

Semantic Density and Gravity in Lay-oriented Medical Knowledge Communication: The Case of the EPAR Summary for the Public

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Abstract

This article explores a particular medico-pharmaceutical genre called the *European Assessment Report (EPAR) summary for the public*, aimed at a lay readership. The texts provide general information about a specific medicinal product and report the outcome of clinical trials preceding marketing authorization of the product in the EU. The aim of this study is to explore the character of the knowledge mediation taking place in the genre, with a specific focus on comprehensibility for lay readers. For analytical methodology, a framework derived from so-called Legitimation Code Theory has been adopted. The framework gauges *semantic density* (how much meaning is 'condensed' into a text) and *semantic gravity* (a text's degree of abstractness/concreteness). The study assumes that high semantic density and a high degree of abstractness may be challenging to some reader groups. Analytical results reveal an overall degree of semantic density that is lower than that of scientific texts, but markedly higher than in non-specialized, everyday discourse. Moreover, across the texts, results reveal marked oscillation in the semantic density of individual words, reflecting what is in effect a fusion of two different registers belonging to very different levels of specialization. In terms of semantic gravity, findings indicate a maximum of abstractness in large parts of the texts. Altogether, the analyses reveal a clear affinity with textbooks that serve to initiate novices into the specialized conceptual 'landscape' of a given field of knowledge. The study ventures the hypothesis that this 'textbook' quality may be one of the most significant obstacles for certain reader groups.

Keywords: medical discourse; expert-to-lay communication; knowledge mediation; semantic density; semantic gravity

1. Introduction

This article is situated at the crossroads between linguistics and health communication studies, being concerned with the semantic profiling of a particular medico-pharmaceutical genre aimed at a lay readership. The

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genre in question is the so-called *European Assessment Report (EPAR) summary for the public*, published by the European Medicines Agency (EMA). As part of the documentation process in connection with the EMA's authorization of a medicinal product for marketing, these texts provide general information about the drug in question and report on the outcome of the clinical trials preceding authorization. In the words of the European Commission, the *raison d'être* behind a genre like the EPAR summary is the following:

Today, patients play an increasingly active role in the pharmaceutical area. Interest in health issues has greatly increased over the years with patients becoming ever more health conscious and wanting to be informed about existing medicines that are available, the grounds on which they have been approved, and how they are monitored. (European Commission n.d.)

Whereas the parallel genre of Patient Information Leaflets has been extensively studied from a number of linguistic and discursive perspectives, EPAR summaries have been largely ignored in research literature, which is a lacuna that the present study seeks to remedy.

As an example of expert-to-public discourse, EPAR summaries represent communication across a *knowledge asymmetry* (see, e.g., Pilnick 1998; Kastberg 2011; Anesa and Kastberg 2012) across which the scientific knowledge of specialists needs to be *recontextualized* (Calsamiglia and van Dijk 2004; Rose 2005) for a lay readership through registerial adaptation. The texts thus belong to a 'family' of genres that are notorious for their communicative pitfalls, especially in terms of comprehensibility for the target audience (see, e.g., De Jong and Schellens 1997; Janssen and Neutelings 2001; Lentz and Pander Maat 2004). This makes the genre one of those focal points where research in the humanities may assist the health care sector in unearthing communicative obstacles between healthcare professionals and patients/lay citizens. The aim of the present study, therefore, is to explore the character of the knowledge mediation taking place in the EPAR summary genre, with a specific view to highlighting aspects of the texts that may pose a challenge to the intended readership.

For materials, a small corpus of six texts from a one-year period (September 2019–September 2020) has been compiled. For analytical methodology, a conceptual framework originating in Legitimation Code Theory (Maton 2006, 2007, 2014; Maton, Hood and Shay 2014) and

developed in collaboration with linguists working within Systemic-Functional Linguistics (SFL) (see Martin and Maton 2017; Matruglio, Maton and James 2014) has been adopted. The framework is designed to gauge two aspects of knowledge-communication texts: *epistemic-semantic density/epistemological condensation* (ESD and EC) on the one hand and *semantic gravity* (SG) on the other (Maton 2014; Maton and Doran 2017a; Maton and Doran 2017b). Briefly told (see section 3 for elaborate definitions), ESD and EC are concerned with the ‘amount’ of meanings that are ‘compacted’ into a text, and SG with a text’s level of concreteness/abstractness. The present investigation is predicated on the assumption that the higher the level of ESD and EC, the greater the challenge for a lay readership. Similarly, with regard to SG, the study assumes that some target audiences are likely to find highly abstract texts more inaccessible than ones with a more concrete character.

2. Contextualization of the EPAR Summary Genre and Data Selection

As a genre, *EPAR summaries for the public* is a relatively recent invention, mandated by EU legislation from 2004, according to which ‘[t]he European Public Assessment Report (EPAR) shall include a summary written in a manner that is understandable to the public’ (European Parliament/European Council 2004: article 13(3)). The contents and the intended target audience were further specified in a reflection paper published by the EMA in 2006:

It is suggested to keep the scope of the EPAR summaries at a basic level. At the same time, the contents should include an appropriate amount of information, enabling patients and the general public to obtain adequate information of the given product. In other words, the summaries will target the ‘average layperson’ both in terms of readability and contents. (EMA 2006: 3)

The contents of the texts originate in two anterior specialized medico-pharmaceutical texts, viz. the *EPAR – public assessment report* and the *Summary of Product Characteristics*. From the former is sourced information about indications (what disease/disorder the drug is developed for), mechanism of action (how it works), and details about the outcome of clinical trials and the drug’s risk profile. From the latter stem details

about how the drug is used (dosage and method of administration).¹ In view of this complex textual genesis, it is no surprise that the genre is particularly prone to comprehensibility problems for its target audience. This was exactly the conclusion of the two extant studies of this aspect of the genre, Askehave and Zethsen (2008)² and Raynor and Bryant (2013), both of which conclude, on the basis of user surveys, that the texts are not sufficiently comprehensible for lay readers.

However, the findings in Askehave and Zethsen (2008) and Raynor and Bryant (2013) date thirteen and eight years back, respectively, and may no longer be representative, especially considering that certain stylistic modifications to the genre were introduced in 2017 (see EMA 2017). To obtain a corpus representative of the genre in 2021, only texts published within the last year from the point of sampling (September 2020) were selected. To ensure representativeness, maximum diversity was aimed for in the sampling, which is why all six texts were selected to represent different ATC categories.³

3. Theoretical Framework: Semantic Density, Condensation and Gravity

3.1. Operationalization of the concepts of ESD and EC in English discourse

ESD and EC are concepts concerned with the complexity of meanings realized in language use, i.e., the comprehensiveness of the set of semantic components ‘compacted’ into wordings (Maton and Doran 2017a: 54). Thus, ESD and EC are variable phenomena: wordings may be more or less semantically dense, depending on the number and constellation of

¹ A specimen of the genre (from the corpus) is given in the Appendix. The example clearly reflects the texts’ generic structure, which all the individual specimens rigidly observe. In connection with in-text citations, the individual texts will be referred to by the name of the medicinal product in question. Full bibliographic details are provided under ‘Corpus texts’ in the references section.

² It should be noted that Askehave and Zethsen’s (2008) study focused on the Danish translation of the texts, whereas the present study is concerned with originals, which are written in English.

³ ATC refers to the Anatomic Therapeutic Chemical classification system, which is ‘an international systematic standard for pharmaceutical drugs that groups them according to the organ or tissue on which they act, their mode of action, and their chemical composition.’ (Porta and Last 2018).

semantic elements coded. This premise (ESD and EC variability) is one of the major strengths of Maton and Doran's (2017a, 2017b) framework, combined with a highly persuasive operationalization in the form of scales with degrees. The operationalization makes for a very 'applicable' analytical framework, designed for the investigation of ESD and EC in any type of English discourse. Three sets of analytical categories are provided: one for the analysis of ESD in wording, i.e., individual words, and two for EC. Of the EC frameworks, however, only one—pertaining to 'clausing', i.e., to the semantics expressed at clause level—proved relevant, which means that the other (concerned with 'sequencing', i.e., the way in which meanings are accumulated across sentences) will be left out of consideration. The framework for 'wording' will be accounted for in 3.1.1, and the one for 'clausing' in 3.1.2.

3.1.1. ESD in words

In defining ESD, Maton and Doran (2017a: 57) emphasize the *relationality*, *differentiation* and *resonance* of words. For the purposes of the present article, these (not entirely transparent) concepts will be interpreted as referring to the *taxonomic* relations between words within a given semantic domain as a key determinant of ESD. In other words, the ESD of a given term is a function of the position it occupies in the relevant classificatory system, insofar as it is this location that determines a word's relation to, and its differentiation from, other terms. Accordingly, ESD increases with a term's number of taxonomic relations with, and its degree of distinction from, other terms.

The question regarding the position of terms in taxonomies is closely linked with another key principle behind the notion of ESD variability, which is degree of specialization. As previously intimated, ESD is conceptualized by Maton and Doran (2017a) as a scale (from 'highest' to 'lowest' degree), and on this scale a primary distinction is between the semantics of technical/specialized terms and everyday vocabulary, giving rise to a first division of the scale into two 'halves'. Underlying this distinction appears to be a central observation in much SFL research on the language of science and technology (e.g. Halliday and Matthiessen 1999, Martin 1993, Halliday 2004), namely the fundamental *contrast* between specialized/scientific taxonomies and 'folk' or 'common-sense' conceptualizations of the same field of knowledge, as manifested in the everyday vocabulary of non-specialists. The point is that

specialized/scientific conceptualizations are much more fine-grained than ‘folk’ ones (see Halliday and Matthiessen 1999: 86), as borne out by the example in Figure 1, which is a scientific taxonomy of infectious diseases:

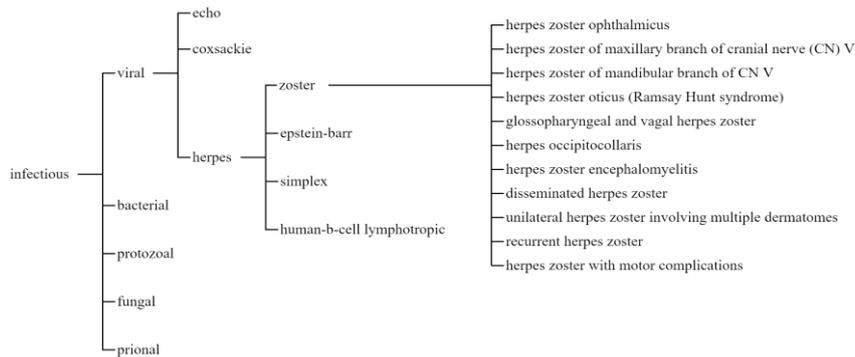


Figure 1. A scientific classification of infectious diseases (adapted from Martin 1993: 226).

To take an example from Figure 1, the scientific term *zoster* refers to the disease that is known as *shingles* in lay terms. Undoubtedly, the two terms overlap in *extensional* meaning (see Lyons 1977), i.e., with regard to the class of referents covered by a term, but in *intensional* (i.e. conceptual) meaning (Lyons 1977), the scientific term includes a number of semantic components that the ‘folk’ term does not: the taxonomy reveals *zoster* to be a subcategory of *herpes*, which is one out of a number of infectious disease types caused by a virus, which means that ‘infectious’, ‘viral’, ‘herpes’ are all semantic components which inhere in *zoster*. These components—in themselves assemblages of a number of semantic elements via each term’s linkage with other medical and microbiological taxonomies—do not enter into the lay term *shingles* (apart, perhaps, from ‘infectious’). Nor does *shingles* offer any taxonomic gateway to further subclassification the way *zoster* does, as illustrated in Figure 1.

On the ESD scale (see Table 1), each of the two ‘halves’, both the ‘technical-term’ and the ‘everyday-vocabulary’ half, are further subdivided in two rounds, yielding altogether eight subcategories or levels on the scale:

Table 1. Complete overview of ESD subcategories (adapted from Maton and Doran 2017a).

ESD	Type	Subtype	Sub-subtype	Definitions
+	<i>Technical</i>	<i>conglomerate</i> (multiple distinct parts)	8. <i>properties</i>	actions/qualities, e.g. <i>cardiovascular</i> ⁴
			7. <i>elements</i>	items, entities or things, e.g. <i>dopa-decarboxylase</i>
		<i>compact</i> (single part only)	6. <i>properties</i>	actions/qualities, e.g. <i>somnolence</i>
			5. <i>elements</i>	items, entities or things, e.g. <i>inhibitor</i>
	<i>Everyday</i>	<i>consolidated</i> (nominalizations)	4. <i>specialist</i>	nominalizations located in texts dominated by technicals, e.g. <i>reaction</i> [if employed e.g. about physiological mechanisms in a medical register]
			3. <i>generalist</i>	nominalizations located in texts dominated by everyday, e.g. <i>attack, robbery, shoot-out</i> .
		<i>common</i> (congruent)	2. <i>nuanced</i>	relatively more differentiated meanings (hyponyms/more specific), e.g. <i>medicine, hospital, patient</i> .
			1. <i>plain</i>	relatively general and less differentiated meanings (hypernyms/less specific), e.g. <i>use, take, give</i> .
-				

The first subdivision of the top half of the scale ('technicals') pertains to the number of parts in a given term: As an example of a 'conglomerate'

⁴ The examples in Table 1 are from the *Inbrija* SmPC (EMA 2020a).

term, Maton and Doran (2017a: 60–61) mention the biochemical term *lipopolysaccharides*, which consists of the three parts, i.e., *lipo-*, *poly-*, and *-saccharides*. Since each part contributes a distinct semantic component (which in itself enters into taxonomic relations with other sememes), ‘conglomerates’ are assumed to be higher in ESD than ‘compact’ terms, i.e., terms consisting of a single part only, e.g., specialized words such as *lymph* or *vein* (Maton and Doran 2017a: 61).

The distinction between ‘properties’ and ‘elements’ for both ‘conglomerate’ and ‘compact’ terms is motivated by the observation that ‘properties’, i.e., actions or qualities, are semantically denser than (mere) ‘elements’ (items/entities/things). The reason is that the former ‘not only denote an action or quality but also imply the elements involved in that action or possessing that quality’ (Maton and Doran 2017a: 62).

In the ‘everyday’-term section of the scale, the first division is between ‘consolidated’ and ‘common’ terms, with the former grammatically represented by nominalizations. Higher ESD is represented by everyday ‘specialist’ terms, i.e., nominalizations that are not in themselves technical terms, but appear in specialized texts. The rationale is that the high ESD of the technical terms proper in such texts is likely to affect co-occurring non-technical nominalizations. The same, on the other hand, cannot be expected of nominalizations appearing in non-specialized texts (‘generalist’ terms), which accordingly are most likely to represent lower ESD. Finally, on the bottom rungs of the ladder are found ‘common, everyday’ terms, divided into ‘nuanced’ and ‘plain’ ones. The distinction is between very simple/highly general everyday meanings vs. more specific terms from everyday vocabulary. For the purpose of analytical distinction, therefore, the criterion will be whether, for a given word, a hypernym can be found. Words for which no hypernym exists will be taken to represent the simplest types of epistemic meaning possible. If a hypernym can be found (making the word in question a hyponym), on the other hand, this will be taken as evidence of more specific meaning, indicative of a broader scope of semantic components.

3.1.2. Epistemological condensation: Clausing

As previously mentioned, *epistemological condensation*, also a scalar concept, applies to meaning established at clause level (Maton and Doran 2017b). What differentiates EC from ESD (apart from the grammatical ‘site’ of realization) is that, whereas ESD may be seen as a ‘static’

phenomenon, EC is a ‘dynamic’ concept, applying to the way and the degree to which the meaning of individual words and word groupings is related to other meanings when entering into clausal configurations with other words/word groups. This ‘dynamic’ feature means that EC is concerned with knowledge *formation* in discourse (Maton and Doran 2017b: 79), and, for present purposes, will therefore be used to investigate the nature of the knowledge building taking place in the EPAR summaries. Eight different types/degrees of ‘relation creation’ are posited and grouped together in two rounds of subdivision. The categories are represented in tabular form below, ranked according to EC degree:

Table 2: A taxonomy of EC types/degrees (adapted from Maton and Doran 2017b: 82)

EC	Type	Subtype	Sub-subtype	
+	<i>Connecting</i>	<i>Taxonomizing</i>	8. <i>Classifying</i>	
			7. <i>Composing</i>	
		<i>Coordinating</i>	6. <i>Causing</i>	
			5. <i>Correlating</i>	
		<i>Augmenting</i>	<i>Characterizing</i>	4. <i>Displaying</i>
				3. <i>Dramatizing</i>
<i>Establishing</i>	2. <i>Positioning</i>			
	1. <i>Positing</i>			
-				

Definitions of the categories (based on the account in Maton and Doran 2017b: 84–88) are the following:

8. ‘Classifying’ clauses come in two varieties: 1) They identify type-subtype relations by relating a type or types of phenomenon/a to a superordinate class, as in a statement like *whales are mammals*⁵, or *mammals include whales*, whereby the item *whales* is subsumed under a hypernymic category. 2) They consist in ‘naming’/‘equating’, whereby a phenomenon is assigned a label as yet unknown to the reader, or the unknown label is explained, e.g., *the specialized term for the breakdown of muscle tissue is rhabdomyolysis*, or *cervical cancer is cancer in the uterus*.

7. ‘Composing’ clauses are concerned with establishing part-whole or part-part relations between phenomena, e.g., *cylinders are the central part of a car engine*, or *a medicinal product consists of two main types of chemical substance: the active substance and excipients*.

6. ‘Causing’ clauses establish causal relations between phenomena, e.g. *lung cancer is often the result of long-time smoking*.

5. ‘Correlating’ clauses, in Maton and Doran’s (2017b: 85) own words, indicate ‘a correlation or dependency but without specifying its nature’: their own example is ‘*pathological myopia is linked with functional blindness*’, where the specific nature of the correlation (e.g., a causal one) is not indicated.

4. ‘Displaying’ clauses ascribe qualities and attributes to phenomena, typically realized in adjectives, e.g., *smoking is bad for you*.

3. ‘Dramatizing’ clauses are action-oriented ones, describing or reporting physical, verbal or mental action that an agent (animate or inanimate, conscious or nonconscious, as the case may be) is engaged in, e.g., *the doctor prescribed the medicine*.

2. ‘Positioning’ clauses simply identify a phenomenon/person/object’s location in space or time, without specifying any action (physical etc.) that the person/object may be engaged in, e.g., *the conference is in two weeks in Barcelona*.

1. ‘Positing’ clauses simply report that an item/phenomenon exists, but nothing else, e.g., *there was darkness*.

What the definitions highlight is the previously made point that the EC ‘clausing’ typology not only represents different *types*, but also different *degrees* of ‘relation creation’. In the two top categories (‘classifying’ and ‘composing’), a two-way relation is established, influencing both items.

⁵ Unless a source is given, all examples are the inventions of the present author.

For example, it is established as a characteristic of *whales* that they belong to the genus of *mammals*, and, vice-versa, that one characteristic of the genus of *mammals* is that it includes *whales*. The ‘causing’ and ‘correlating’ categories also link items in a two-way relation, but the link is less pronounced: for instance, it is a characteristic of *smoking* that it is associated with *lung cancer* and vice-versa, but the two are not mutually defining concepts. In ‘displaying’ clauses, the relation is one-way only: *bad (for you)* is established as a characteristic of *smoking*, but *smoking* does not reflect back on *bad*. In the ‘dramatizing’ and ‘positioning’ categories, then, only relatively weak relations are established: in a clause like *the doctor prescribed the medication*, it is indicated that *the doctor* can perform the action, but *the doctor* and *prescrib[ing]* are not made to share any characteristics in either a one- or two-way relation (see Maton and Doran 2017b: 88). Finally, in ‘positing’ clauses, no relation at all is created with other items.

3.2. Operationalization of semantic gravity

Semantic gravity is concerned with degrees of abstraction/concreteness in messages, ranging from maximum concreteness, or ‘strongest’ semantic gravity, where utterances are wholly oriented towards the ‘here-and-now’ of the speech situation, to ‘weakest’ gravity, or highest level of abstraction, where timeless statements are made about completely generalized phenomena (Maton 2014: 107). What is missing from the LCT concept of semantic gravity, however, is any real operationalization of the concept into a set of clearly defined analytical categories. For the purpose of operationalization, therefore, recourse will here be taken to Hasan et al. (2007), who offer a set of discrete categories conceptualizing the semantics of messages (termed *rhetorical units*, RUs, and grammatically realized in ranking clauses) in respect of their context-(in)dependence/level of abstraction. Hasan et al. (2007) posit the following stages or categories of RU types along a cline from ‘most concrete’ to ‘most abstract’:

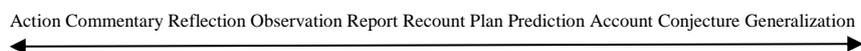


Figure 2. A cline of RU types from ‘most concrete’ to ‘most abstract’ (adapted from Hasan et al. 2007: 724)

The positioning of the categories relative to each other on the cline is determined by the combination of semantic values in two particular features of an RU: the type of *Central Entity* (CE) and the type of *Event Orientation* (EO). Grammatically, the CE is identical with the Subject of a ranking clause, and the EO is a feature of the grammatical Verb. For present purposes, the following typology of CEs (based on Hasan et al. 2007: 722) is relevant, differentiated according to their closeness to/remoteness from the ‘here’ of the communicative event:

Types of Central Entity:

- 1. interactant (i.e., speaker or receiver)
- 2. co-present person/object, e.g., *That hat is new, isn't it?*
- 3. absent person/object, e.g., *Did you hear that John has moved to the US and is not coming back?*
- 4. generalized person/object, e.g., *Pandas are an endangered species.*

A typology of Event Orientation, graded according to their closeness to the ‘now’ of the speech event, is the following (based on Hasan et al. 2007: 722):

1. proposal (i.e., ‘command’ or ‘request that action be taken’, typically realized by means of an imperative or modals such as *must* or *should*, e.g., *Stop that!* or *You must stop that immediately!*)
2. concurrent, non-habitual (i.e., happening in the ‘now’ of the speech event and with no recurrence, e.g., *Why are you sniggering like that?*)
3. concurrent, habitual (i.e., taking place in the present, and with recurrence, e.g., *Do you really have to smoke at every party you go to?*)
4. prior (taking place in the past, e.g., *I sent you an email a few days ago.*)
5. forecast (i.e., relating to the future), non-hypothetical, volitional, e.g., *I will definitely come and visit you later this week.)*

6. forecast, non-hypothetical, non-volitional (e.g., *There will be rain later today.*)
7. forecast, hypothetical (e.g., *You may end up with lung cancer with that kind of heavy smoking!*)

As already mentioned, each of the message types in Figure 2 represents a particular combination of values in CE and EO (adapted from Hasan et al. 2007: 722).

Table 3: Types of rhetorical units defined and exemplified

	Type of CE	Type of EO	Examples
1. Action	interactant	proposal	(From <i>Hamlet</i> , Act I, sc. i, l. 49) <i>Stay! Speak, speak! I charge thee, speak!</i> ⁶
2. Commentary	interactant	concurrent, non-habitual	(From <i>Hamlet</i> , Act I, sc. i, l. 51) <i>How now, Horatio? You tremble and look pale.</i>
3. Reflection	interactant	concurrent, habitual	(From <i>Hamlet</i> , Act III, sc. i, ll. 125-126) <i>I am very proud, revengeful, ambitious, with more offences at my beck ...</i>
4. Observation	co-present person/object	concurrent, habitual	(From <i>Julius Caesar</i> , Act I, sc. ii, ll. 194-195) <i>Yond Cassius hath a lean and hungry look. He thinks too much.</i>
5. Report	absent person/object	concurrent, non-habitual	From <i>Hamlet</i> , Act I, sc. i, l. 57) <i>Is it not like the king?</i> [with it referring to the ghost that has just left the stage.]
6. Recount	[all types]	prior	(From <i>Hamlet</i> , Act I, sc. ii, ll. 59-60)

⁶ The examples, from Shakespeare, were selected by the present author, to illustrate the timelessness of the categories.

			<i>Such was the very armour he had on / When he the ambitious Norway combated.</i>
7. Plan	interactant	forecast, non-hypothetical, volitional	(From <i>Hamlet</i> , Act II, sc. ii, ll. 556-558) <i>I'll have these players / Play something like the murder of my father / Before my uncle. I'll observe his looks.</i>
8. Prediction	co-present, absent or generalized person/object	forecast, non-hypothetical, non-volitional	(From <i>Hamlet</i> , Act I, sc. ii, l. 28) <i>Tush, tush. 'twill not appear.</i>
9. Account	absent person/object	concurrent, habitual	(From <i>Hamlet</i> , Act II, sc. ii, ll. 561-562) <i>... the devil hath power / T' assume a pleasing shape.</i>
10. Conjecture	[all types]	forecast, hypothetical	(From <i>Hamlet</i> , Act III, sc. 1, 136-137) <i>If thou dost marry, I'll give thee this plague for thy dowry.</i>
11. Generalization	generalized person/object	concurrent, habitual	(From <i>Hamlet</i> , Act III, sc. i, ll. 113-114) <i>Ay, truly, for the power of beauty will sooner / Transform honesty from what it is to a bawd than / The force of honesty can translate beauty into his likeness.</i>

4. Analytical approach and results

The analytical approach has consisted in manual analysis (conducted by the present author) of the whole corpus, with all lexical words having been categorized in terms of ESD, and clauses categorized in terms of EC and SG, based on the author's judgments. ESD results will be detailed in 4.1, EC in 4.2, and SG in 4.3.

4.1 ESD at the level of words

In terms of comprehensibility, ESD at the level of words is likely to be by far the most significant factor, simply because every single lexical word makes a contribution in this regard, posing some degree of semantic challenge, high or low. EC and SG, on the other hand, are clause-level features.

In 4.1.1, the frequencies of the individual ESD categories across the corpus will be reported and put into perspective through comparison with two other genres. A more detailed examination of ESD variation at sentence level is provided in 4.1.2.

4.1.1. ESD category frequencies

The statistics regarding the distribution of words across the eight ESD categories in the six texts are set out in Table 4.

Table 4: Distribution of ESD categories (word level) in the corpus

	Beovu (%)	Inbrija (%)	Kaftrio (%)	Nustendi (%)	Recarbrio (%)	Rinvoq (%)	Average (%)	St. dev. (%)
8. Tech.: congl.: properties	2.8	0.9	0	1.2	1.7	3.9	1.8	1.4
7. Tech.: congl.: elements	0.9	2.3	3.8	1.9	0.8	1.3	1.8	1.1
6. Tech.: comp.: properties	5.4	5.3	10.2	5.3	8.1	6	6.7	2
5. Tech.: comp.: elements	17	17.9	17.3	23.9	25.6	14.8	19.4	4.3
4. Everyday: cons.: spec.	6.6	12.6	10.7	9.5	12.9	13.2	10.9	2.6
3. Everyday: cons.: gen.	0	1.1	0.6	0.5	0	1.3	0.6	0.5
2. Everyday: comm.: nuanc.	25.6	26.4	25.7	25.3	23	31.6	26.3	2.9
1. Everyday: comm.: plain	35.1	33.5	31.7	32.5	27.8	29.7	31.7	2.6

Table 4 shows a remarkably homogeneous picture with regard to ESD category frequencies across the texts, with standard deviations (abbreviated *St. dev.* in the table) generally quite low. The averaged values reflect that while a majority of words in the texts belong to the two lowest ‘everyday’ categories (58% on average), the top five categories are all represented in some measure, but especially categories 4, 5 and 6. In themselves, however, these values may not be sufficiently telling, and will only gain significance in comparison with other genres. For comparison and contrast, therefore, two other genres were considered: One highly technical and the other completely non-technical. To represent the former type, an expert-oriented medico-pharmaceutical text, the *Summary of Product Characteristics* (SmPC) relating to the product *Nustendi* (EMA 2020b) was selected, from which an extract of circa one standard page

(2400 characters) was analyzed.⁷ The extract was deliberately selected so as to represent, on a *prima-facie* judgment, a maximum degree of specialization. For comparison with completely non-technical discourse, an article from the celebrity-gossip section of a tabloid newspaper (Delaney 2022) was selected, to represent something close to the opposite extreme, i.e., completely non-specialized, colloquial discourse. The two sets of results are given in Tables 5 and 6:

Table 5: Distribution of ESD categories in the *Nustendi* SmPC extract

Nustendi SmPC (%)	
Cat. 8	4.7
7	15.9
6	15.9
5	18.3
4	9.2
3	0
2	23.7
1	12.2

Table 6: Distribution of ESD categories in the *Daily Mirror* article

Daily Mirror article (%)	
Cat. 8	0
7	0
6	0
5	0
4	0
3	6.1
2	53.1
1	40.8

Interestingly, the analysis of the SmPC extract reveals, perhaps counterintuitively, that the lexis of highly specialized discourse is not limited to the top four ‘technical’ categories but is in fact relatively evenly distributed across all categories (apart from category 3), both ‘technical’ and ‘everyday’ ones. The tabloid article, on the other hand, completely conforms to expectations, with the vast majority of items distributed

⁷ The specific extract selected was section 5.1 of the document.

between the two lowest ‘everyday’ categories, and with no ‘technical’ whatsoever. In comparison, the category distribution in the EPAR summaries means that this genre occupies a middle ground between the other two. The overall ESD level of the EPAR summaries can thus be inferred to be significantly lower than specialized discourse on the one hand, but significantly higher than markedly colloquial discourse on the other.

4.1.2. Sentence-internal variation in ESD

As a consequence of the ESD profile established above, the EPAR summaries show a clear tendency towards marked sentence-internal oscillation in semantic density between individual words. A typical instance of this, to be analyzed in detail, is shown in example (1):

- (1) It must also not be used in patients taking medicines known as non-selective monoamine oxidase (MAO) inhibitors or in patients with a history of neuroleptic malignant syndrome or rhabdomyolysis. (*Inbrija* EPAR summary, sentence 27)

In example (1), high-value ESD is represented by the specialized medico-pharmaceutical words *non-selective*, *monoamine*, *oxidase*, *inhibitors* and similarly the words *neuroleptic*, *malignant*, *syndrome* and *rhabdomyolysis*. Of these, *rhabdomyolysis* belongs in the very top category, being a ‘technical conglomerate’ that refers to an ‘action/quality’ (a pathological process or condition, really) rather than an ‘item/entity/thing’. The term, which means ‘breakdown of skeletal muscle cells’ (Law and Martin 2020b) is a ‘conglomerate’ since it consists of multiple parts: *rhabdo-* (‘skeletal’), *my-* (muscle (cells)) and *-(o)lysis* (‘breakdown’). To the category ‘technical: conglomerate: element’ belong the words *monoamine* and *oxidase*. The latter, which covers a type of enzyme that catalyzes oxidation of amines (Law and Martin 2020a), consists of the two parts *oxid-* (referring to the element of ‘oxidation’) and *-ase* (denoting ‘enzyme’). In *monoamine*, the two parts are *mono-*, i.e., ‘only one’ and *-amine*, with the term as a whole denoting a type of amines containing only one amino group (NH₂) (Colman 2015). One step further down the ESD scale, in the category ‘technical: compact: properties’, are

found the terms *non-selective*, *neuroleptic*, *malignant* and *syndrome*⁸, and in the lowest technical category, ‘technical: compact: elements’ is found the single item *inhibitor*.

With regard to everyday words in example (1), the items are *used*, *patients*, *taking*, *medicines*, *known* and *history*. Of these, *used*, *taking* and *known* must be categorized as ‘everyday: common: plain’, belonging to the group of core-vocabulary words that represent some of the simplest types of meaning expressible in the English language. *Patients*, *medicines* and *history*, on the other hand, must be classified as ‘everydays: common: nuanced’, belonging to a core, everyday vocabulary also, but encompassing a larger range of semantic components. Thus, *patient* may be defined as consisting of semantic elements such as ‘person’ + ‘suffering from a medical disorder’ + ‘hospitalized/under medical attention’. Similarly, *medicines* combine the semantic elements of ‘substance’, ‘chemical’ and ‘curative’, and *history* combines elements such as ‘past’, ‘series’ and ‘events’.

What explains the specific juxtaposition of everyday and specialized words in example (1) is that the string *must ... not be used in patients* appears to be a non-technical paraphrase of a single corresponding word in the *Inbrija* SmPC, viz. the medical term *contraindications* (denoting medical factors rendering a particular type of therapy risky and inadvisable, such as other illnesses that the patient is suffering from or other medicines that s/he is already taking). In the *Inbrija* SmPC (EMA 2020a: 3, section 4.3), the term *contraindications* is simply the headline of a list of such factors, of which the relevant one in this case is *Co-administration with non-selective monoamine oxidase (MAO) inhibitors*. As another instance of non-technical paraphrase, the SmPC term *Co-administration (with)* has been replaced by the word *taking* in the EPAR summary. As for the presence of the word *medicines*, which is not traceable back to a source term in the SmPC, the most plausible explanation is that this word, being a hypernym of the following specialized term, has been inserted to give the reader just a general idea of what *non-selective monoamine oxidase inhibitors* are. The words *known*

⁸ The term *syndrome* is analyzed as belonging to this category for being synonymous with ‘disorder’, i.e., denoting an ‘action/quality’, or a process/state of affairs, rather than an item/thing/entity.

as, then, connect the hypernym and the name of the specific class of drugs being referred to.

4.2 Epistemological condensation ('clausing')

From the analyses of EC in the sample, the following statistics emerge:

Table 7: Distribution of EC ('clausing') types in the corpus

	Beovu (%)	Inbrija (%)	Kaftrio (%)	Nustendi (%)	Recarbrio (%)	Rinvoq (%)	Average (%)	St. dev. (%)
8: classifying	15.3	15.6	9.7	9.7	6.0	10.2	11.1	3.7
7: composing	1.8	5.2	2.9	2.2	1.2	0.9	2.4	1.6
6: causing	6.3	8.3	15.5	16.1	10.7	9.3	11.0	4.0
5: correlating	0	0	0	0	0	0	0	0
4: displaying	22.5	15.6	27.2	19.4	20.2	16.7	20.3	4.2
3: dramatizing	53.2	54.2	40.8	52.7	57.1	68.5	54.4	8.9
2: positioning	0.9	0	1.0	0	2.4	3.7	1.4	1.5
1: positing	0	1.0	2.9	0	1.2	0	0.9	1.1

The values in Table 7 are remarkably consistent, with the highest standard deviation at 8.9 (the 'dramatizing' category) and all the other seven considerably lower. The statistics show four types of clausing to be the predominant ones: 'classifying' (category 8), 'causing' (category 6), 'displaying' (category 4), and 'dramatizing' (category 3). Other than these four, the 'correlating' (category 5), 'positioning' (category 2) and 'positing' (category 1) categories are either completely or virtually non-existent in the texts, and so will not be further commented on, and nor will the 'composing' category (7), of which only one or two instances occur per text. In the following, the level 8, 6, 4 and 3 categories will be exemplified, and their function (specifically the way they contribute to knowledge mediation) in the corpus commented on.

'Classifying' clauses:

In the top-level category (category 8), both the 'subtyping' and the 'equating' subcategories (see 3.1.3) are represented. Thus, the opening sentence of all texts is concerned with 'subtyping' the medicinal product in question: see example (2):

- (2) Nustendi is a medicine for lowering levels of cholesterol in the blood. (*Nustendi*, sentence 1)

In each case, the drug in question is taxonomized as a specific subcategory of a superordinate class of drugs (here: cholesterol-lowering medicines). In fact, three taxonomic levels are established or invoked in example (2): 1) medicines in general, 2) cholesterol-lowering ones, and 3) Nustendi as a particular brand or subtype of cholesterol-lowering drugs. As for the ‘equating’ subcategory, two varieties are represented: one in which the technical labelling occurs in the clause in question (see example (3), bolded postmodifying clause), and one where the clause provides a paraphrase or ‘translation’ of the medical/pharmaceutical concept in lay terms (see example (4), bolded parenthesis):

(3) Brolucizumab has been designed to attach to and block a substance called vascular endothelial growth factor A (VEGF-A). (*Beovu*, sentence 17)

(4) an increase of around 2% with placebo (a dummy treatment). (*Nustendi*, sentence 22)

It should be noted that a number of the strings analyzed as ‘classifying’ clauses take the shape of bracketed inserts as in example (4), which, admittedly, makes it debatable whether such examples should be regarded as clauses in the first place. Nevertheless, the view taken here is that such inserts should be interpreted along the lines of non-restrictive relative clauses, with example (4), e.g., being paraphrasable as ... *placebo, which is/means a dummy treatment*.

Though not especially frequent in the texts (averaging only 11.1%), the ‘classifying’ clauses all serve, across the specific varieties (‘subtyping’ and ‘equating’ ones), to link specialized medico-pharmaceutical concepts with a general-language vocabulary. This includes the ‘subtyping’ variety, where the superordinate concept (as in example (2): ‘Nustendi is a medicine’) is typically represented by either a lay, or at least register-neutral, term such as *medicine*, *disease* and *condition*, or terms that are, strictly speaking, specialized terms, but likely to be known to the average, well-informed adult. These include terms such as *protein*, *antibody*, *infection*, *active substance* and *antibiotic*.

‘Causing’ clauses:

Straightforward instances of clauses concerned with ‘causing’ are ones

featuring the very word *cause*, as is the case twice in example (5):

- (5) The wet form of AMD is caused by choroidal neovascularisation (the abnormal growth of blood vessels under the macula), which may leak fluid and blood and cause swelling. (*Beovu*, sentence 3)

Apart from near-synonyms of *cause* such as *make*, *result in* or *lead to*, which all figure in the corpus, other verbs are also interpretable as denoting more specific kinds of ‘causing’, such as *reduce* and *increase* (= ‘cause to become smaller/larger (in number, size or volume)’), or *improve* (‘cause to become better’), as in example (6):

- (6) Two of the active substances in Kaftrio, elexacaftor and tezacaftor, increase the number of CFTR proteins on the cell surface and the other, ivacaftor, improves the activity of the defective CFTR protein. (*Kaftrio*, sentence 24)

As is to be expected, clauses of ‘causing’ particularly occur in section 3 of the texts (‘*How does X work*’), detailing the drug’s mechanism of action in the organism, but also in the introductory section (‘*What is X and what is it used for*’), where ‘causing’ sometimes appears in the description of the disease for which the drug is designed.

‘Displaying’ clauses:

As the second-most frequent clausing category (averaging 20.3% of clauses across the sample), level-4 clauses are prevalent in all texts and in all sections, serving to associate a wide variety of qualities with the drug itself and the disease targeted by the drug, as in examples (7) and (8):

- (7) Kaftrio’s benefits are greater than its risks (*Kaftrio*, sentence 42)
- (8) High cholesterol is a risk factor for heart disease. (*Nustendi*, sentence 20).

It may have to be noted that although the clause in example (8) is grammatically similar to a classifying clause such as the one in example (2) (‘... *is a* ...’), example (8) is not semantically concerned with locating *high cholesterol* in a taxonomy of *risk factor[s] for heart disease*, but with

establishing *high cholesterol* as a quality or phenomenon associated with *heart disease* and vice versa.

‘Dramatizing’ clauses:

Averaging 54.4%, ‘dramatizing’ clauses are by far the most frequent type in the EPAR summaries. Being typically realized by so-called ‘material’ clauses, i.e., clauses semantically concerned with ‘doings and happenings’ (see Halliday and Matthiessen 2014: 224–245), the high frequency is unsurprising, since ‘material’ clauses altogether are the most predominant clause type across genres. Nevertheless, the frequency does reflect a high degree of ‘action-orientedness’ in the texts. Thus, the texts detail a wide range of processes, pertaining to both the producer of the medicine (engaged in actions such as ‘marketing’, ‘providing’ and ‘informing’), the EMA (dramatized as ‘deciding’, ‘monitoring’ and ‘authorizing’) and the consumer, who is engaged in ‘taking’ and ‘using’ the drug. Similarly, a number of ‘dramatizing’ clauses detail the ‘actions’ of the drug in itself, as in example (9), where the ‘agents’ involved are (bio)chemical substances and bodily organs:

- (9) Ezetimibe works by binding to a gut protein (*Nustendi*, sentence 17)

4.3 *Semantic gravity in the corpus*

Probably owing to the high degree of standardization of the EPAR summaries, corresponding sections across the individual texts are remarkably similar in terms of semantic gravity. All six texts conform to the same pattern, with most sections largely dominated by one type of SG only. Thus, the following generic profile emerges:

Section 1: ‘*What is X and how is it used*’: Generalization (category 11)

Section 2: ‘*How is X used*’: Generalization

Section 2: ‘*How does X work*’: Generalization

Section 4: ‘*What benefits of X have been shown*’: Recount (category 6)

Section 5: ‘*What are the risks*’: Level 11: Generalization

Section 6: ‘*Why is X authorised in the EU*’: Recount (+ Generalization + Prediction (category 8))

Section 7: ‘*What measures are being taken*’: Report + Prediction + Recount

Section 8: ‘*Other information about X*’: Recount

Thus, four out of eight sections are taken up by Generalization, the highest degree of abstraction, and most of the remaining sections are taken up by Recount (mid-level semantic gravity), with a few sections also featuring Report and Prediction. Given this picture, i.e., with two categories as the predominant ones by far and with most sections in the texts largely dominated by one category only, exact statistics have been deemed irrelevant. For the same reason, exemplification will be confined to Generalization and Recount, and the two marginal categories (Report and Prediction) not further commented on. Examples (10) and (11) illustrate Generalization:

- (10) [α] *Inbrija* contains levodopa[,] [β 1] which converts into dopamine in the brain [β 2] and helps to restore dopamine levels, [γ] thereby improving the symptoms of the condition. (*Inbrija*, sentence 12)

In all four clauses in example (10), the Central Entity (realized by the grammatical subject *Inbrija* in [α], the anaphoric relative *which* in [β 1] referring back to *levodopa*, and the presupposed subjects in [β 2] and [γ] (in both cases *levodopa*)) is a ‘generalized object’, viz. either the medicinal product as a type/brand or its active substance. The Event Orientation is similarly generalized, being ‘concurrent, habitual’, i.e., referring to a timeless state of affairs. All clauses providing information about the qualities of the drug in itself, including its mechanism of action, belong to this highest degree of abstraction, and the same applies to the clauses characterizing the kind of disorder or disease that is targeted by the drug:

- (11) [α] In patients with rheumatoid arthritis, the immune system (the body’s defences) attacks healthy tissue, [β] causing inflammation in the joints. (*Rinvoq*, sentence 14)

Here, again, the Central Entity (*the immune system*) is a generalized ‘object’, and the Event Orientation (realized in the verbs *attacks* and *causing*) is likewise that of a ‘timeless truth’.

As already mentioned, the other most predominant level of abstraction/concreteness is the Recount category, occurring mainly in the

section detailing the outcomes of the clinical trials preceding the authorization of the drug (section 4) and in section 6, which further details trial outcomes providing grounds for authorization. Thus:

- (12) [α] Of patients treated with Inbrija, 71% reported [β] that their symptoms were improved, compared with 46% of patients on placebo. (*Inbrija*, sentence 19)

In both clauses (α and β), the Event Orientation is ‘prior’, realized by the two past-tense verbs *reported* and *were improved*, making the two clauses recounts of past events occurring as part of the clinical trials.

The significance of the findings regarding semantic gravity will be considered in the next section.

5. Discussion and conclusion

What the semantic profiling of the EPAR summaries has revealed is a highly genericized text type: *inside* the individual texts, ESD, EC and SG values vary to quite a large extent, but the same clearly identifiable *patterns* of variation recur in all texts. These patterns of variation reflect that the texts are not simply discourse in a lay register; rather, the texts merge what is at some points a specialized register with a more lay-oriented one, thus representing an ongoing text-*internal* mediation, or ‘translation’ even, between specialized concepts and a lay ‘understanding’ of the field of medicine. This explains the level of ESD in the texts, which was judged to be lower than that of an expert-oriented register, but higher than informal quotidian discourse. At the same time, the merging of two different registers accounts for the marked variation in sentence-internal ESD values.

With regard to pragmatic function, the SG analyses similarly revealed the texts to be internally heterogeneous, with the two message types Recount and Generalization being particularly prevalent. In terms of more generally known pragmatic categories, the Generalization RUs must be characterized as being essentially *didactic* in function, in effect positioning the reader in the role of novice/learner in the field of medicine. This picture emerges when the intersection of SG and EC values is considered: the Generalization RUs are also those where the qualities of the drug are ‘dramatized’ and ‘displayed’, where the causes of the disease are specified, and where the drug and the disease are taxonomically and (for

the drug's part) compositionally defined. Thus, like textbooks, these sections serve to impart not only generalized factual, but also abstract *conceptual* knowledge about field-specific phenomena (here: the drug and the disease).

The hypothesis adopted here is that the combination of the two central characteristics noted above, i.e., on the one hand the text-internal fusion of, and oscillation between, different ESD levels, and, on the other, the strong presence of a 'textbook' element with a high level of abstraction, may pose a significant challenge to some reader groups. It is beyond the scope of the present study to suggest remedies for the situation; indeed, a second hypothesis is that the presumed challenges are not to any significant extent remediable, given that content requirements for the genre are what they are. Thus, the aim of the present study is to contribute to a recognition (as well as acceptance) of the situation that, rather than necessarily targeting 'the average lay person', the EPAR summary genre is a more demanding text type than, e.g., a parallel lay-oriented text type like the Patient Information Leaflet (which accompanies the packaging of a drug, and which to a large extent has the character of an instruction manual). The conclusion of the present study is that, in comparison with a more concrete, instruction-based genre like PILs, the EPAR summaries are more suitable for a target audience used to reading conceptually abstract texts.

Appendix: Sample Text (Nustendi)



EMA/66076/2020
EMA/H/C/004959

Nustendi (*bempedoic acid / ezetimibe*)

An overview of Nustendi and why it is authorised in the EU

What is Nustendi and what is it used for?

Nustendi is a medicine for lowering levels of cholesterol in the blood.

It is used in patients with primary hypercholesterolaemia or mixed dyslipidaemia (conditions that cause high levels of fats, including cholesterol, in the blood). Patients taking the medicine are required to be on a low-fat diet.

Nustendi contains the active substances bempedoic acid and ezetimibe.

Nustendi is used in combination with a statin in patients whose cholesterol levels are not lowered enough by the maximum dose of a statin taken together with ezetimibe. Nustendi can also be used alone in patients who cannot take statins and whose cholesterol levels are not lowered enough by ezetimibe. The medicine can be used to replace separate tablets of bempedoic acid and ezetimibe in patients already taking them.

How is Nustendi used?

Nustendi can only be obtained with a prescription and is available as tablets (180 mg bempedoic acid / 10 mg ezetimibe). The recommended dose of Nustendi is one tablet a day.

For more information about using Nustendi, see the package leaflet or contact your doctor or pharmacist.

How does Nustendi work?

The active substances in Nustendi, bempedoic acid and ezetimibe, work in different ways to lower blood cholesterol.

Bempedoic acid works by blocking an enzyme in the liver called adenosine triphosphate citrate lyase, which is involved in making cholesterol. This leads to a reduction of the level of low-density lipoprotein (LDL) cholesterol, known as 'bad' cholesterol, in the blood and also reduces other fatty substances made by the liver.

Ezetimibe works by binding to a gut protein called 'Niemann-Pick C1 Like 1', preventing cholesterol from being absorbed into the blood from the gut.

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What benefits of Nustendi have been shown in studies?

Two studies showed that bempedoic acid and ezetimibe (the active substances of Nustendi) effectively reduced LDL cholesterol levels in patients with hypercholesterolaemia and heart disease or who were at high risk of heart disease. High cholesterol is a risk factor for heart disease.

The first study involved 382 patients also taking the maximum tolerated doses of statins. After three months, LDL cholesterol levels were reduced by 36% in patients taking bempedoic acid and ezetimibe compared with a reduction of 23% with ezetimibe alone, 17% with bempedoic acid alone and an increase of around 2% with placebo (a dummy treatment).

The second study involved 269 patients with high cholesterol levels who were not able to take a statin or were taking a low dose of a statin. All the patients were also taking ezetimibe. After three months, LDL cholesterol levels were reduced by 23% in patients taking bempedoic acid in addition to ezetimibe compared with an increase of around 5% in patients taking placebo and ezetimibe.

What are the risks associated with Nustendi?

The most common side effects with Nustendi (which may affect around 1 in 20 people) are hyperuricaemia (high blood levels of uric acid) and constipation.

Nustendi must not be used in pregnant or breast-feeding women. When Nustendi is taken in combination with a statin called simvastatin it can increase the risk of side effects of simvastatin, therefore the dose of simvastatin must not be higher than 40 mg daily. Nustendi must not be taken with a statin in patients with active liver disease or with unexplained high levels of serum transaminases (blood test results that could indicate liver problems).

For the full list of side effects and restrictions with Nustendi, see the package leaflet.

Why is Nustendi authorised in the EU?

Nustendi was shown to reduce levels of LDL cholesterol and so is expected to help reduce the risk of heart disease. The safety profile of Nustendi was considered acceptable. Nustendi may increase the risk of side effects of statins and these should be managed appropriately. The European Medicines Agency therefore decided that Nustendi's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Nustendi?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Nustendi have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Nustendi are continuously monitored. Side effects reported with Nustendi are carefully evaluated and any necessary action taken to protect patients.

Other information about Nustendi

Nustendi received a marketing authorisation valid throughout the EU on 27 March 2020.

Further information on Nustendi can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/nustendi.

Note that page 3 is not included here, as it merely adds 'This overview was last updated in 03-2020'.

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