setting only | Reference to a 'patient satisfaction questionnaire' |
| Ivemend | 11 January 2008 | Prevention of (acute and delayed) nausea and vomiting associated with moderately/ highly emetogenic cancer/ cisplatin-based cancer chemotherapy in adults | 100mm VAS, global satisfaction with anti-emetic treatment |
| Kivexa | 17 December 2004 | In antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection in adults and adolescents from 12 years of age | Reference to a total satisfaction score |
| Lumigan | 08 March 2002 | Reduction of elevated intraocular pressure in chronic open-angle glaucoma and ocular hypertension in adults (as monotherapy or as adjunctive therapy to beta-blockers) | Satisfaction questionnaire using a 7-point scale |
| Lyrica | 06 July 2004 | In epilepsy, as an adjunctive therapy in adults with partial seizures with or without secondary generalisation | Treatment Satisfaction and Compliance Scale |
| Nevanec | 11 December 2007 | Prevention and treatment of postoperative pain and inflammation associated with cataract surgery | Reference to evaluating patient comfort and satisfaction |
| Optisulin | 27 June 2000 | For the treatment of adults, adolescents and children of 6 years or above with diabetes mellitus, where treatment with insulin is required | Diabetes Treatment Satisfaction Questionnaire (DTSQ) |
| Preatact | 24 April 2006 | Treatment of osteoporosis in postmenopausal women at high risk of fractures | No details. |
| Protaphane | 07 October 2002 | Treatment of diabetes mellitus | Overall treatment satisfaction |
| Ranexa | 09 July 2008 | As add-on therapy for the symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies | Treatment satisfaction dimension of the Seattle Angina Questionnaire. |
| Xenical | 29 July 1998 | In conjunction with a mildly hypocaloric diet for the treatment of obese patients with a BMI greater or equivalent to 30kg/m ² , or overweight patients (>28 kg/m ²), with associated risk factors | No details |

Table 2. Pharmaco-therapeutic groups of labels with reference to treatment satisfaction

| Pharmaco-therapeutic groups | Number of Treatment Satisfaction Approvals |
|---|--|
| Insulin and analogues for injection, long acting | 4 |
| Anti-emetics and anti-nauseants | 2 |
| Other cardiac preparations | 2 |
| Anti obesity agent | 1 |
| Anti-epileptics | 1 |
| Anti-inflammatory agents, non steroids | 1 |
| Anti-virals for treatment of HIV infections, combinations | 1 |
| Norelgestromin and estrgoen | 1 |
| Opioid analgesics (phenylpiperidine derivative) | 1 |
| Other anti-glaucoma preparations | 1 |
| Parathyroid hormones and analogues | 1 |
| Urinary anti-spasmodics | 1 |

Conclusions

- Treatment satisfaction is a valuable endpoint for clinical studies of treatments for chronic conditions where treatment compliance and adherence are considered issues.
- Treatment satisfaction has been used in a limited way to support EMEA drug approvals.
- This may be due in part to a limited number of generic treatment satisfaction measures or a lack of guidance from the EMEA regarding the role of treatment satisfaction as a PRO endpoint.
- Treatment satisfaction PROs used in clinical studies reviewed by the EMEA involving PROs that have not been validated are less credible.
- Treatment satisfaction data should be collected with carefully developed and validated PRO measures, with careful attention to PRO description and data reporting in approval documents.

References

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