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Coherence in hybrid texts: The case of the Patient Information Leaflet genre

Abstract

This article investigates the degree of coherence in a particular type of hybrid text, viz. the Patient Information Leaflet, which is a lay-oriented genre fusing original and derived textual elements. Having their source in the specialized genre named Summary of Product Characteristics, derived segments undergo various kinds and degrees of registerial simplification in the transfer to the Patient Information Leaflet. Given this complex textual genesis, the aim of the article is to investigate the nature and degree of coherence in the Patient Information Leaflet genre, and, more specifically, to investigate the degree of integration between derived and non-derived elements. Following Halliday/Hasan's (1976) definition of the coherence concept, the article examines the genre's contextual coherence in the form of registerial consistency and its text-internal coherence in the form of cohesiveness. For the investigation of cohesiveness, the analytical framework known as Cohesive Harmony Analysis (Hasan 1984, 1985) has been applied to a sample text from the genre, and likewise to a parallel lay-oriented, but non-hybrid text from the health column of a British quality newspaper, which serves as a control. While the investigation confirms already well-known problems with registerial consistency in the Patient Information Leaflet genre, the analytical results reflect a high degree of cohesiveness, and one that is even markedly higher than that of the non-hybrid control text. Further, the results reflect a high level of integration between derived and non-derived segments in the Patient Information Leaflet.

Keywords

hybridity; derivation; Patient Information Leaflets; coherence; contextual consistency; cohesive harmony

1. Introduction

The present article[1] is situated at the crossroads between the research fields of expert-lay communication, text linguistics and genre studies, being concerned with the question of coherence in the type of hybrid texts that are partially original and partially composed of segments derived from an anterior text from a more specialized register. The particular genre selected for the investigation is the one known as the Patient Information Leaflet (PIL), i.e. the small brochures that accompany the packaging of medicinal products, and which contain information, instructions and warnings about the drug relevant for the patient. As van Vaerenbergh/Schubert (2010: 16-17) point out, a number of external factors, or what they term *controlling influences*, constrain the decision process behind the text production of the individual leaflet: It is most likely to be the work of a team rather than a single author, it is a lay-oriented adaptation of selected segments from a specialized document (the so-called Summary of Product Characteristics), and the genre as a whole is a highly standardized one subject to minute legal regulation of its contents (for details, see section 3). All these external constraints on the text production process are circumstances which, jointly or separately, must be considered potential impediments to textual coherence, in so far as correspondingly little room for manoeuvre is left to the individual author's 'private' attempts[2] to

1 I would like to thank my colleague Lotte Dam for valuable comments on a first draft of this article.

2 Conversely, it may be argued that by placing rather specific constraints on the contents of the text, there is also the possibility that the rigid standardization may contribute to heightened coherence. The ambiguity of this question (the effect of the standardization on the coherence of the texts) only confirms the relevance of investigating the matter formally.

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create a text that is properly integrated in terms of content and style from beginning to end (for a more elaborate definition of coherence, see section 2). The purpose of this article, therefore, is to investigate whether coherence constitutes a problem in this hybrid genre. Accordingly, the article conducts an exploratory case study aimed at identifying *how* and *to what extent* coherence is created in this text type.

Following Hasan (1984: 184), the article is premised on the following three assumptions: 1) coherence is an essential property of texts, which means that for a text to be perceived as a well-functioning piece of (in this case) writing, coherence is a prerequisite; 2) normal speakers are sensitive to variation in coherence, which entails that 3) coherence is a matter of degree. Since coherence is an essential property of texts, and since lack of coherence must be considered a potential source of confusion for readers (see also Sanford 2006: 585), part of the research aim is to contribute to the investigation of an important lay-oriented genre in which the avoidance of any source of confusion is critical. In the first round, therefore, the nature and degree of coherence in a specimen of the PIL genre will be investigated on its own terms, i.e. without considering the hybridity (between derived and non-derived segments) of the textual genesis. Another part of the investigation will be concerned with specifically relating the question of coherence to the hybridity of the genre. Here, the aim will be to investigate the extent to which *integration* between derived and non-derived segments has been achieved to form a coherent text.

The central analytical method adopted is so-called **cohesive harmony analysis** (CHA) (Hasan 1984, 1985), designed to quantify coherence. Given that coherence is a relative phenomenon, the method will be applied not only to a PIL but also to a control text for comparison. This text represents a parallel type of lay-oriented, but non-hybrid (and non-derived) genre, to be introduced in Section 3.

The structure of the article will be the following: Section 2 sets out the theoretical foundations of the article, and Section 3 introduces the PIL genre, including its mandatory structure and the nature of its derivation from the specialized Summary of Product Characteristics (SmPC). This section also features a brief investigation of the registerial consistency (so-called **contextual coherence**; for a definition, see section 2) of the sampled PIL. Section 4 introduces the analytical framework, and section 5 documents the individual steps of the analyses and presents the results. The results are discussed in section 6.

2. Theoretical foundations: The concept of coherence

In defining the concept of coherence, one perspective is the psycholinguistic/cognitive approach, which views coherence as a (purely) mental phenomenon (e.g. Carrell 1982, Blum-Kulka 1986, Stoddard 1991: 11, Givón 1995, Seidlhofer/Widdowson 1999), and according to which "the idea of coherence in text itself is meaningless" (Sanford/Moxey 1995: 183). In contrast, the functionalist perspective (primarily represented by Halliday/Hasan 1976, Hasan 1984, 1985, Hoey 1991a, 1991b, Fries 2004) conceives of coherence as a quality immanent in texts. The present article will be premised on the latter perspective, for which a few arguments will be given in the following.

As a point of departure for a debate between the two approaches, it may be noted that what divides them appears to be the central question of where coherence is 'located' (in text or in the mind) rather than the nature/content of the concept as such. Hasan (1984: 181) thus defines the concept in relatively plain terms as semantic unity in a text, or the property of a text 'hanging together', which must be deemed perfectly compatible with a definition (from the cognitive approach) which stresses semantic connectedness and consistency between sentences and the continued relevance of each sentence to the underlying topic/context (Sanford/Moxey 1995: 162) (the requirement of contextual/topical consistency is similarly a point stressed in the functional approach – see below). Also, when scholars from the functionalist tradition emphasize that coherence must necessarily be *cued* by textual, i.e. lexicogrammatical, means (e.g. Parsons 1991, Thompson 1994, Hoover 1997, Tanskanen 2006: 20-21), this is a claim which proponents of the cognitive approach (e.g. Givón

1995: 82) appear to acknowledge. Really, the difference between the two perspectives (regarding the question of the ultimate 'address' (textual or mental) of coherence) seems to derive from the fundamental disagreement about the very nature of meaning as such: *Contra* the cognitive approach to meaning, it is a central tenet in the functionalist tradition, especially the Systemic-Functional variety, that meaning is a social phenomenon (cf. Halliday 1978, 1985) rather than, or at least before it is, a cognitive one. In the words of Hasan (1984: 161-162):

> I believe that the act of meaning is made possible only through the creation and existence of codes which provide the potential for meaning; and that in a very important sense, we are able to mean through language, by virtue of the fact that the signs of language have meanings quite irrespective of what any one individual might contrive them to mean on an individual occasion. [...] When I say that coherence in a text is the property of hanging together, I mean that the patterns of language manifest – or realize – the existence of semantic bonds, because it is in their nature to do so; not simply because someone is making them do so.

It is this conception of language as a socially determined semiotic code that underlies the view that when coherence equals the presence of semantic bonds in a text (cf. Halliday/Hasan 1976: 10), it follows that coherence is a text-*immanent* quality that is independent of the receiver's perception of it (for certain caveats, see below). This does not mean to say that coherence is a given in any text; on the contrary, as already mentioned in the introduction, the assumption made here is that the phenomenon is a variable quality in respect of which texts can be more or less successful.[3] That is why the aim of the present article is to investigate the *measure* of coherence in a text type whose genesis is surrounded by circumstances that may impede its successful achievement.

Compared with the preliminary definition of coherence given above (coherence as semantic unity), a more elaborate, functionalist definition of the concept is the following:

> A text is a passage of discourse which is coherent in these two regards: It is coherent with respect to the context of situation, and therefore consistent in register; and it is coherent with respect to itself, and therefore cohesive. Neither of these two is sufficient without the other, nor does the one by necessity entail the other. (Halliday/Hasan 1976: 23)

This definition will be the one adopted for present purposes. Of the definition's two aspects, it is the second (internal coherence manifested in cohesiveness, or *texture* (Fries 2004: 10 et passim)) that is the primary focus of this investigation. Problems with registerial inconsistencies in PILs have already been frequently researched, and so will be only briefly considered (in section 3). A summary definition of the very concept of **context of situation** is therefore deemed to suffice: The concept is a tri-partite construct consisting of the parameters **field**, **tenor** and **mode**, with **field** referring to the activity surrounding the communication or its subject matter, **tenor** referring to the role relationship between sender and addressee, and **mode** referring to the role assigned to the language in the event, including "rhetorical mode, as narrative, didactic, persuasive, 'phatic communion' and so on"[4] (1976: 22; for parallel definitions of context in the systemic-functional tradition, see e.g. Halliday 1978: 142-43, 1985: 12). Context and language are connected via the concept of **register**, which denotes the particular type of language associated with a given type of situational context (Halliday/Hasan 1976: 23; Halliday 1978: 123 et passim). The dialectical relation between context and language (context as a semiotic construct *expressed* in language)

3 Obviously, the presence of text-immanent coherence is no guarantee that it will actually be perceived by the receiver. A receiver's understanding of a text (in which process the perception of coherence is a crucial element) is, as noted by Seidlhofer/Widdowson (1999: 207), a matter of convergence between the context evoked by the text and the receiver's contextual understanding (see also Hasan 1985: 48). Thus, as Myers (1991) points out, in reading a specialized text, the reader's ability to perceive the relations between vocabulary items that underlie the text's lexical cohesion (see section 4 of this article) is contingent on his/her knowledge of the specialized field in question.

4 The mode parameter of context encompasses further dimensions, in fact, but the only one relevant for the present purpose is rhetorical mode – corresponding to functions of language in classic linguistic theories, e.g. Bühler (1934) and Jakobson (1960).

is a fundamental Systemic-Functional tenet (see e.g. Martin 1992: 493-97) which explains why contextual coherence manifests itself in registerial consistency.

3. Data selection and introduction to the Patient Information Leaflet genre

The sample of PILs to be analyzed will consist of a single text only, viz. the PIL for the product named *Daptomycin Hospira* (Hospira UK Ltd 2017).[5] The text was selected for its length (4 pages), which is average for the genre. In the present section, the contents and mandatory move structure of PILs will be presented in section 3.1, followed by an account of, and multiple perspectives on, the derivational nature of the genre (3.2). Problems with registerial inconsistencies will be briefly documented in subsection 3.3 as part of this general introduction to the genre, and will not form part of the investigation proper. In the final subsection (3.4), the control text will be introduced.

3.1. Contents and move structure of PILs

As mentioned in the introductory section, PILs are a highly standardized genre, subject to a completely fixed move structure and to minute regulation of the contents of each section (European Medicines Agency 2016). Lexicogrammatically, the standardization also manifests itself in a general prevalence of formulaic wordings occurring across texs, mandated by the EMA template for the genre (European Medicines Agency 2016). Section 1 in the genre is thus preceded by a short 8-line introduction (admonishing the patient to read the leaflet carefully and to keep it) whose wording is completely invariant in all PILs.

The headlines and content of the six mandatory sections are:

1. *What [X] is and what it is used for.* This section specifies the type of medical conditions that the drug is meant to treat and (typically) the way the drug works.

2. *What you need to know before you use [X]*. Here, a number of circumstances are listed where use of the drug is not recommended. Moreover, all or most PILs contain subsections providing information (sometimes warnings) about use of the drug in connection with pregnancy and breast-feeding and in connection with driving and the use of machines.

3. *How to use [X]*. This section provides dosage instructions and specification of the so-called method of administration (the way the drug is to be taken by or given to the patient).

4. *Possible side effects*. Potential side effects graded into four different groups of frequency (ranging from 'very common' to 'rare') are listed here.

5. *How to store [X]*. Storage advice is given, e.g. whether to keep the drug refrigerated or not.

6. *Contents of the pack and other information*. The exact chemical composition of the drug and the way it is packaged are specified.

3.2. PILs as products of derivation

Apart from being a highly standardized genre, PILs are also derived texts, since they are legally required to be "drawn up in accordance with the summary of product characteristics" (European Commission 2004). Furthermore, detailed guidelines regulating the correspondence between

5 For convenience, the text will be referred to by the product name in the rest of this article.

the individual PIL and SmPC sections are provided by the European Medicines Agency[6] (2016: 25-39) (see also van Vaerenbergh 2007: 172). This is why a majority of PIL segments can be directly traced back to corresponding SmPC segments. For a minority of PIL segments, on the other hand, no specific origin can be identified in the SmPC, which means that these must be considered original elements. The **manifest intertextuality** (Fairclough 1992: 271) of the genre, i.e. its origins in the SmPC, and the hybridity between derived and original parts will be briefly illustrated in section 3.2.1.

Considering, however, that the meanings transferred from the SmPC to the PIL are (in most cases) not simply reproduced or paraphrased, but linguistically simplified,[7] also in accordance with legal requirements (European Commission 2009; European Medicines Agency 2016: 25), the genre may be conceptualized as popularization (Hill-Madsen/Pilegaard 2019), by serving to bridge a knowledge divide or asymmetry between experts and non-experts (see Gotti 2014: 16 et passim, Camus 2009: 466, Kastberg 2011, Montalt/Shuttleworth 2012). By instantiating popularization discourse, PILs involve recontextualization (see Ciapuscio 2003: 210, Calsamiglia/van Dijk 2004: 370, Motta-Roth/Scherer 2016), by virtue of the very fact that the knowledge originally communicated within an expert-oriented context is linguistically transformed so as to suit a new, viz. lay, readership. A slightly different conceptualization, yet one closely associated with the popularization perspective, places greater focus on the linguistic shifts taking place between the SmPC and the PIL, viewing the transformation as a special case of translation, viz. intralingual translation (e.g. Zethsen 2007, Ezpeleta Piorno 2012, Hill-Madsen 2015a, Zethsen/Hill-Madsen 2016, Muñoz-Miquel et al. 2018). This interpretation stresses the fact that the linguistic transformation serves to neutralize a comprehension barrier, exactly as is the case with translation in the ordinary sense of the word, i.e. interlingual translation (for the conceptual distinction between the two types of translation, see Jakobson 1959: 233). The main difference is that the comprehension barrier is not posed by a difference between ethnic languages but between language-internal registers (see also García-Izquierdo/Montalt 2013).[8]

3.2.1. The character of SmPC>PIL derivation

To illustrate the character of SmPC>PIL derivation, a table has been inserted below (Table 1). The table features an extract from section 2 of the *Daptomycin Hospira* PIL reproduced in the right-hand column and the corresponding source extracts from the SmPC in the left-hand column. The PIL extract is quoted without interruptions, whereas only those parts of the SmPC are reproduced from which PIL segments are derived. Derived PIL segments have been bolded and numbered sequentially, with the same numbers inserted in the SmPC extract at the beginning of corresponding segments. This means that non-highlighted and unnumbered PIL segments have no derivational base in the SmPC.

6 The European Medicines Agency (EMA) is the agency responsible for authorizing medicinal products for marketing in EU countries.

7 The specific nature of the simplification procedures behind the textual transformation from SmPC to PIL is of limited relevance to the present investigation and is therefore ignored. For detailed inquiries into this question, see Ezpeleta Piorno (2012), Hill-Madsen (2015a), Hill-Madsen (2015b) and Hill-Madsen (in press).

8 For examples of opposition to the interpretation of registerial simplification as intralingual translation, see Camus (2009: 466), Ciapuscio (2003: 209), Raichvarg (2010) and Mossop (2016).

Daptomycin Hospira SmPC[9]	*Daptomycin Hospira* PIL
4.4 Special warnings and precautions for use **3) Increases in plasma creatine phosphokinase (CPK; MM isoenzyme) levels associated with muscular pains and/or weakness** and cases of myositis, myoglobinaemia and rhabdomyolysis **have been reported during therapy with daptomycin** (p. 5, section 4.4). **4) Any patient** that develops unexplained muscle pain, tenderness, weakness or cramps **should have CPK levels monitored** every 2 days. **Daptomycin Hospira should be discontinued in the presence of unexplained muscle symptoms ...** (p. 6, section 4.4) **2) An adjustment of daptomycin dose interval is needed for patients** whose creatinine clearance is <30 ml/min. (p. 6, section 4.4) Caution is advised when administering daptomycin to **1) patients who already have some degree of renal impairment** (creatinine clearance <80 ml/min) before commencing therapy with Daptomycin Hospira. (p. 6, section 4.4) **5) In obese subjects with Body Mass Index (BMI) >40 kg/m2** but with creatinine clearance >70 ml/min, **6) the AUC0-∞ daptomycin was significantly increased (mean 42% higher) compared with non-obese matched controls.** There is limited information on the safety and efficacy of daptomycin in the very obese and so **7) caution is recommended.** (p. 7, section 4.4)	**Warnings and precautions** Talk to your doctor or nurse before you are given Daptomycin Hospira. **- 1) If you have, or have previously had kidney problems. 2) Your doctor may need to change the dose of Daptomycin Hospira (see section 3 of this leaflet).** **- 3) Occasionally, patients receiving Daptomycin Hospira may develop tender or aching muscles or muscle weakness** (see section 4 of this leaflet for more information). If this happens tell your doctor. **4) Your doctor will make sure you have a blood test and will advise whether or not to continue with Daptomycin Hospira.** The symptoms generally go away within a few days of stopping Daptomycin Hospira. **- 5) If you are very overweight. 6) There is a possibility that your blood levels of Daptomycin Hospira could be higher than those found in persons of average weight 7) and you may need careful monitoring in case of side effects.** - If any of these applies to you, tell your doctor or nurse before you are given Daptomycin Hospira. (pp. 34-35, section 2)

Table 1: Derivation of PIL segments from corresponding PIL segments

Table 1 illustrates that 1) PILs are only partially a product of derivation, and 2) that the derivation is very far from being linear. Moreover, whereas all the derived segments of the PIL extract in Table 1 can in fact be traced back to the same SmPC section, albeit non-sequentially, in certain other cases two adjacent sentences in the PIL are derived from different SmPC sections, as in Table 2 below, where three different SmPC sections are represented within a space of only three PIL sentences:

Daptomycin Hospira SmPC	*Daptomycin Hospira* PIL
1a+b) Each vial contains 350 mg daptomycin[10] (p. 2, section 2) **1b)** (1. NAME OF THE MEDICINAL PRODUCT) Daptomycin Hospira 350 mg powder for solution for injection/infusion (p. 2, section 1) **2)** Daptomycin is active against Gram positive bacteria only (p. 3, section 4.1). **3)** Daptomycin is indicated for the treatment of the following infections in adults (see sections 4.4 and 5.1). - Adult patients with complicated skin and soft-tissue infections (cSSTI). (p. 2, section 4.1)	**1. What Daptomycin Hospira is and what it is used for** **1a) The active substance** in **1b) Daptomycin Hospira powder for solution for injection/infusion** is **daptomycin. 2) Daptomycin is an antibacterial that can stop the growth of certain bacteria. 3) Daptomycin Hospira is used in adults to treat infections of the skin and the tissues below the skin.** (p. 34, section 1)

Table 2: Derivation of PIL segments from corresponding PIL segments

Out of a total of 1981 words in the *Daptomycin Hospira* PIL, 1233 words occur in derived sections and 748 words in non-derived, i.e. original, segments. This means that derived segments constitute approximately two thirds of the text, and original segments approximately a third.

3.3. (Lack of) contextual coherence in PILs

A close reading of the *Daptomycin Hospira* PIL reveals that despite being aimed at a lay readership, a lay-oriented tenor is far from being consistently achieved throughout the text. An important part of the explanation is the fact that a number of wordings from the SmPC have been transferred to the PIL without any lexical or grammatical adaptation, thus introducing a number of specialized items into the PIL. One example is the following string from section 4 of the *Daptomycin Hospira* PIL ('Possible side effects'), where key elements evidence transformationless derivation: *A hypersensitivity reaction (serious allergic reaction including anaphylaxis, angioedema, drug rash with eosinophilia and systemic symptoms (DRESS)) has been reported* (*Daptomycin Hospira* PIL, p. 36, section 4). The corresponding SmPC wording (from a tabular representation of side effects) is: *Hypersensitivity, manifested by isolated spontaneous reports including, but not limited to angioedema, drug rash with eosinophilia and systemic symptoms (DRESS)* (*Daptomycin Hospira* SmPC, p. 9, sectdion 4.8). Other instances of specialized lexis from the *Daptomycin Hospira* PIL are *antibacterial* (p. 34, section 1), *sodium hydroxide* (p. 34, section 2), *oral anti-coagulants* (p. 35, section 2) and *antibacterial-associated colitis, including pseudomembranous colitis* (p. 38, section 4). Substantial parts of the PIL are in fact sourced from SmPC wordings without any transformation having taken place, resulting in recurrent deviations from the lay-oriented register and with a concomitant reduction in readability for the intended readership – a flaw for which the genre has been repeatedly criticized over the years (e.g. Bradley et al. 1994, Bjerrum/Foged 2003, Askehave/Zethsen 2003, Harwood/Harrison 2004, Ross et al. 2006, Clerehan/Buchbinder 2006, Raynor et al. 2007, Pander Maat/Lentz 2010, Hadjipavlou et al. 2013).

Similarly, there are inconsistencies in the contextual parameter of mode, more particularly *rhetorical mode*. As van Vaerenbergh (2003: 212) points out, PILs encompass descriptive as well as instructive/appellative elements, with the descriptive mode featuring e.g. in section 1, which, as previously mentioned, specifies what particular type of medicine the product is and how it works, and with instructive/appellative elements being represented e.g. in dosage and storage

instructions. To these may be added a third component, viz. a didactic one. Albeit most likely unintended, certain parts, in fact, have the function of educating the reader on the meaning of certain specialized terms. This is the case in the following example, which occurs in a list of medicines that may negatively impact on the effect of Daptomycin Hospira or vice-versa: *It is particularly important that you mention the following [to your doctor]: - Medicines called statins or fibrates (to lower cholesterol) or ciclosporin (a medicinal product used in transplantation to prevent organ rejection or for other conditions, e.g. rheumathoid arthritis or atopic dermatitis)* (*Daptomycin Hospira* PIL*,* p. 35, section 2). This statement really serves to explain the meaning of the medical terms *statins*, *fibrates* and *ciclosporin*, which is achieved in the form of definitions (see Hank 2006: 399) along the classical lines of *genus*, i.e. superordinate class + *differentiae*, i.e. distinguishing properties. Here, the genus is specified as that of *medicines*/*medicinal products*, and the differentiae as *to lower cholesterol* and *used in transplantation to prevent organ rejection or for other conditions, e.g. rheumathoid arthritis or atopic dermatitis*. Being didactic in character, such definitions make these statements reminiscent of textbook genres[9] aimed at introducing students within a given field to field-specific terms and their meaning (see also Hill-Madsen/Pilegaard 2019). Because of these irregularities of mode as well as tenor, the conclusion, therefore, is that the *Daptomycin Hospira* PIL is not contextually coherent.

3.4. The control text: A newspaper health column

The control text,[10] entitled *Seven ways to minimise the risk of having a stroke* (Robinson 2018), stems from the health column of the British daily newspaper *The Guardian*. Written by a General Practitioner, the text (henceforth *Seven ways*) is largely comparable with the PIL genre in terms of contextual configuration, being concerned with the field of health care and representing an expert-to-lay tenor just like PILs. Both texts, moreover, are addressed to anonymous mass readerships. A significant difference is the fact that *Seven ways* is only concerned with medication to a very limited extent, and is thus practically devoid of the pharmaceutical element that is prominent in PILs. As for the rhetorical mode, the two texts are close to each other, though not completely parallel, in so far as *Seven ways* is advisory rather than instructional, yet, like the PIL genre, features a strong informative element also. Despite the divergences, the degree of contextual overlap between the two texts must be deemed sufficient for *Seven ways* to be able to function as a non-hybrid control text.

4. Analytical framework: Cohesive Harmony Analysis

Within functionalist linguistics, the so-called **cohesive harmony analysis** (CHA) framework, to be detailed in sections 4.1 and 4.2, is designed to measure the internal coherence of texts, and has been widely utilized since its conception by Hasan (1984, 1985; for more recent re-articulations of the framework, see Parsons (1996) and Khoo (2016)). It has been applied e.g. in reading research (Fulcher 1989) and in the investigation of children's writing (Spiegel/Fitzgerald 1990), the academic writing of native and non-native speakers (Parsons 1991, 1996), letter writing by native and non-native speakers (Demantik 2008), and aphasic discourse (Bottenberg et al. 1985, Armstrong 1987, 1991), to name just a few applications. The present study, on the other hand, represents the first application of the framework to the type of hybrid texts represented by the PIL genre.

A limitation of the framework, however, is that, while being based on a minute analysis of cohesive relations between individual grammatical and lexical items, a CHA analysis really serves to establish a 'panoptic' perspective on the internal coherence of a text as a whole. While the

9 From the perspective of Fairclough's Critical Discourse Analysis, this intrusion of a different genre would correspond to interdiscursivity (e.g. Fairclough 1992), and would correspond to genre-bending or appropriation of generic resources from the point of view of Bhatia's Critical Genre Analysis (e.g. Bhatia 2010).

10 The full text is reproduced in Appendix 3.

conceptual framework of CHA is rigorously defined (see section 4.1 below), and hence a highly reliable analytical 'toolbox' when considered in isolation, a severe deficiency is the fact that, in the words of Martin (1992: 433), it ignores the "organic" aspect of textual coherence, i.e. the question of whether and how continuity is established from sentence to sentence. Without a supplementary framework to investigate sentence-to-sentence progression, therefore, the investigation would be incomplete and its validity in jeopardy, which is why such tools will be introduced in section 4.3.[11]

4.1. Basic tenets of cohesive harmony theory

According to Hasan (1984: 181), text-internal coherence, or so-called **cohesive harmony**, is a matter of semantic unity in a text, or the property of a text 'hanging together'. At the lexicogrammatical stratum, such semantic unity manifests itself in two different, but interrelated ways, namely as 1) cohesive chains and 2) connections between such chains, so-called **chain interaction**. Of these two factors, the notion of cohesive chains, first proposed by Halliday/Hasan (1976), is a well-known text-linguistic phenomenon consisting in chains of cohesive ties between message components, either in the form of co-reference (e.g. *the medicine ... it .... it*) or in the form of lexical cohesion (e.g. *medicine ... medicine ... medicinal product ... medication*), i.e. semantic ties such as synonymy, hyponymy or meronymy (Hasan 1985: 82, Martin 1992: 333) between lexical items across sentence boundaries (and sometimes also within sentences). Cohesive chains are thus carriers of semantic unity running 'vertically' through a text.

However, although the presence of cohesive chains is a necessary condition for cohesive harmony, it is not a sufficient one. Links *between* different cohesive chains are also needed. In Hasan's own words (1985: 91),

> [i]t is important to recall here that in constructing [cohesive] chains, we are concerned with components of messages. [...] On the other hand, it is only message as message that has any textual viability. And it is only at the rank of clause or above that any lexico-grammatical unit is contextually viable: it is only at this rank – or above – that a linguistic unit can encode a complete message. Although the chains go a long way towards building the foundation for coherence, they are not sufficient: we need to include some relations that are characteristic of those between components of a message. This is the relation that I refer to as CHAIN INTERACTION [*emphasis as in the original*].

In other words, cohesive relations between individual message *components* across (and within) sentence boundaries are a prerequisite for establishing semantic ties between sentences, but a coherent text is, in the last resort, a string of connected *messages*, and messages are realized grammatically by sentences and clauses, in which message components are combined structurally. The ultimate text-forming property, therefore, resides with messages rather than message components, which is why the relation between chain-member components *within* a message must be integrated in the model. This relation, termed **chain interaction**, therefore represents the second of the two types of unifying force that contribute to coherence. While chains in themselves represent the 'vertical' aspect, chain interaction is a 'horizontal' force (or 'vector', to use Hasan's (1985: 92) expression) of semantic unity, manifesting itself in grammatical relations between individual message components, first and foremost (but not exclusively) at clause level. One such connection may be that between Subject and Verb or between Verb and Direct Object.[12] Thus, if, in a clause such as *you must take your medicine*, we imagine that *take* and *medicine* are tokens that belong to two different cohesive chains, then the two chains interact in the present example via a Verb (*take*) + Direct Object (*medicine*) configuration.

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11 In fairness to Hasan (1985), it should be noted that she herself points to the incompleteness of the framework, suggesting certain supplementary tools needed for a full analysis of text-internal coherence. These tools are the ones that will be introduced in section 4.3.

12 The generally known grammatical terms 'Subject', 'Verb' and 'Direct Object' are used here for preliminary exemplification only. The terms that were actually applied in the analyses are those from the so-called experiential part of Systemic-Functional Grammar (see section 5.3).

A single point of interaction between two chains, however, is insufficient for chain interaction to be present. The reason is the obvious one that since all message components participate in grammatical relations, then all chains without exception are automatically connected with other chains (Hasan 1985: 91). Single-point grammatical relations, therefore, do not create any further semantic unity *between* chains. Instead, for semantic unity to arise 'horizontally', a minimum of two points of similar grammatical interaction between two chains is a requirement. In this way, the similarity between messages effected by recurrent chain interaction becomes a cornerstone in text-internal coherence, the rationale being, in Hasan's (1985: 94) words, that "in a coherent text, one says similar kinds of things about similar phenomena." For present purposes, the term **chain interaction series** (henceforth CIS) will be adopted to refer to the repetition of a particular grammatical configuration of items from two different chains. If, for example, we imagine the configuration *take* + *medicine* occurring four times in the same text, then the eight tokens altogether constitute a CIS.

The principles of Cohesive Harmony Analysis are illustrated in Figure 1 below, which is a diagrammatic representation of Hasan's own cohesive harmony analysis of a short narrative produced by a child:

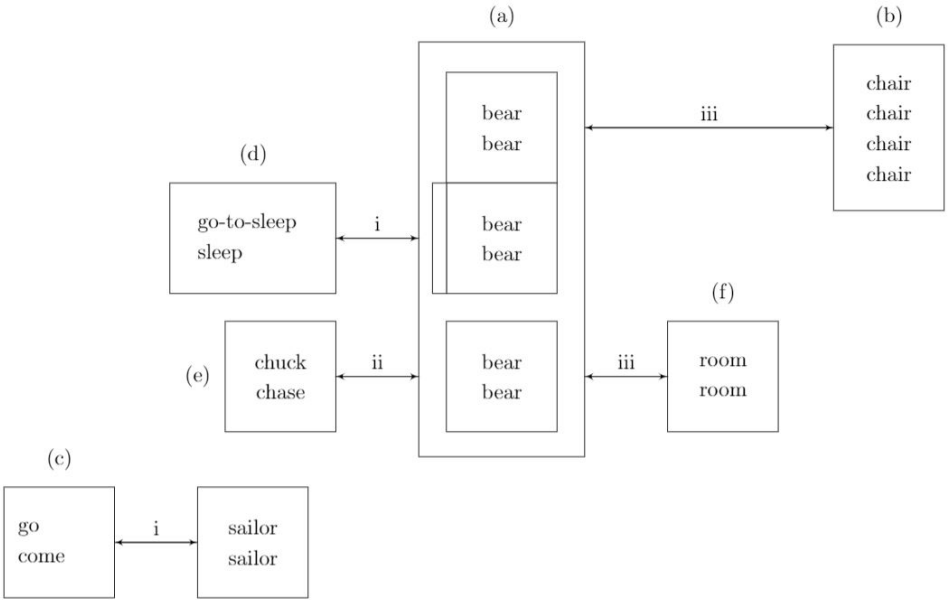

Figure 1. Reproduction of diagram from Hasan (1985: 93).

Each word in the diagram represents an individual instantiation of a message component (realized by a lexical item), with the boxes representing cohesive chains. The 'bear' chain thus numbers 6 tokens altogether, but three smaller boxes dividing the 6 tokens into three 2-item groups illustrate how subsets of the chain interact with altogether four other chains, symbolized by the arrows (the lowercase Roman numerals (i-iii) above the arrows refer to types of grammatical relations that will not be commented on here). The tokens on both sides of an arrow thus constitute a CIS. What Figure 1 also illustrates is the phenomenon termed **interactive gaps** (Hasan 1984: 2018): The 'go-come' chain and the 'sailor' chain form a CIS, but neither of the two chains interacts with any of the other chains, thus leaving a gap in the 'mesh' of interacting chains.

4.2. Operationalization of the principles of cohesive harmony

The above tenets are crystallized by Hasan (1985: 93) into the following conceptual distinctions: Firstly, she coins the term relevant tokens to represent those items in a text that participate in cohesive chains, as opposed to peripheral tokens, referring to those that do not. Secondly, relevant tokens further subdivide into central and non-central ones, with central tokens representing those that enter into CISs and non-central ones being those that do not. These conceptual distinctions are then operationalized by Hasan as three interrelated parameters of cohesive harmony. The degree of coherence in a text, Hasan (1985: 93-94) claims, correlates with:

1. The ratio of **relevant tokens** to **peripheral** ones. The higher the ratio, the stronger the coherence (is likely to be).
2. The ratio of **central tokens** to **non-central** ones. The higher the ratio, the stronger the coherence (is likely to be).
3. The number of **interactive gaps**. The *lower* the number of such gaps, the more coherent the text.

The ratio of relevant tokens to peripheral ones serves to measure the experiential domain's (subject matter's) degree of integratedness: A low number of peripheral tokens means few items falling outside the experiential focus or foci of the text, leaving the correspondingly high number of relevant tokens to ensure a high degree of integratedness in terms of subject matter(s). However, as already indicated, a high ratio of relevant to peripheral tokens is, according to Hasan (1985: 94), a necessary, but not a sufficient condition for coherence. For coherence to be achieved, a high score on the second ratio (central to non-central tokens) is also needed. The number of connections *between* chains, in other words, also needs to be sufficiently high. Finally, in a coherent text, the development of the subject matter from one subtopic to another will be a fluid or gradual process without abrupt transitions or interruptions (Hasan 1985: 94). Such interruptions would manifest themselves in interactive gaps.

4.3. Sentence-to-sentence continuity: Analytical tools

To investigate the semantic continuity from sentence to sentence, a simple shift in focus on the cohesive relations charted in connection with a cohesive-harmony analysis might, at first glance, suffice. Once a CHA has been conducted on a text, It might appear sufficient to revisit the analysis of cohesive chains (see section 5.2) and note the number of cohesive relations within all pairs of adjacent sentences and adjacent clauses. However, a more focused analysis is needed: Not only does a superficial reading of the sampled PIL reveal that such connections are indeed present in the majority of adjacent-sentence pairs. What is more, Hasan herself (1985: 81) points out three specific lexicogrammatical devices by which semantic continuity is created betwen two consecutive sentences: These are 1) **grammatical parallelism**, 2) so-called **conjunctive relations**, and 3) the interaction between the **Theme-Rheme** and the **Given-New** structure in each sentence.[13] Each of these will be briefly explained in the following:

1) Grammatical parallelism simply refers to the repetition of identical grammatical structures. For example, in Julius Caesar's famous, historic statement in Latin, *veni, vidi, vici* ('I came, I saw, I conquered'), the repetition of the same verb form (1st person, perfect tense in Latin) indicates a semantic relation of temporal succession between the three.

13 A fourth device (noted by Halliday/Hasan 1976: 327) is adjacency pairs in conversation. This is obviously irrelevant to the present investigation.

2) So-called conjunctive relations between sentences may be signalled by conjunctive adverbials (also termed *connectives*) such as *however, moreover, more specifically, therefore*, *next*, which establish semantic relations such as 'contrast', 'addition', 'elaboration/specification', 'cause/consequence', 'temporal succession' etc. between sentences (e.g. Martin 1992 ch. 4, Halliday/Matthiessen 2014: 609-22). More or less the same types of relations exist *intra*-sententially between clauses (see e.g. Martin 1992: ch. 4), but since semantic linkage is guaranteed between clauses in multi-clause sentences (because such linkage is *necessarily* coded by means of conjunctions such as *if, when, because* etc.), the investigation can safely exclude this aspect. Instead, the analysis on this point will be confined to the identification of explicit *inter*-sentential conjunctive relations.

Before leaving this second device, it may be noted that the notion of conjunctive relations has clear affinities with the framework known as Rhetorical Structure Theory (e.g. Mann/Thompson 1988, Mann *et al*. 1992, Bateman/Rondhuis 1997, Taboada/Mann 2006, Matthiessen/Teruya 2015), although the two (RST and the SFL theory of conjunctive relations) are not completely parallel. The reason why RST has been excluded from the present investigation is that the theory posits the existence of logical (or 'rhetorical' relations) between *any* two adjacent sentences in a text, even where such a connection is not explicitly coded. The stance taken here is that, while implicit logical relations do exist, also in the sampled PIL, they cannot be taken for granted where they are not explicitly coded (see also Halliday/Matthiessen 2014: 622). Moreover, in those cases where an implicit relation actually *can* be identified, its creation and identification will depend on the presence of *other* cohesive means signalling a connection between the two sentences (see also Das/Taboada 2018). Seeking to answer the question of how and to what extent the sampled text *creates* coherence, the investigation is concerned with identifying the actual lexicogrammatical items *encoding* these connections.

3) The third device is a structural one, viz. **Theme-Rheme** structure in combination with **Given-New**. As the name implies, the former is concerned with thematic structure in clauses and sentences, whereas the latter is concerned with information structure. In Systemic-Functional Grammar, the Theme is interpreted as the first so-called experiential constituent of the clause (in English represented either by the grammatical subject or an adjunct), which is interpreted as "the point of departure" (Halliday/Matthiessen 2014: 89), signifying what the message of the clause or sentence will 'be about' (in a multi-clause sentence, an initial subordinate clause functions as Theme for the whole of the sentence (Halliday/Matthiessen 2014: 552). The Rheme, then, is the rest of the clause or sentence, providing the actual content of the message. As for Given and New, the former refers to information or elements that have already been introduced, or are otherwise known, to the receiver and which are therefore recoverable. The term New, as the name implies, refers to new, unknown information. Since Given-New structures are realized via intonation patterns (Halliday/Matthiessen 2014: 114-119), the two elements are only explicitly cued in spoken discourse whereas in written discourse, judgment is required on the reader's part to identify the two elements (Given elements are recognizable in the form of phoric[14] noun phrases (NPs) or lexical units which link with a previous item). What matters to the present purpose is the relation between thematic structure and information structure: As Halliday/Matthiessen (2014: 119) point out, although the two structures are independent of each other (see also Fries 1983), the conflation of Theme with Given is the unmarked relation. This must be taken to imply that a clause or sentence can, by default, be expected to be grounded in already known information. It further implies that whenever such conflation obtains, the effect is immediate, and hence strong, semantic linkage of a sentence to its context, either preceding text or the external 'here-and-now' of the situation (in the case where the Given element consists in an exophoric reference). For this reason, every sentential Theme in the sampled text will be examined to establish the absence or

14 A phoric NP is one which signals (in English e.g. by means of the definite article or a demonstrative pronoun) that the identity of its referent is recoverable, either from surrounding text or from the 'here-and-now' of the communicative event (Martin 1992: 98).

presence of Given elements, and, if a Given element is present, whether the presupposed element is recoverable from the immediately preceding sentence (see also Halliday/Hasan 1976: ch. 8).

5. Analytical procedures and results

In this section, the individual steps of the analysis of the *Daptomycin Hospira* PIL will be documented through exemplification and the results presented. In accordance with the principles of Cohesive Harmony Analysis outlined in section 4, the analytical procedure was three-fold:

- As a foundational step, all cohesive chains (co-referential and lexical) were identified through analysis of cohesive relations in the entire text. This part of the analysis will be briefly documented in section 5.2, which will also feature a list of all the chains identified.
- As the second step, grammatical analysis of all clauses and all relevant phrases was conducted, enabling the identification of CISs. These analyses will be briefly documented in section 5.3.
- As the third step, a map of the total 'mesh' or network of CISs was drawn in order to determine the number of **interactive gaps**. This map is rendered in section 5.4.

It should also be noted that, concurrently with the second analytical step, i.e. the identification of CISs, all the individual instances of chain interaction within each CIS were marked for derivational status (derived/non-derived). This made it possible to determine the degree of integration between derived and non-derived segments in each CIS. The results of this part of the analysis will be presented in subsection 5.3.1. In the final subsection (5.5), the quantitative results for both the *Daptomycin* PIL and the control text *Seven ways* (i.e. the ratio between **relevant** and **peripheral tokens**, the **central-non-central** ratio and the number of **interactive gaps**) will be presented and compared. Prior to the documentation of the analyses and results, however, certain theoretical problems arising from the analyses need to be addressed (section 5.1).

5.1. The concept of message parts

In connection with the analysis of lexical cohesion specifically, one problem needs to be highlighted, which is the very problem of deciding the size of lexical units. Single-word lexical items rarely present any difficulty in this connection, whereas multi-word expressions often do, as pointed out by Martin (1992: 290). A case in point is the idiomatic expression *go to sleep*, which is treated as a single item by Hasan in the analysis diagrammed in Figure 1. The solution proposed by Martin (1992: 290-93) is the concept of **message parts**,[15] or **discourse-semantic units**, which will be adopted in the present investigation. Taking his point of departure in the conceptual structure of semantic domains (i.e. the contextual parameter of **field**), Martin (1992: 293) writes:

> For a given field, [a] message part realises (i) one of the features taxonomising people, places and things, or (ii) one of the actions configuring with people, places and things [...], or (iii) one of the qualities associated with people, places things and actions. The message part may or may not be realised by a single lexical item.

A message part, in other words, is a semantic unit corresponding to either 1) an item in a taxonomy of phenomena ('people, places and things') associated with a given field, 2) an action associated with one of these phenomena, or 3) a quality. Lexicogrammatically, the majority of message parts are realized by single-word lexical items, but two exceptions relevant for the present purpose should be highlighted. The most important one is NPs with a structure consisting of a classifying premodifier followed by a head noun (in Systemic-Functional Grammar termed Classifier + Thing), e.g. medicinal product, which Martin (1992: 297) treats as constituting a single message part only. This is because

15 Martin's approach does not in fact appear to be at odds with Hasan (1985: 91), who also points out that "in constructing chains, we are concerned with components of messages [my emphasis]."

the presence of a classifying premodifier in a NP simply indicates a subclass of the superordinate class denoted by the head noun. Thus, medicinal products signifies a subclass of products, i.e. a single, unified phenomenon, and not two different message components. Similarly, NPs with a structure encoding part/whole relations have been treated as unified message parts. Martin's examples are the top of the bridge and the biggest of the melons (1992: 314), in both of which cases a single message part ('a particular place' and 'one particular piece of fruit') is intended. NP structures consisting of a descriptive premodifier followed by a head noun (in Systemic-Functional Grammar termed Epithet + Thing), on the other hand, are treated as realizing two message parts, viz. as a 'quality' and a 'thing/entity'.[16] The same applies to determiner+head noun structures (Deictic + Thing in SFG terminology), where the determiner is realized by a possessive pronoun such as your or another NP in the genitive. Accordingly, structures such as your doctor or the patient's doctor have been interpreted as consisting of two message parts. In connection with collocations and phraseology, judgement is required in the individual case to decide whether one or several message parts are involved. Thus, although there is a collocational bond between *smoke* and *pipe* in a clause such as he smokes a pipe, there are still two separate message parts, viz. the 'act' (*smoke*) and the 'tool' (*pipe*). Multi-word expressions such as *take a bath* and *fall asleep*, on the other hand, encode a single message part only (an 'act').

In connection with co-reference, phoric pronouns (e.g. *it* referring back to a referent such as *the medicinal product*) have – perhaps obviously – been treated as realizing one message part, viz. the same one as its referent.

5.2. Cohesive relations and cohesive chains in the *Daptomycin Hospira* PIL

Although the nature of cohesive ties in the *Daptomycin Hospira PIL* is not in itself an object of interest in this investigation, the general characteristics of these ties should be briefly indicated, considering that they form the basis of the three-step **Cohesive Harmony Analysis**. The main characteristics are the following:

- The vast majority of cohesive chains, of which 85 altogether have been identified, are lexical ones ('similarity chains' in Hasan's (1985) terminology), with the most important exception consisting in the repetition of an exophoric reference to the patient/reader (*you*) which runs through all sections of the text.

- The majority of lexical ties consist in repetition. Within the individual chains, this is by far the most predominant type of tie, e.g. *leaflet*, which is repeated 21 times, *doctor*, repeated 15 times and the product name *Daptomycin Hospira*, repeated 45 times. Notable exceptions occur in chains of terms for symptoms and side effects, especially in section 4 of the PIL, where a number of possible side effects are listed, e.g. *chest pain, wheezing*, *dizziness*, *hot flushes* etc., forming a chain of co-hyponyms. The other notable exception is evidenced in a major chain (42 instantiations) of terms for parts or 'components' of the body, e.g. *skin*, *blood, tissue, hands, feet, breast milk* etc., which are linked by co-meronymy, i.e. as different parts of the same whole (the body).

All the chains identified are listed below with a title that best captures the semantic content of the individual chain. A few instantiations will be indicated for each chain, with numbers in square brackets referring to Appendix 1, where the whole of the Daptomycin Hospira PIL is reproduced with segments numbered. Cohesive relations between individual items will only be exemplified – and exemplified only – in connection with the so-called **focal** chains, i.e. chains whose high number of interactions make them the backbone of the whole skeleton of interacting chains (Hasan 1985: 94). Since the specific nature of cohesive relations in the PIL is not the main

16 An exception made in the present investigation, however, concerns certain multi-word NPs derived from specialized medical terms, such as *low blood pressure* (*Daptomycin Hospira* PIL, p. 37, section 4), which is derived from the SmPC term *hypotension* (*Daptomycin Hospira* SmPC, p. 9, section 4.8). In spite of the presence of an Epithet (here: *low*), such NPs have been analyzed as single, unified message parts whenever the existence of a single-word SmPC 'source' term proves that the whole of the reworded expression in the PIL must be regarded as a unified concept.

focus of this article, a more elaborate account of this part of the analyses is omitted to avoid an unnecessary level of detail. Anticipating the results of the chain interaction analysis, the chains can be grouped according to the number of CISs that a given chain participates in:

a) Five chains are the **focal** ones:
- 'The patient' (enters into 13 CISs): e.g. *patient* [1] – *you* [4].
- 'The medicinal product' (enters into 12 CISs): instantiated in items such as *Daptomycin Hospira* [1] – *medicine* [4] – *active substance* [15], i.e. with a hyponymic relation between *Daptomycin Hospira* and *medicine* and a meronymic relation between *medicine* and *active substance*.
- 'Body parts' (part of 10 CISs): e.g. *skin* [17] – *tissue* [18] – *blood* [18] (related via co-hyponymy, as already mentioned).
- 'Being' (part of 17 CISs): *be* repeated mostly in the infinitive and in the present tense form.
- 'Side effects' (part of 9 CISs): e.g. *side effects* [11] – *kidney problems* [27] – *antibacterial-associated colitis* [106] (with *side effects* as the superordinate term and the terms for specific side effects as co-hyponyms).

b) Two chains participate in five CISs each. The two chains are:
- 'Symptoms': e.g. *symptoms* [33] – *chest pain* [88] – *muscle breakdown* [90].
- 'Infections': e.g. *infections* [17] – *heart infection* [18] – *skin infections* [74].

c) Two chains participate in four CISs each. These two chains are:
- 'Consultation': e.g. *ask* [7] – *talk to* [11] – *tell* [23].
- 'Treatment': the lexeme *treat* [e.g. 19] repeated in both verbal and nominal form.

d) Seven chains participate in three CISs:
- 'The leaflet': e.g. *leaflet* [4] – *section 6* [22] – *end of the leaflet* [81].
- 'Healthcare professionals': e.g. *doctor* [7] – *pharmacist* [67] – *nurse* [108].
- 'Administration' (i.e. the way the drug is given to the patient'): e.g. *injection* [2] – *infusion* [15] – *give* [21] – *administer* [52].
- 'Containing': the lexeme *contain* [e.g. 4] repeated mostly in verbal form.
- 'Experiencing': *experience* [39] – *notice* [42].
- 'Receiving': *receive* [77] – *have* [32].
- 'Frequency': *once* [74] – *daily* [74] – *less often* [77] – *frequency* [91].

e) 13 chains participate in two CISs each:
- 'Information': the lexeme *information* [e.g. 1] repeated mostly in nominal form.
- 'Age/patient groups': e.g. *adults* [17] – *adolescents* [51] – *children* [52].
- 'Hypersensitivity': the lexeme *allergic* [e.g. 22] repeated in adjectival form.
- 'Development': *develop* [e.g. 29] repeated mostly in verbal form.
- 'Monitoring': *monitoring* [35] – *check* [45].
- 'Affecting': *affect* [e.g. 59] repeated mostly in verbal form.
- 'Deciding': *decide* [e.g. 41] repeated in verbal form.
- 'Measure': *mg* [74] – *kg* [74].
- 'Description': *describe* [e.g. 84] repeated in verbal form.
- 'Reporting': *report* [e.g. 86] repeated in mostly verbal form.

- 'Functioning': *work* [e.g. 54] repeated in verbal form.
- 'Continuation': *continue* [e.g. 32] repeated in verbal form.
- 'Data': *data* [e.g. 92] repeated.

f) 41 chains participate in only one CIS each:[17]
'Using', 'machines', 'duration' (*last* [e.g. 75]), 'below', 'getting', 'solution', 'reading', 'consumption' (*take* [56] – *use* [17]), 'importance', 'having', 'prescribing', 'possibility', 'listing', 'bacteria', 'causing', 'knowing', 'applying', 'thinking', 'advice', 'happening', 'pregnancy', 'breast-feeding', 'usuality', 'tests' (e.g. *blood test – laboratory tests*), 'time spans' (e.g. *days* [33] – *week* [79]), 'stopping', 'weight' (*weigh* [73] – *overweight* [34] – *body weight* [74]), 'immediacy' (*straight away* [37] – *immediate* [87]), 'following', 'seriousness' (*serious* [38] – *severe* [42]), 'newness', 'deterioration' (*worsen* [43]), 'rareness', 'naming', 'condition' (*condition* [45] – *health* [50]), 'interfering', 'estimation', 'wellness', 'vial', 'availability', 'including'.

g) 15 chains, as already mentioned, do not interact with other chains:
'Persistence', 'suggesting' (*suggest* [47] – *indicate* [52]), 'disorders', 'highness', 'needing', 'carefulness', 'prevention', 'effects', 'clotting', 'driving', 'cases', 'storage', 'expiry date', 'cases', 'associating with'.

5.3. Chain interaction analysis

A few examples of the way all sentences in the *Daptomycin Hospira* PIL have been analyzed for grammatical relations between message parts will be given below. In accordance with Hasan (1984: 212-213, 1985: 93), the grammatical framework relied on is the experiential part of Systemic-Functional Grammar (Halliday and Matthiessen 2014: 211-332, 364-386).

Example 1. *Talk to your doctor or nurse before you are given Daptomycin Hospira.* [26]

Five different cohesive chains run through the message parts of Example 1: 'Consultation' (*Talk to*), 'the patient' (*you* and *your*), 'healthcare professionals' (*doctor* and *nurse*), 'administration' (*given*) and 'the medicinal product' (*Daptomycin Hospira*). At clause level, the 'consultation' chain interacts with the 'healthcare professional' chain via the combination of a verbal process (*Talk to*) with two Receivers (*doctor* and *nurse*), and the 'patient' chain interacts with the 'administration' chain via the combination of a material process (*given*) with a Recipient (*you*). Finally, the 'administration' chain (*given*) and the 'medicinal product' chain (*Daptomycin Hospira*) are linked through the configuration of a material process with a Goal. At phrase level, Example 1 features one highly frequent combination in the text, viz. *your* + *doctor*, in which *your* (representing the 'patient' chain) serves as Deictic (or 'determiner') and *doctor* (representing the 'healthcare professional' chain) takes up the role of Thing (or 'Head').

Example 2. *Do not breast-feed if you are receiving Daptomycin Hospira, because it may pass into your breast milk and could affect the baby.* [68]

In Example 2, the following six chains are represented: 'breast-feeding', 'the patient', 'receiving', 'the medicinal product', 'body part' (*breast milk*), 'affecting' and 'age groups' (*baby*). Of these, only the 'breast-feeding' chain does not interact with any of the other chains (because *breast-feed* appears as an intransitive verb in the imperative here), whereas *you* and *receiving* combine as Actor and material process, and *receiving* and *Daptomycin Hospira* combine as material process

17 Except where otherwise indicated, the label given to a chain (e.g. 'machines') is in most cases the nominal or gerund form of the very lexeme which constitutes the chain via repetition through the text.

and Goal. Referring anaphorically to *Daptomycin Hospira, it* is an instantiation of the 'medicinal product' chain, which, however, does not interact with another chain here, since *pass into*, a material process with *it* configures as Actor, is not part of any chain. This also means that *breast milk* does not interact with another chain either, since the grammatical relation that *breast milk* does enter into is that of Goal vis-a-vis the material process *pass into*. Both *affect* and *baby*, on the other hand, participate in chains and stand in a material process + Goal relation to each other. *Your breast milk* is the only combination of two chains at phrase level in the example, with *Your* (the 'patient' chain) serving as Deictic in the phrase and *breast milk* as Thing.[18]

On the basis of these analyses, 126 different CISs were identified, of which a few examples will be given in section 5.3.1 (for a complete list of CISs, see Appendix 2).

5.3.1. Integration of derived and non-derived PIL segments in CISs

The following exemplifies two aspects of the analyses: The first is the mapping of all the CISs that a single, select chain participates in. For each CIS, e.g. 'patient' + 'administration', the specific type of recurrent grammatical configuration between the members of the two chains (e.g. Actor + material process) is indicated. The second aspect is the number of instantiations encompassed by the CIS. '7 interactions', for example, means that a given configuration, such as 'patient' + 'administration', connected as Recipient + material process, occurs 7 times. More importantly, it is specified how many instantiations occur in segments derived from the SmPC and how many in non-derived segments. In example 3 below, the 'patient' chain has been selected for its representativeness with regard to the presence of derived and non-derived segments in the various CISs in which the chain participates:

Example 3
'Patient' + 'getting': Actor + material process (2 interactions: both non-derived)
'Patient' + 'consumption': Actor + material process (3 interactions: all non-derived)
'Patient' + 'receiving': Actor + material process (7 interactions: all derived)
'Patient' + 'administration': Recipient + material process (7 interactions: 5 non-derived, 2 derived)
'Patient' + 'being': Carrier + relational process (6 interactions: 4 non-derived, 2 derived)
'Patient' + 'having': Carrier + relational process (3 interactions: 1 non-derived, 2 derived)
'Patient' + 'applying': Attribute + relational process (2 interactions: both non-derived)
'Patient' + 'affecting': Goal + material process (4 interactions: all derived)
'Patient' + 'reporting': Circumstantial element[19] + verbal process (2 interactions: both derived)
'Patient' + 'experiencing': Senser + mental process (6 interactions, all non-derived)
'Patient' + 'healthcare professonals': Deictic + Thing (24 interactions: 17 non-derived, 7 derived)
'Patient' + 'body part': Deictic + Thing (6 interactions: 1 non-derived, 5 derived)
'Patient' + 'continuation': Actor + material process (2 interactions: 1 non-derived, 1 derived)
'Patient' + 'thinking': Senser + mental process (2 interactions, both non-derived)
'Patient' + 'development': Actor + material process (2 interactions, 1 non-derived, 1 derived)

What appears from Example 3 is that out of the 15 CISs, one (the 'patient' + 'receiving' constellation) consists of derived segments only, five consist of non-derived segments only, and nine consist of a mixture of derived and non-derived segments. From the chain interaction analysis of the *Daptomycin Hospira* PIL as a whole, the following picture emerges: 19 CISs consist of

18 *Breast milk* is of course a Classifier + Thing configuration, but since, as argued in section 5.1, such a combination must be regarded as a unified message part, *breast* must be included in the Thing in the present type of analysis.

19 Circumstantial elements correspond to adjuncts in other representations of English grammar (see e.g. Huddleston/ Pullum 2002: 663-784).

non-derived segments only, 43 consist of derived segments only, and 27 consist of a mixture of derived and non-derived segments (for a discussion of these findings, see section 6).

5.4. A map of the CIS network in the *Daptomycin Hospira* PIL

The interconnection of CISs in the PIL is illustrated in Figure 2 below:

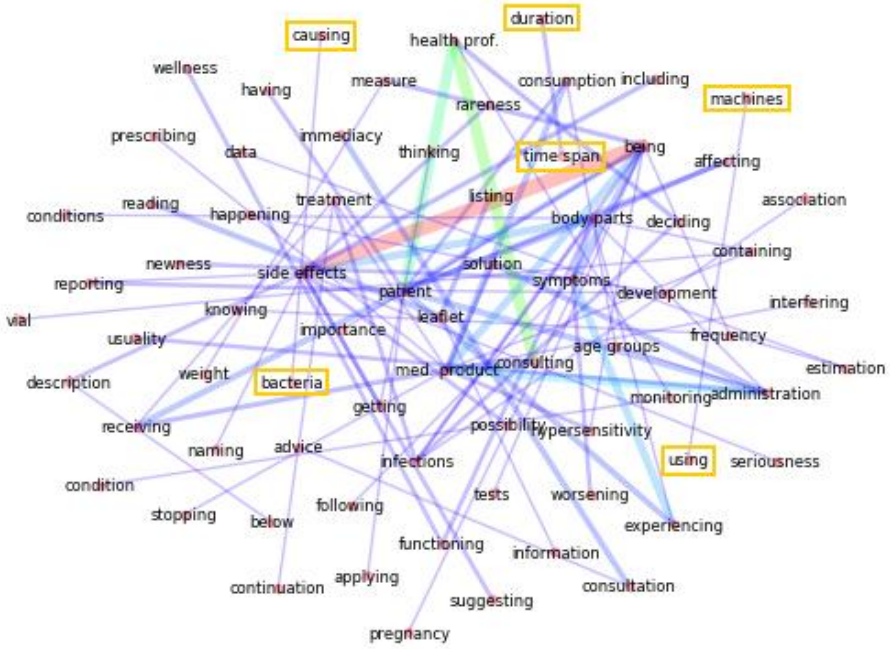

Fig. 2: A map of the interlinked CISs in the *Daptomycin Hospira* PIL

Fig. 2 reveals that only three CISs, viz. 'causing' + 'bacteria', 'using' + 'machines' and 'duration' + 'time span', stand in isolation from the 'mesh' or network of interacting chains, i.e. neither of the two chains in each of these three CISs interact with 'third-party' chains, which is what causes their isolation, and hence the **interactive gaps** between them and the rest of the 'mesh'.[20]

5.5. A comparison of the *Daptomycin Hospira* PIL with the control text

The numerical results of the Cohesive Harmony Analysis conducted on the *Daptomycin Hospira* PIL are the following:

- The ratio of **relevant** to **peripheral tokens** (i.e. message parts) is 854:86. This means that **relevant tokens** constitute 90.1% of the total number of **message parts** and **peripheral tokens** 9.9%.

- The ratio of **central** to **non-central tokens** is 698:156. **Central tokens** thus constitute 81.7% and **non-central** ones only 18.3% of relevant tokens. As a percentage of the total number of message parts (which is 940), **central tokens** make up 74.3%.

20 Admittedly, the representation of the figure in the size allowed by the present format does not do justice to all details. In close-up, however, the figure does serve the purpose of revealing interruptions in the network of CISs.

- As previously mentioned, altogether 85 chains and 89 CISs were identified, with only three CISs standing apart from, and thus creating three **interactive gaps** in the network of chains and interactions.

For the control text *Seven ways*,[21] the numerical results are:

- The ratio of **relevant** to **peripheral tokens** is 378:144. This means that **relevant tokens** constitute 72.4% of the total number of **message parts** and **peripheral tokens** 27.6%.

- The ratio of **central** to **non-central tokens** is 209:169. **Central tokens** thus constitute 55.3% and **non-central** ones 44.7% of **relevant tokens**. As a percentage of the total number of **message parts** (which is 522), **central tokens** make up 40.0%.

In a network of 41 chains and 42 CISs, two isolated CISs create interactive gaps. The results will be discussed in section 6.

5.6. Sentence-to-sentence continuity in the *Daptomycin Hospira* PIL

This subsection details the analytical results regarding 1) grammatical parallelisms, 2) conjunctive relations, and 3) the interaction of Theme-Rheme with Given-New patterns:

1) The analysis reveals that grammatical parallelism is a cohesive tool that is only rarely used to connect sentences in the sampled PIL. In fact, only two clear instances have been recorded, the first being sentences [4] and [5]: [4] *Read all of this leaflet carefully …* [5] *Keep this leaflet.* Both sentences are initiated with a verb in the imperative + *the leaflet* as direct object. The other instance is [88] and [89], where the exact same three words are repeated: *Tell your doctor* [...]. In [113] and [114], there is also repetition of an imperative and *this medicine* as direct object, but the parallelism is obscured by the presence of negation in the structure in [114]. Apart from these few instances of grammatical parallelism, a similar semiotic, though non-linguistic, tool should be mentioned, which is the widespread use of bullet points in the text. These occur in all sections except sections 1 and 3. Being used for enumeration (sometimes of sentences, in other cases of sentence elements), the effect is clearly that of establishing connectivity in a paragraph.

2) Like grammatical parallelism, the use of conjunctive adjuncts for cohesive effect is very infrequent. Only four cases have been registered: The item *Therefore* is used in sentence [48], encoding a relation of ‘consequence’ (see Martin 1992: 179), and is also used in [18], [19] and [110], signalling relations of ‘addition’ (see Martin 1992: 179).

3) The analysis reveals that it is the interaction of Theme-Rheme with Given-New patterns that carries the main responsibility for linking adjacent sentences in the text. Examples are:

- Sentences [15] and [16]: In [16], the Theme is a a repetition of the item *Daptomycin* from the previous sentence.

- Sentences [35] and [36]: In [36], the subordinate clause *If any of these applies to you* functions as Theme for the clause complex (multi-clause sentence) in its entirety. The Theme includes an anaphoric reference (*any of these*) to side effects and conditions mentioned in the previous sentences and a repetition of the exophoric reference to the reader (*you*). As Halliday/Hasan (1976: 13) note, although exophoric reference is a text-forming resource (because it (also) serves to establish contextual relevance by linking the text with the ‘here-and-now’ of the speech event), it is not in fact a

21 For an overview of cohesive chains and CISs identified in the control text, see Appendix 4

> *cohesive* resource since it does not tie together two *textual* elements. However, in this particular case, including a number of parallel cases in the sampled text, the item *you* occurs in both of the two adjacent sentences, which must be regarded as a textual, i.e. cohesive, link.

The overall result of the analysis is that the overwhelming majority of adjacent sentences are cohesively linked by one or several of the above three types of means. Exceptions to this trend are e.g. sentences [56] and [57]: [56] *Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.* [57] *It is particularly important that you mention the following.*[22] In [57], there is neither grammatical parallelism nor a conjunctive adverbial to establish a link with [56], and the Theme of [57] (*It*) is a cataphoric reference to the subject clause *that you mention the following*. An example of a tenuous link is the [67]-[68] pair: [67] [...] *ask your doctor or pharmacist for advice before you are given this medicine.* [68] *Do not breastfeed ...* . Whether or not the mere repetition of the imperative form (with no other structural or lexical features to support the cohesion) qualifies as grammatical parallelism must remain an open question. A closely connected question that must likewise be left open to debate is whether the implicit subjects of the imperatives (*you*) are cohesive. An argument against identifying such a link is the fact that Halliday and Hasan (1976) only recognize **ellipsis** (the actual elision of an element mentioned in a preceding sentence), but not implicitness, as having a cohesive effect.

This concludes the analysis of the *Daptomycin Hospira PIL*. Since the results reflected a degree of sentence-to-sentence continuity that is self-evidently unproblematic, no comparative analysis was found necessary to support this finding. For this reason, the control text *Seven ways* has purposely not been analyzed for sentence-to-sentence continuity.

6. Discussion and conclusion

What emerges from the above case study is most importantly a picture of strong and unproblematic text-*internal* coherence in a specimen of a genre characterized by at least potential impediments to textual unity: The Cohesive Harmony Analysis revealed that on all three parameters (**relevant-peripheral** ratio, **central-non-central** ratio and number of **interactive gaps**), the values for the *Daptomycin Hospira* PIL are high: The vast majority of tokens enter into cohesive chains, and a large majority of the cohesive tokens participate in Chain Interaction Series. According to Hasan, for a text to be deemed "unquestionably coherent" (1984: 218), **central** tokens must constitute at least 50% of the total number of tokens, which the *Daptomycin Hospira* PIL far exceeds (74.3%). Also, apart from a mere three out of 89, all CISs were found to be linked in an uninterrupted network, which proves that subtopics in the text are appropriately connected and the transition between them a properly fluid process. Further, the investigation has established a relatively high degree of integration between derived and non-derived segments, which manifested itself in the 27 CISs representing a mixture of derived and non-derived segments. Integration between original and derived elements thus does not present any problem. As for the sentence-to-sentence continuity, the analyses revealed that although the use of grammatical parallelism and conjunctive adverbials in the *Daptomycin Hospira* PIL is very limited, the interaction between Theme-Rheme patterns and Given-New is such that there is clear semantic progression from sentence to sentence in most of the text.

The contextual coherence of the PIL, on the other hand, turned out to leave something to be desired, with a number of registerial inconsistencies being in evidence. The overall conclusion is therefore the somewhat paradoxical one that the hybrid nature of such a text – especially its partial derivation from an anterior, highly specialized source – may be a significant cause of problems regarding contextual coherence, whereas hybridity is no impediment to text-internal unity. In

22 It may be worth emphasizing that in sentence [57] as a whole there are numerous cohesive links with the preceding sentence, but they do not occur in thematic, i.e. sentence-initial, position, which – apart from the absence/presence of grammatical parallelism and conjunctive adverbials – was the focus of this part of the investigation.

fact, the comparison with the control text Seven ways revealed the level of cohesive harmony to be significantly higher in the sampled PIL: In respect of both relevant-peripheral ratio, central-non-central ratio and the number of central tokens as a percentage of the total number of tokens, the values in Seven ways are significantly lower than in the PIL, which means that the latter in fact outperforms a parallel piece of lay-oriented writing found suitable for a major British quality newspaper.

Two features of the PIL may be highlighted that particularly contribute to its high level of cohesive harmony: One is the fact that some of the non-derived segments are highly repetitive, featuring a number of chain interactions that recur a very large number of times. This especially pertains to exhortations to consult a health professional for advice in case of doubt or problems in connection with the treatment. Running through the text almost as a kind of refrain, these exhortations ensure a high degree of coherence across a number of the sections. Another feature that stands out is the large number of side effects (all derived elements) mentioned in section 4: The individual items are cohesively linked, and they all participate in a CIS, which means that they all become central tokens.

When it comes to the contextual part of the coherence, a possible explanation for the problems identified (and repeatedly documented in the scientific literature) may be certain deeply entrenched generic traditions that appear to persist: At least, a simple reading of a number of other PILs reveals that with regard to the import of inappropriate, specialized wordings from the SmPC, this is indeed a recurrent phenomenon in the genre (see also Hill-Madsen 2015a), but one for which possible solutions belong to a different line of investigation.

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Appendix 1: The *Daptomycin Hospira* PIL

[1] Package leaflet: Information for the patient

[2] Daptomycin Hospira 350 mg powder for solution for injection/infusion

[3] daptomycin

[4] Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- [5] Keep this leaflet. [6] You may need to read it again.
- [7] If you have any further questions, ask your doctor or nurse.
- [8] This medicine has been prescribed for you only. [9] Do not pass it on to others. [10] It may harm them, even if their signs of illness are the same as yours.
- [11] If you get any side effects, talk to your doctor or nurse. [12] This includes any possible side effects not listed in this leaflet. [13] See section 4.

1. [14] What Daptomycin Hospira is and what it is used for

[15] The active substance in Daptomycin Hospira powder for solution for injection/infusion is daptomycin. [16] Daptomycin is an antibacterial that can stop the growth of certain bacteria. [17] Daptomycin Hospira is used in adults to treat infections of the skin and the tissues below the skin. [18] It is also used in adults to treat infections in the tissues that line the inside of the heart (including heart valves) which are caused by a bacterium called Staphyloccocus aureus and to treat infections in the blood caused by the same bacterium when associated with skin or heart infection.

[19] Depending on the type of infection(s) that you have, your doctor may also prescribe other antibacterials while you are receiving treatment with Daptomycin Hospira.

[20] What you need to know before you are given Daptomycin Hospira

[21] You should not be given Daptomycin Hospira

[22] If you are allergic to daptomycin or to sodium hydroxide or to any of the other ingredients of this medicine (listed in section 6).

[23] If this applies to you, tell your doctor or nurse. [24] If you think you may be allergic, ask your doctor or nurse for advice.

[25] Warnings and precautions

[26] Talk to your doctor or nurse before you are given Daptomycin Hospira.

- [27] If you have, or have previously had kidney problems. [28] Your doctor may need to change the dose of Daptomycin Hospira (see section 3 of this leaflet).
- [29] Occasionally, patients receiving Daptomycin Hospira may develop tender or aching muscles or muscle weakness ([30] see section 4 of this leaflet for more information). [31] If this happens tell your doctor.

[32] Your doctor will make sure you have a blood test and will advise whether or not to continue with Daptomycin Hospira. [33] The symptoms generally go away within a few days of stopping Daptomycin Hospira.

- [34] If you are very overweight. [35] There is a possibility that your blood levels of Daptomycin Hospira could be higher than those found in persons of average weight and you may need careful monitoring in case of side effects.
- [36] If any of these applies to you, tell your doctor or nurse before you are given Daptomycin Hospira.

[37] Tell your doctor straight away if you develop any of the following symptoms:

- [38] Serious, acute allergic reactions have been observed in patients treated with nearly all antibacterial agents, including Daptomycin Hospira. [39] Tell a doctor or a nurse straight away if you experience symptoms suggestive of allergic reaction, such as wheezing, difficulty breathing, swelling of the face, neck and throat, rashes and hives, fever (see section 4 of this leaflet for more information).
- [40] Any unusual tingling or numbness of the hands or feet, loss of feeling or difficulties with movements. [41] If this happens, tell your doctor who will decide whether you should continue the treatment.
- [42] Diarrhoea, especially if you notice blood or mucus, or if diarrhoea becomes severe or persistent.
- [43] New or worsening fever, cough or difficulty breathing. [44] These may be signs of a rare but serious lung disorder called eosinophilic pneumonia. [45] Your doctor will check the condition of your lungs and decide whether or not you should continue Daptomycin Hospira treatment.

[46] Daptomycin Hospira may interfere with laboratory tests that measure how well your blood is clotting. [47] The results can suggest poor blood clotting when, in fact, there is no problem. [48] Therefore it is important that your doctor takes into account that you are receiving Daptomycin Hospira. [49] Please inform your doctor that you are on treatment with Daptomycin Hospira.

[50] Your doctor will perform blood tests to monitor the health of your muscles both before you start treatment and frequently during treatment with Daptomycin Hospira.

[51] Children and adolescents

[52] Daptomycin Hospira should not be administered to children below one year of age as studies in animals have indicated that this age group may experience severe side effects.

[53] Use in elderly

[54] People over the age of 65 can be given the same dose as other adults, provided their kidneys are working well.

[55] Other medicines and Daptomycin Hospira

[56] Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. [57] It is particularly important that you mention the following:

- [58] Medicines called statins or fibrates (to lower cholesterol) or ciclosporin (a medicinal product used in transplantation to prevent organ rejection or for other conditions, e.g. rheumathoid arthritis or atopic dermatitis). [59] It is possible that the risk of side effects affecting the muscles may be higher when any of these medicines (and some others that can affect muscles) is taken during treatment with Daptomycin Hospira. [60] Your doctor may decide not to give you Daptomycin Hospira or to stop the other medicine for a while.

- [61] Pain killing medicines called non-steroidal anti-inflammatory drugs (NSAIDs) or COX-2 inhibitors (e.g. celecoxib). [62] These could interfere with the effects of Daptomycin Hospira in the kidney.
- [63] Oral anti-coagulants (e.g. warfarin), which are medicines that prevent blood from clotting. [64] It may be necessary for your doctor to monitor your blood clotting times.

[65] Pregnancy and breast-feeding

[66] Daptomycin Hospira is not usually given to pregnant women. [67] If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you are given this medicine.

[68] Do not breast-feed if you are receiving Daptomycin Hospira, because it may pass into your breast milk and could affect the baby.

[69] Driving and using machines

[70] Daptomycin Hospira has no known effects on the ability to drive or use machines.

2. [71] How Daptomycin Hospira is given

[72] Daptomycin Hospira will usually be given to you by a doctor or a nurse.

[73] The dose will depend on how much you weigh and the type of infection being treated. [74] The usual dose for adults is 4 mg for every kilogram (kg) of body weight once daily for skin infections or 6 mg for every kg of body weight once daily for a heart infection or a blood infection associated with skin or heart infection. [75] In adult patients, this dose is given directly into your blood stream (into a vein), either as an infusion lasting about 30 minutes or as an injection lasting about 2 minutes. [76] The same dose is recommended in people aged over 65 years provided their kidneys are working well.

[77] If your kidneys do not work well, you may receive Daptomycin Hospira less often, e.g. once every other day. [78] If you are receiving dialysis, and your next dose of Daptomycin Hospira is due on a dialysis day, you will be usually given Daptomycin Hospira after the dialysis session.

[79] A course of treatment usually lasts for 1 to 2 weeks for skin infections. [80] For blood or heart infections and skin infections your doctor will decide how long you should be treated.

[81] Detailed instructions for use and handling are given at the end of the leaflet.

3. [82] Possible side effects

[83] Like all medicines, this medicine can cause side effects, although not everybody gets them. [84] The most serious side effects are described below:

[85] Very rare serious side effects (may affect up to 1 in 10,000 people)

[86] A hypersensitivity reaction (serious allergic reaction including anaphylaxis, angioedema, drug rash with eosinophilia and systemic symptoms (DRESS)) has been reported, in some cases

during administration of daptomycin. [87] This serious allergic reaction needs immediate medical attention. [88] Tell your doctor or nurse straight away if you experience any of the following symptoms:

- Chest pain or tightness,
- Rash with blistering, sometimes affecting the mouth and genitals,
- Swelling around throat,
- Rapid or weak pulse,
- Wheezing,
- Fever,
- Shivering or trembling,
- Hot flushes,
- Dizziness,
- Fainting,
- Metallic taste.

[89] Tell your doctor straight away if you experience unexplained muscle pain, tenderness, or weakness. [90] In very rare cases (reported in less than 1 in every 10,000 patients), muscle problems can be serious, including muscle breakdown (rhabdomyolysis), which can result in kidney damage.

[91] Serious side effects with frequency not known [92] (frequency cannot be estimated from the available data)

[93] A rare but potentially serious lung disorder called eosinophilic pneumonia has been reported in patients given daptomycin, mostly after more than 2 weeks of treatment. [94] The symptoms can include difficulty breathing, new or worsening cough, or new or worsening fever. [95] If you experience these symptoms, tell your doctor or nurse straight away.

[96] If you experience raised or fluid-filled skin spots over a large area of your body, tell your doctor or nurse straight away.

[97] The most frequently reported side effects are described below:

[98] Common: [99] may affect up to 1 in 10 people

- Fungal infections such as thrush,
- Urinary tract infection,
- Decreased number of red blood cells (anaemia),
- Dizziness, anxiety, difficulty in sleeping,
- Headache,
- Fever, weakness (asthenia),
- High or low blood pressure,
- Constipation, abdominal pain,
- Diarrhoea, feeling sick (nausea) or being sick (vomiting),
- Flatulence,
- Abdominal swelling or bloating,

- Skin rash or itching,
- Pain, itchiness or redness at the site of infusion,
- Pain in arms or legs,
- Blood testing showing higher levels of liver enzymes or creatine phosphokinase (CPK).

[100] Other side effects which may occur following daptomycin treatment are described below:

[101] Uncommon: [102] may affect up to 1 in 100 people

- Blood disorders (e.g increased number of small blood particles called platelets, which may increase the tendency for blood clotting, or higher levels of certain types of white blood cells),
- Decreased appetite,
- Tingling or numbness of the hands or feet, taste disturbance,
- Trembling,
- Changes in heart rhythm, flushes,
- Indigestion (dyspepsia), inflammation of the tongue,
- Itchy rash of skin,
- Muscle pain, cramping, or weakness, inflammation of the muscles (myositis), joint pain,
- Kidney problems,
- Inflammation and irritation of the vagina,
- General pain or weakness, tiredness (fatigue),
- Blood test showing increased levels of blood sugar, serum creatinine, myoglobin, or lactate dehydrogenase (LDH), prolonged blood clotting time or imbalance of salts,
- Itchy eyes.

[103] Rare: [104] may affect up to 1 in 1,000 people

- Yellowing of the skin and eyes,
- Prothrombin time prolonged.

[105] Frequency not known: [106] frequency cannot be estimated from the available data

Antibacterial-associated colitis, including pseudomembranous colitis (severe or persistent diarrhoea containing blood and/or mucus, associated with abdominal pain or fever).

[107] Reporting of side effects

[108] If you get any side effects, talk to your doctor, pharmacist or nurse. [109] This includes any possible side effects not listed in this leaflet. [110] You can also report side effects directly via the national reporting system listed in Appendix V. [111] By reporting side effects you can help provide more information on the safety of this medicine.

4. [112] How to store Daptomycin Hospira

- [113] Keep this medicine out of the sight and reach of children.
- [114] Do not use this medicine after the expiry date which is stated on the carton and label after EXP. [115] The expiry date refers to the last day of the month.
- [116] Store in a refrigerator (2°C – 8°C).

5. [117] Contents of the pack and other information

[118] What Daptomycin Hospira contains

- [119] The active substance is daptomycin. [120] One vial of powder contains 350 mg daptomycin.
- [121] The other ingredient is sodium hydroxide.

[122] What Daptomycin Hospira looks like and contents of the pack

[123] Daptomycin Hospira powder for solution for injection/infusion is supplied as a pale yellow to light brown cake or powder in a glass vial. [124] It is mixed with a solvent to form a liquid before it is administered.

[125] Daptomycin Hospira is available in packs containing 1 vial or 5 vials.

[126] Marketing Authorisation Holder and Manufacturer

Hospira UK Ltd Horizon, Honey Lane Hurley

SL66RJ

United Kingdom

[127] For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

Appendix 2: Chain Interaction Series in the *Daptomycin Hospira* PIL

‘leaflet’ + ‘reading’, 6 instantiations
‘leaflet’ + ‘information’, 2
‘patient’ + ‘getting’, 2
‘patient’ + ‘consumption’, 3
‘patient’ + ‘receiving’, 7
‘patient’ + ‘administration’, 7
‘patient’ + ‘being’, 6
‘patient’ + ‘having’, 3
‘patient’ + ‘applying’, 2
‘patient’ + ‘affecting’, 4
‘patient’ + ‘reporting’, 3
‘patient’ + ‘experiencing’, 6
‘patient’ + ‘health prof.’, 24
‘patient’ + ‘body parts’, 6
‘patient’ + ‘continuation’, 2
‘med. product’ + ‘consumption’, 7
‘med. product’ + ‘administration’, 15
‘med. product’ + ‘receiving’, 4
‘med. product’ + ‘stopping’, 2
‘med. product’ + ‘interfering’, 2
‘med. product’ + ‘being’, 12
‘med. product’ + ‘containing’, 2
‘med. product’ + ‘hypersensitivity’, 3
‘med. product’ + ‘treatment’, 2
‘med. product’ + ‘consulting’, 7
‘med. product’ + ‘solution’, 3
‘med. product’ + ‘prescribing’, 2
‘solution’ + ‘administration’, 6
‘importance’ + ‘being’, 2
‘consulting’ + ‘health prof.’, 31
‘monitoring’ + ‘health prof.’, 2
‘getting’ + ‘side effects’, 3
‘symptoms’ + ‘being’, 8
‘symptoms’ + ‘experiencing’, 12
‘side effects’ + ‘being’, 54
‘side effects’ + ‘suggesting’, 3
‘side effects’ + ‘including’, 4
‘side effects’ + ‘description’, 3
‘side effects’ + ‘reporting’, 2
‘side effects’ + ‘seriousness’, 2
‘possibility’ + ‘side effects’, 3
‘listing’ + ‘leaflet’, 4
‘bacteria’ + ‘causing’, 2
‘age groups’ + ‘consumption’, 2
‘age groups’ + ‘administration’, 3
‘treatment’ + ‘infections’, 3
‘treatment’ + ‘receiving’, 2
‘treatment’ + ‘continuation’, 2
‘infections’ + ‘being’, 3
‘infections’ + ‘association’, 2
‘infections’ + ‘deciding’, 3
‘body parts’ + ‘infections’, 2
‘body parts’ + ‘symptoms’, 6
‘body parts’ + ‘experiencing’, 2
‘body parts’ + ‘conditions’, 2
‘body parts’ + ‘affecting’, 4
‘body parts’ + ‘administration’, 2
‘body parts’ + ‘side effects’, 11
‘body parts’ + ‘containing’, 2
‘knowing’ + ‘frequency’, 2
‘hypersensitivity’ + ‘being’, 2
‘thinking’ + ‘patient’, 2
‘advice’ + ‘consultation’, 2
‘development’ + ‘patient’, 2
‘development’ + ‘symptoms’, 2
‘happening’ + ‘symptoms’, 2
‘tests’ + ‘being’, 2
‘time span’ + ‘duration’, 2
‘weight’ + ‘measure’, 2
‘monitoring’ + ‘condition’, 2
‘immediacy’ + ‘consultation’, 6
‘following’ + ‘symptoms’, 2
‘deciding’ + ‘health prof.’, 4
‘newness’ + ‘symptoms’, 3
‘worsening’ + ‘symptoms’, 3
‘rareness’ + ‘side effects’, 3
‘naming’ + ‘side effects’, 2
‘frequency’ + ‘being’, 2
‘frequency’ + ‘estimation’, 2
‘data’ + ‘estimation’, 2
‘functioning’ + ‘body parts’, 3
‘functioning’ + ‘wellness’, 3
‘being’ + ‘pregnancy’, 2
‘usuality’ + ‘administration’, 3
‘using’ + ‘machines’, 2
‘measure’ + ‘being’, 4
‘below’+ ‘description’, 2
‘containing’ + ‘vial’, 2
‘availability’ + ‘data’ 2

Appendix 3: Control text

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Seven ways to minimise the risk of having a stroke

Knowing the signs and seeking early treatment can lessen damage caused by a stroke, or prevent them altogether. Here are steps you can take, from monitoring your blood pressure to keeping cholesterol in check.

Know the signs; early treatment prevents lasting damage

A stroke is the damage caused by a clot or a bleed in the brain. It is the major cause of serious long-term disability in the UK. A quarter of strokes occur in people under 65, and the damage caused ranges from minimal changes picked up on a scan, through to loss of speech, difficulty finding words and loss of power down one side of the body or face. Up to a fifth of strokes are fatal. Prompt diagnosis and treatment means a better outcome. The Fast test is useful: Face – can you smile? Is your face lopsided? Arms – can you raise them and keep them there? Speech – is it slurred or hard to understand? Time – to call 999 if you see any of these three signs. Other symptoms to urgently act on are sudden weakness or numbness on one side of the body, sudden blurred or loss of vision, unexplained confusion, a sudden fall and very severe headache.

Keep your blood pressure in check

High blood pressure is an important preventable risk factor. Have it checked at a pharmacy, GP surgery or buy your own gadget and check it yourself. In the US, pharmacists are checking and treating blood pressure in barbershops as black men are underdiagnosed, undertreated and under-represented in clinical trials. There is evidence that, in the UK, people from African-Caribbean backgrounds are more prone to high blood pressure, strokes and diabetes – although less prone to heart disease. A blood pressure monitor costs less than £25 and you should let your GP know if readings are consistently over 140/90. Lifestyle changes and, if necessary, medication work for most. Some people's blood pressure remains high despite all conventional treatment; a new technique using ultrasound to zap part of the nerve supply to the kidneys offers hope for the most tricky cases.

Check your pulse

An irregular heart rate (atrial fibrillation, AF) increases the risk of stroke because the heart can throw off small bits of debris when it goes in and out of an irregular rhythm that travel up to the brain and cause a blockage. Thinning the blood (anticoagulation) significantly reduces the risk of strokes. AF may revert to normal, regular (sinus) rhythm on its own but tends to recur and it is this fluctuation that is most dangerous. The heart can also be given an electrical shock (cardioversion), treatment to destroy the rogue electrical source of the problem (ablation) or a pacemaker to override the irregular heart beat. Some people in AF will experience palpitations, but many won't feel any symptoms. The best way to detect it is to check your pulse; we all get occasional extra beats but if the rate is consistently irregular, see your GP. There are apps to diagnose and manage AF.

Are you diabetic?

One in 16 of us is living with diabetes and an estimated 12% don't know it. Undiagnosed and undertreated diabetes is a major risk factor for stroke. You are more likely to be diabetic if it runs in your family, if you are overweight or have southeast Asian or African-Caribbean background. You can buy self-test kits, but it is cheaper and more holistic to get a complete NHS health check if you are aged 40-74 – or see your GP if you think you are at risk. If you are diagnosed with diabetes, careful management to get your blood glucose levels back to the normal range will reduce your stroke risk. If you are diabetic, your blood pressure should be kept under 140/80 and cholesterol below 5mmol/l to keep stroke risk as low as possible.

The more you smoke, the more you stroke

The more you smoke, the greater the risk, so if you can't quit, at least cut down. If you do manage to quit, your risk of stroke will be that of a never-smoker within five years. Vaping is almost certainly better than cigarettes, but there are concerns that the nicotine may still increase stiffness of arteries and the risk of heart disease and stroke.

Check your cholesterol

High levels of cholesterol in the blood can clog up arteries. If early heart disease or stroke (under the age of 60) runs in your family, you may have a genetic tendency to abnormally high cholesterol levels, even if you lead an impeccably healthy lifestyle. A one-off blood test (fasting) will tell you whether you have a problem or not. Again, you can buy a self-test kit or get it done at your GP surgery or pharmacy. To reduce the risk of heart disease and stroke, blood pressure, cholesterol and glucose levels all need to be measured; there is no point in treating one and ignoring the others. High cholesterol levels can be lowered by losing excess weight, by exercising, by cutting down on cholesterol-rich foods and, if necessary, by taking drugs such as statins; they get a bad press but they do work.

Mini-strokes

Transient ischaemic attacks (TIAs) cause the same warning signs as a stroke (see Fast above) but typically last for about half an hour resolve completely within 24 hours. However, 40% of people with a TIA will go on to have a stroke, and the risk of that is greatest if you are over 70, have high blood pressure or diabetes and have symptoms that last longer than 90 minutes. Treatments for TIAs include blood thinning drugs (anticoagulation) and careful control of the risk factors (glucose, cholesterol and blood pressure). People are often dismayed that they end up on a cocktail of drugs despite having made a complete recovery from TIA, but it really is worth popping the pills to avoid a stroke.

Appendix 4: Cohesive chains and Chain Interaction Series in *Seven ways*

60 cohesive chains have been identified altogether:

'steps/measures', 'reducing', 'risk', 'getting', 'stroke', 'knowing', 'signs/symptoms', 'earliness', 'treatment', 'damage', 'causing', 'preventing', 'being', 'the reader', 'monitoring', 'blood pressure', 'controlling', 'keeping', 'cholesterol', 'body parts', 'countries', 'health institutions', 'healthcare professionals', 'visiting', 'losing', 'apparatus', 'purchasing', 'patient groups', 'experiencing', 'heart disorder', 'management', 'glucose (level)', 'time span', 'lasting', 'medication', 'taking', 'having', 'carefulness', 'risk factor', 'age', 'years', 'quitting', 'cutting down', 'moreness', 'greatness', 'normality', 'diagnosis', 'diabetes', 'running', 'heart rate', 'regularity', 'highness', 'necessity', 'test', 'speech', 'weight', 'family', 'proneness', 'measuring', 'rhythm'.

The following Chain Interaction Series have been identified:

'reducing' + 'risk'
'getting' + 'stroke'
'stroke' + 'risk'
'causing' + 'stroke'
'stroke' + 'being
'knowing' + 'signs/symptoms'
'signs/symptoms' + 'being'
'experiencing' + 'signs/symptoms'
'earliness' + 'treatment'
'the reader' + 'blood pressure'
'the reader' + 'heart rate'
'the reader' + 'being'
'the reader' + 'purchasing'
'the reader' + 'smoking'
'the reader' + 'risk'
'the reader' + 'having'
'monitoring' + 'blood pressure'
'keeping' + 'blood pressure'
'health care institutions' + 'monitoring'
'visiting' + 'health care professionals'
'purchasing' + 'apparatus'
'patient groups' + 'being'
'patient groups' + 'having'
'patient groups' + 'experiencing'
'patient groups' + 'getting'
'heart disorder' + 'risk'
'time span' + 'lasting'
'taking + 'medication'
'having' + 'blood pressure'

‘carefulness’ + ‘management’
‘risk factor’ + ‘being’
‘the reader’ + ‘quitting’
‘moreness’ + ‘smoking’
‘greatness’ + ‘being’