

## Chapter 7

# The Legal Nature of Informal International Law

## A Legal Theoretical Exercise

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### A. Introduction: avoiding a paradox

One of the most difficult questions in the informal international lawmaking (IN-LAW) project as reflected in the present book, concerns the legal nature of the norms. In fact, during debates on the nature of IN-LAW it was precisely its legal nature that was questioned. As described in the first Chapter of this book international lawmaking is believed to be informal when it dispenses with certain formalities traditionally linked to international law. These formalities may have to do with output, process, or the actors involved. In our view, it is the notion of output informality in particular that raises the question to which extent informal law can be regarded as law. The purpose of the present contribution is simple: it aims to find out how we can keep informal international lawmaking within the realm of law. We will do so on the basis of a legal theoretical exercise, using insights developed in the so-called institutional legal theory (ILT). Admittedly, we do not treat the issue as an open question and merely look for arguments which would allow IN-LAW to be seen as part of the legal world, a presumption that lies beneath the IN-LAW project.

Thus, we leave aside the question whether or not it matters to bring something within the legal realm, a question that was addressed by Pauwelyn in the previous Chapter. Other contributions in this Project extensively referred to the existing body of literature on informal and soft law. We are aware of the existing debates, but chose to start from scratch by using a different method. In doing so we hope to add a new dimension to the discussion on the legal nature of IN-LAW, albeit that the direction we propose remains to be developed further.

In the previous Chapter Pauwelyn pointed to the idea that not all law or legal norms impose or proscribe specific behaviour or legally binding rights and obligations. Normativity

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must not be confused with imperativity. And, quoting Lalande, he argues: ‘The normative is a genus with two main species: the imperative and the appreciative.’<sup>2</sup> As we will see, this notion lies at the back of our analysis as well. Indeed, the debate between those who argue in favour of a bright line between law and non-law<sup>3</sup> and those arguing for the existence of a grey zone<sup>4</sup> is well-known. In practice the divide may not always be clearly visible: ‘for the bright line school something may be law; for the grey zone school it may not be law (or fall in the grey zone between law and non-law) but still have legal effects, with little practical difference between the two approaches.’<sup>5</sup> Yet, large parts of the debate have been devoted to the establishment of one or more criteria to decide what makes an instrument law (be it sanctions, formalities, intent, effect, substance, or belief). Thus, depending on how one distinguishes between law and non-law, IN-LAW output may or may not be part of international law. If formalities or intent matter, a lot of the informal output would not be law. If, in contrast, effect or substantive factors decide, it would be law.

Taking a somewhat different stance, d’Aspremont points to the fact that the empiricism of the IN-LAW project and comparable projects ‘has impelled their promoters to loosen their legal concepts and abandon a strict delineation of their field of study. In that sense [. . .], confronted with a pluralisation of norm-making at the international level, international legal scholars have come to pluralise their concept of international law’.<sup>6</sup> It is the normative impact of the variety of informal output that has led to perhaps a ‘legal overstretch’. However, such a de-formalization does come at a price and it is not made clear why lawyers so desperately wish to capture the new phenomena as international law. ‘[W]hy not coming to terms with the interdisciplinary aspects of such an endeavour and recognize that, even as international legal scholars, we can zero in on non-legal phenomena without feeling a need to label them law?’

Yet, the question in the present contribution is whether it is not possible (or perhaps even more logical) to view these *prima facie* non-legal phenomena as law. One of the obstacles seems to be found in the use of the term non-binding, which is often used to label the IN-LAW output. Thus, in his chapter Flickiger reminds us of the widely accepted idea that non-binding norms may have legal effects, which makes them relevant for lawyers. At the same time, however, the non-binding nature of norms is reflected in the fact that ignoring them would not lead to a formal infringement and hence not to legal consequences: ‘No offence is committed when a non-binding act is breached.’<sup>7</sup>

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<sup>2</sup> A Lalande, *Vocabulaire Technique et Critique de la Philosophie* (Presses Universitaires de France, Paris 1993), entry: ‘Normatif’.

<sup>3</sup> eg P Weil, ‘Towards Relative Normativity in International Law?’ (1983) 77 *American Journal of International Law*, 413, 415, 417–18; and J Klabbers, ‘The Redundancy of Soft Law’ (1996) 65 *Nordic Journal of International Law* 167, 181.

<sup>4</sup> eg RR Baxter, ‘International Law in “Her Infinite Variety”’ (1980) 29 *International and Comparative Law Quarterly*; and O Schachter ‘The Twilight Existence of Nonbinding International Agreements’ (1977) 71 *American Journal of International Law* 296.

<sup>5</sup> Chapter 6 (Pauwelyn) in this Volume.

<sup>6</sup> Chapter 9 (d’Aspremont) in this Volume.

<sup>7</sup> Chapter 19 (Flickiger) in this Volume.

Indeed, the non-binding or non-legally binding nature which is said to characterize the IN-LAW output may be seen as a reason to treat it as an extra-legal phenomenon. Yet, output informality sheds a sharp light on (1) a threatening paradox, and (2) an important terminological ambiguity, which are both associated with this notion. To avoid the paradox, the ambiguity has to be resolved.

The looming paradox can be paraphrased with the following question: How can one use the term international lawmaking to designate forms of cross-border cooperation which produce norms that admittedly do not constitute international law stemming from any recognized legal source?

This question has also been at the heart of the debates in ILT. Over the years these debates led to a broader picture of what could count as ‘law’. What ILT basically does is combine legal positivism with the institutionalism that can be found in the linguistic philosophy of John Searle. According to Searle (1969) speaking is more than just uttering sounds; it is both a regulated and a regulating activity. This is reflected in the possible relations between, what he calls, ‘word’ and ‘world’. Depending on the type of speech act the world adapts itself to the words that are uttered in its context, or vice versa. But, it is equally possible that there is no relation between word and world or even that there exists a mutual adaptation. This way language does not merely convey content (as a locutionary act), but the speaker also performs an action in saying something (an illocutionary act). Translated to legal theory this means that this illocutionary act consists in the creation of legal rights and duties, once it is performed by a competent actor. Both the creation of ‘legal acts’ and the existence of a ‘legal competence’ form important elements in our analysis.

As stated above, the purpose of this contribution is to capture informal international lawmaking under the umbrella of law and our exercise should be read with that objective in mind. We believe that ILT may be helpful in opening new avenues for those who are not prepared to *a priori* disregard the ‘increasingly rich normative output’ as part of the international legal order as it does not fit into ‘old bottles labelled “treaty”, “custom”, or (much more rarely) “general principles”’.<sup>8</sup> In the following section we will first focus on two interpretations of the term legally binding (section B). This will be followed by a representation of the classification of legal acts as developed in ILT (section C). Section D will follow up on this classification and will present types of norms that can be issued by informal legal instruments. In section E we will make an empirical excursus into the documents of a body which is allegedly involved in informal international lawmaking: the Global Harmonization Task Force (GHTF). The outcome of these analyses will be used to answer the question whether informal bodies, such as the GHTF, can issue non-mandatory legal acts (section F). Finally, in section G, we will point to a number of implications of our approach.

## **B. Legally binding: obligating versus committing**

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<sup>8</sup> J Alvarez, *International Organizations as Law-Makers* (Oxford University Press, Oxford 2005).

The ambiguity we referred to in the previous section hinges on the meaning of the term legally binding. This term can be interpreted in two ways. In the first interpretation, legally binding means legally obligating. If this interpretation is adopted, the paradox is simply avoided by the conclusion that IN-LAW is not law at all because it simply lacks the defining feature of being legally obligating. However, avoiding the paradox in this way comes at a high price, for precisely all the problems that have triggered the research project are thus defined away and not solved.

In the second interpretation legally binding means what we would term legally committing. Legally committing does include 'legally obligating' but encompasses much more. To give an example of domestic as well as international legal norms that are committing but not obligating in character, we mention norms ascribing legal personality to organizations. Although the quality legal personality may entail all kinds of legal obligations, it is itself not a legally binding norm in the sense of obligating. Yet, it is a legally binding norm in the sense of committing, that is to say, of having the purpose that the entire legal community involved ought to accept the organization in question as an agent capable of having and expressing a will and, therefore, of being made responsible for social behaviour controlled by that will.

When the interpretation of legally binding as legally committing is adopted, the paradox is avoidable by arguing that although informal international lawmaking does not produce international law in the sense of obligating legal norms, it does produce international law in the sense of committing legal norms. It follows that IN-LAW is made by means of legal instruments that are not intended to be binding in the sense of obligating but exclusively in the sense of committing. Accordingly, we term such instruments exclusively committing legal instruments.

The primary task is to fill in the term exclusively committing legal instrument. We propose to interpret the term instrument as a document that expresses norms purporting to cause a social practice of their general acceptance and, thereby, becoming social facts themselves. An instrument is legal when the social practice of general acceptance of the norms it expresses is pursued by their transformation into elements of the legal system regulating the community. In an interpretation of legally binding as legally obligating the category of norms fit to be expressed in a legal instrument would in principle be restricted to mandatory norms. (Possibly, room could be made for permissive norms, as the negations of mandatory norms, and power-conferring norms, as the sources of mandatory and permissive norms, but that would be it.) If we wish to interpret legally binding as legally committing, we must widen the range of items termed legal norms. We propose to use a wide concept of legal norms including not only mandatory legal norms but all institutional facts—as distinguished from brute, physical facts—which are the case by virtue of legal rules, such as marriages, corporations, money, pollution equivalents, nature reserves, and so on. In this wide interpretation, a legal instrument commits a legal community in case the norms—institutional facts—it brings to expression constitute valid elements of the legal system regulating that community.

This may be illustrated by way of example. A marriage certificate is an instrument, namely a document expressing the norm—institutional fact—of the marriage between two natural persons with the aim that these two will for all purposes be treated as a couple by the

community in which they live. The marriage certificate is a legal instrument, because general acceptance of the persons as a couple is pursued by making their marriage a valid element of the legal system of their society. The certificate is committing in so far as the legal validity of the marriage requires its realization in the form of a social practice of dealing with the two as having a marital relation. As we will see in our empirical excursus (section E), this is exactly what many of the informal acts purport.

A second example will serve to illustrate the difference between binding law in the sense of obligating and in the sense of committing, respectively. A deed of gift is an instrument expressing a gift of one particular party, the giver, to another particular party, the donee. According to Dutch law, a gift is a contract without consideration (for nothing) to the effect that the giver shall enrich the donee at the expense of his own capital (Article 7:175(1) Civil Code). The deed of gift is a legal instrument because general acceptance of the giver's duty to keep his promise is pursued by transforming it into an obligation that enjoys validity under Dutch civil law. The deed is binding in the sense of obligating in so far as the giver must transfer the given asset to the donee, and binding in the sense of committing in so far as the legal validity of the obligation requires it to be socially treated as a debt of the giver to the donee.

The preceding exposition justifies the following hypothesis: if parties to informal instruments intend these instruments to constitute sources of non-mandatory international law, then the legal norms issuable by such instruments are restricted to types other than mandatory norms.

The question then arises what other types of legal norms there are. International law doctrine does not comprise a systematic survey of such types. This survey can, however, be provided by ILT, which is on this score inspired and informed by general speech act theory. In section C, an outline of speech act theory and of a typology of legal acts derived from it in ILT will be presented.

### **C. Towards a classification of legal acts**<sup>9</sup>

The following section aims to provide a summary of the arguments used in ILT to classify legal acts and to reveal that the distinction between binding and non-binding may be less helpful in determining what belongs to the legal order. We will try and present the arguments step by step. Section C(1) is used to outline the main theoretical arguments of speech act theory (and may be skipped by the impatient reader); in section C(2) we will come to the classification of all possible legal acts.

Legal norms deriving their validity from a legal instrument have been issued. To issue a legal norm is to declare it legally valid. To that end the text of the instrument is enacted in some more or less formal procedure. Declaring a norm legally valid, however, does not suffice to confer legal validity on it. For the declaration to be successful, appeal must be made to a valid legal norm determining that the party making the declaration is capable of

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<sup>9</sup> DWP Ruiter, 'Legal Powers' in SL Paulson and B Litschewski Paulson (eds), *Normativity and Norms, Critical Perspectives on Kelsenian Themes* (Clarendon Oxford, 1998) 471–91, 472–83.

conveying legal validity to the first-mentioned norm by following the prescribed procedure. The capacity to convey legal validity to a norm by enacting it is termed a legal power. Legal powers are ascribed to subjects by a power-conferring legal norm. Power-conferring legal norms specify acts whose performance by empowered authorities yields valid legal norms. We term acts specified by power-conferring norms as legal acts.

The relationship between power-conferring legal norms and legal acts is a specific case of the general relationship between what has been called declarative speech acts and constitutive rules in speech acts theory. Following John Searle, a constitutive rule has the form ‘*x* counts as *y* in context *c*’. In this formula, *x* stands for a specification of a speech act while *y* represents a specification of the type of result performances of that act have in the institutional context *c*, of which the constitutive rule is a part. Searle’s famous example is the constitutive rule of promising: ‘Promising counts as the undertaking of an obligation to do some act.’<sup>10</sup> It does not take a great deal of imagination to recognize a constitutive rule, too, in the provision of the Dutch Civil Code incorporating into the Dutch legal system the concept legal act: ‘A legal act requires a will that is directed to a legal effect and has been divulged in a declaration.’ This can be rephrased as: ‘Declaring a will directed to a legal effect (*x*) counts as performing a legal act (*y*) in the Dutch legal system’ (Article 3:3).

Legal acts are specific speech acts. The consequences of this conclusion deserve closer scrutiny. With this in mind, we should like to invite attention to some key concepts in speech act theory. These concepts are drawn from the work of Searle and Vanderveken.<sup>11</sup>

### (1) Speech act theory

As we have seen, speech acts have an internal purpose or illocutionary point: the speaker performs an action in saying something. Since, according to Searle and Vanderveken, there are five illocutionary points, speech acts divide into five classes:<UL>

*Assertive speech acts*: The purpose internal to asserting is to provide a faithful representation of a part of reality. This assertive illocutionary point is distinctive of assertive speech acts. Assertive speech acts have a word-to-world direction of fit, for performances of assertive speech acts achieve success of fit only if their content is true—that is to say, it corresponds to reality. The phrase ‘it is raining’ achieves success of fit just in case it is raining.

*Commissive speech acts*: The purpose internal to promising is to undertake an obligation to perform some act. This commissive illocutionary point is distinctive of commissive speech acts. Commissive speech acts have a world-to-word direction of fit, for performances of commissive speech acts achieve success of fit only if the speaker sees to it that reality is changed to correspond to their contents. The phrase ‘I shall come’ achieves success of fit just in case I come.

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<sup>10</sup> J Searle, *Speech Acts. An Essay in the Philosophy of Language* (Cambridge University Press, Cambridge 1969) 63.

<sup>11</sup> J Searle and D Vanderveken, *Foundations of Illocutionary Logic* (Cambridge University Press, Cambridge 1985).

*Directive speech acts:* The purpose internal to ordering is to oblige someone else to perform some act. This directive illocutionary point is distinctive of directive speech acts. Directive speech acts, too, have a world-to-word direction of fit, for performances of them achieve success of fit only if the addressee sees to it that reality is changed to correspond to their contents. The imperative ‘come!’ achieves success of fit just in case the ordered person comes.

*Expressive speech acts:* The purpose internal to congratulating is to communicate one’s pleasure in the achievement, success, or good fortune of another. This expressive illocutionary point is distinctive of expressive speech acts. Expressive speech acts have a null or empty direction of fit, for their performances serve to express attitudes of speakers. Although it is presupposed that that which the attitudes are about exists, the attitudes themselves are part of the speaker’s mind and not of reality. In the exclamation ‘happy birthday!’ it is assumed that it is the addressee’s birthday. However, the conveying of congratulations relates not to reality but to a psychological state of the speaker.

*Declarative speech acts:* The purpose internal to appointing a committee is to transform a collection of persons into a single unitary body by presenting them as thus transformed. This declarative illocutionary point is distinctive of declarative speech acts. Declarative speech acts have a double direction of fit, for performances of them change reality in conformity with their contents by presenting reality as thus changed. The declaration ‘I appoint you chairman’ achieves success of fit when the appointed person becomes chairman by virtue of the declaration.

Of the five classes of speech acts distinguished above, declarative and commissive speech acts are the most problematic. With respect to assertive, directive, and expressive speech acts, reality is conceived of as standing apart from the contents of performances of them. That is to say, reality is not changed by making assertions. Demands must be met to achieve success of fit on the directive illocutionary point; in other words, something must actually be done in order to change reality according to the contents of performances of directive speech acts. And in the case of performances of expressive speech acts, reality is taken for granted. By contrast, declarative and commissive speech acts appear to relate to a kind of reality that can be changed through performances of them. Performances of declarative speech acts produce facts by declaring them existent. In the same way, performances of commissive speech acts produce obligations on the part of the speakers.

For the purpose of the present contribution, it is important to establish how language can change reality. In order to answer this question, one must appreciate that Searle and Vanderveken use the term world to refer indiscriminately to two wholly different kinds of reality. The first kind we shall term a real world. A real world is a part of reality as it is. The second kind we shall term an institutional world. An institutional world is the meaning-content of an institutionalized normative system. A meaning-content of this kind offers an overall picture of a real world with an eye to bringing about a social practice in which that picture is actualized. Thus, institutional worlds aim at effectuating congruent real worlds.

Real worlds stand just as apart from performances of declarative and commissive speech acts as they do from performances of speech acts of the other three classes. Declarative and commissive speech acts can be performed in order to add elements to the institutionalized normative systems to which they belong and in this way to change the institutional world that

the system constitutes. The mode of existence of these elements, however, is no more than *validity* within an institutional system. Just as something must be done to adapt reality to a request, for example, so something must be done to adapt a real world to a performance of a declarative or commissive speech act. To that end, social practice must change in accordance with the contents of performances of these speech acts.

Elements created by performances of declarative speech acts are institutional facts. Actually, institutional facts are not facts at all; rather they are verbal presentations of facts enjoying validity in the institutionalized normative system of a community. From the validity of such verbal presentations it follows that they purport to be made true by general acceptance. General acceptance takes the form of a social practice that can be interpreted as resulting from a common belief in the facts presented by the verbal presentations. For example, John and Mary's giving their daughter the name Louise is a performance of a declarative speech act creating the institutional fact that their daughter's name is Louise. Creating this institutional fact is tantamount to achieving success of fit on the double direction of fit that is characteristic of the declarative illocutionary point. It is only the first step, however, for the institutional fact that the daughter's name Louise is meant to create a practice of calling the daughter Louise. The practice of calling her Louise forms the social realization of the institutional fact that her name is Louise.

Performances of commissive speech acts, too, produce institutional facts. These institutional facts, however, are of the special kind usually called 'obligations'. An obligation is a valid verbal presentation of an order. An order, in turn, is the result of ordering—that is, telling someone to do something under threat. The standard example is the gunman's order to hand over money. His order achieves success of fit on the directive illocutionary point if his victim is obliged to do as he is told. Plainly, a promise is not the result of a promisor's telling himself to do something under threat. Yet, a promise binds the promisor. How is this possible? The puzzle is solved when one sees that promises are valid presentations of orders to the promisors that are established by the promisors themselves. Being institutional facts, promises purport to be made true by a social practice that can be interpreted as resulting from a common belief that promisors are obliged to keep their promises. Thus, although we cannot order ourselves, we are quite capable of obligating ourselves.

Declarative and commissive speech acts are performable only in the context of institutionalized normative systems that include their respective constitutive rules. By contrast, assertive, directive, and expressive speech acts are normally used in a purely linguistic way. For example, the speech acts marked by the verbs assert, warn, and congratulate can all be performed by simply using natural language. However, each of these three classes also includes speech acts whose performance must take place in the context of an institutionalized normative system. The umpire's authoritative assertion 'you are out' establishes the institutional fact of your being out. The sergeant's command to the soldier to dig a foxhole establishes the soldier's obligation to dig a foxhole. The letter of condolence of a head of State to the government of another State on the occasion of the death of the latter State's head of State establishes the institutional fact of the sympathy of the former State with the bereavement of the latter State. The objectives of performances of speech acts in the three examples are similar to the objectives of performances of declarative and commissive speech acts. The umpire's decision purports to be made true by being generally accepted as truthful.



The sergeant's command has the purpose of being made true by the military community's acceptance of the fact that the soldier is obligated to dig a foxhole. The letter of condolence of the head of State aims at being made true by international recognition of the sympathy it expresses.

Assertive, directive, and expressive speech acts can be either purely linguistic or declarative forms. In contrast, commissive speech acts can only be declarative forms. The reason is that commissive speech acts are declarative forms belonging to a larger class of speech acts that also include purely linguistic forms. This larger class consists of all speech acts that can be performed in order to express speakers' purposes of taking certain courses of conduct, irrespective of whether or not the speakers are obligated to taking them. The speech act performance marked by the phrase 'I'll see whether I can come tomorrow' achieves success of fit on the world-to-word direction of fit when I turn up the next day. The phrasing is so chosen, however, that I am not obligated to come tomorrow. The class of speech acts to which commissive speech acts belong shall be termed purposive speech acts.

In fact, non-obligating speech acts are not the only declarative forms of purposive speech acts. Non-committal declarative forms occur, too. For example, a certain State formally threatens another State with lawful retaliation. Under public international law the threat is a valid presentation of the first State's purpose of taking some action to the detriment of the latter State. Recognition of the threat by the international community does not, however, obligate the first State to carry out the threat.<sup>12</sup>

These amendments to Searle and Vanderveken's general classification lead to a classification of declarative speech acts that can at the same time be read as the classification of legal acts we are looking for in order to make sense of the plurality of formal and informal international legal output.

## **(2) A classification of legal acts<sup>13</sup>**

We can now make this more concrete by classifying the possible legal acts that would follow the speech acts. Examples can easily be found of all of them in most legal systems. We chose examples from the European Union legal system. The classification reveals the rich variety of possible legal acts and will help us later on to regard IN-LAW as being part of the legal system. In fact, no one is likely to deny the legal nature of all of these types of acts.<UL>

*Exclusively declarative legal acts:* The constitutive rule of an exclusively declarative legal act determines that a performance of the act brings about a legally valid presentation of a state of affairs. The presentation's legal validity commits the legal community to a social practice that can be interpreted as resulting from a common belief that the state of affairs is the case.

Example: 'Citizenship of the Union is hereby established. Every person holding the nationality of a Member State shall be a citizen of the Union. Citizenship of the Union shall be additional to and not replace national citizenship.' (Article 20 Treaty on the Functioning of the European Union.)

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<sup>12</sup> Ruiters, (n 8) 479–80.

<sup>13</sup> (n 8).

*Self-obligating legal acts:* The constitutive rule of a self-obligating legal act determines that a performance of the act brings about an obligation of the performer, that is, a legally valid presentation of an order to the performer to take a certain course of conduct. The presentation's legal validity commits the legal community to a social practice that can be interpreted as resulting from a common belief that the performer is obliged to take the course of conduct.

Example: 'The Union shall accede to the European Convention for the Protection of Human Rights and Fundamental Freedoms.' (Article 6 Treaty on European Union.) (The term commissive legal act is avoided to prevent confusion with the term 'committing' in the sense employed here.)

*Purposive legal acts:* The constitutive rule of a purposive legal act determines that a performance of the act brings about a legally valid presentation of the performer's purpose to take a certain course of conduct. The presentation's legal validity commits the legal community to a social practice that can be interpreted as resulting from a common belief that the performer indeed has that purpose.

Example: 'Resolved to implement a common foreign and security policy including the progressive framing of a common defence policy.' (Preamble of the Treaty on European Union.)

*Imperative legal acts:* The constitutive rule of an imperative legal act determines that a performance of the act brings about an obligation of one or more other persons, that is, a valid presentation of an order to them to take a certain course of conduct. The presentation's legal validity commits the legal community to a social practice that can be interpreted as resulting from a common belief that the addressed person or persons are obliged to take the course of conduct.

Example: 'The High Representative shall represent the Union for matters relating to the common foreign and security policy. He shall conduct political dialogue with third parties on the Union's behalf and shall express the Union's position in international organisations and at international conferences.' (Article 27 (2) Treaty on European Union.)

*Hortatory legal acts:* The constitutive rule of a hortatory legal act determines that a performance of the act brings about a valid presentation of a non-obligating incitement to another person to take a certain course of conduct. The presentation's legal validity commits the legal community to a social practice that can be interpreted as resulting from a common belief that the other person is given a serious incentive to take the course of conduct.

Example: 'The European Council urges parties to the [Treaty on Conventional Armed Forces in Europe] to take the necessary steps in order to achieve its entry into force.' (European Council in Lisbon, 1992.)

*Expressive legal acts:* The constitutive rule of an expressive legal act determines that a performance of the act brings about a valid presentation of an attitude about something. The presentation's legal validity commits the legal community to a social practice that can be interpreted as resulting from a common belief in that attitude.

Example: 'The European Union expresses its grave concern by the situation unfolding in Libya. We strongly condemn the violence and use of force against civilians and deplore the repression against peaceful demonstrators which has resulted in the deaths of hundreds of

civilians.’ (Declaration by the High Representative Catherine Ashton on behalf of the European Union on Libya, 23 February 2011.)

*Assertive legal acts:* The constitutive rule of an assertive legal act determines that a performance of the act brings about a valid representation of a state of affairs. The representation’s legal validity commits the legal community to a social practice that can be interpreted as resulting from a common belief in its truthfulness.

Example: ‘We take note of the fact that the European Union is ready to play an active role in the bilateral or regional talks.’ (Article 2.4 Concluding Document on the Stability Pact in Europe, annexed to Council Decision 94/367/CFSP.).</UL>

## **D. Types of norms issued by legal instruments**

In order to establish how IN-LAW could be seen as law, we proposed the classification as a tool to be used in finding an answer to the question: What other types of legal norms than mandatory norms are distinguishable? This question had become relevant in light of the hypothesis that parties to informal international instruments do not intend the legal norms expressed in such instruments to be binding in the sense of obligating. We have reached the point at which we can give the following answer: Norms that are only fit to be expressed in formal international legal instruments are: valid obligations resulting from self-obligating or imperative legal acts.

Norms that are possibly fit also to be expressed in informal international legal instruments are:

- (1) valid institutional facts resulting from performances of exclusively declarative legal acts;
- (2) valid purposes resulting from performances of purposive legal acts;
- (3) valid incitements resulting from performances of hortatory legal acts;
- (4) valid attitudes about facts resulting from performances of expressive legal acts;
- and
- (5) valid propositions resulting from performances of assertive legal acts.

This short analysis reveals that norms in informal instruments may be expressed in a number of ways.

### **(1) The functions of different types of legally valid norms**

It is important to make a distinction between the function of the legal validity of a norm and the function of the norm itself. Legal validity as used here means having existence within the legal system. As announced earlier, we build our arguments on the assumption that the norms at stake are valid (exist) within the international legal system. The function of a norm’s legal validity is to bring about its general acceptance as a social fact by the legal community. Valid institutional facts produced by performances of exclusively declarative legal acts have only this function. For instance, legally valid legal persons have as their only function that they will be accepted as existent social subjects. Legally valid norms of other types have additional

functions that are determined by their contents. The function of legally valid obligations is to coerce addressees to taking certain courses of conduct. A debt has the function of coercing the debtor to pay the creditor. The function of legally valid purposes is to disclose non-committal intentions. Many government proposals disclose unenforceable intentions of policy-makers. The function of legally valid incitements is to convince addressees of taking a certain course of conduct. Formal pieces of advice are meant to bring the advised parties to heed them. The function of legally valid attitudes is to disclose states of mind about something. Formal excuses are meant to convey to others one's regret about something unpleasant experienced by them for which one takes responsibility. The function of legally valid propositions is to establish a fact authoritatively. A proclamation of the state of emergency establishes authoritatively the occurrence of a serious crisis.

## **(2) Provisional observations**

### *(a) Kind of norms to be expected in informal legal instruments*

If we assume, again for the sake of argument, that informal international legal instruments ought to be only employable to issue valid norms of international law, provided that they shall not obligate, one might expect the types of norms to be found in such instruments to be restricted to legally valid international facts, purposes, incitements, attitudes, or propositions. Whether this is actually the case can only be established by a detailed investigation of the contents of existing informal international legal instruments. As long as this investigation has not taken place, we can distil out of the characterizations of IN-LAW as guidelines, standards, declarations, and the like to be found in the available literature, that we may expect only sporadically legally valid attitudes. However, we might expect standards with the form of valid institutional facts (eg international measuring standards), valid purposes (eg memoranda of understanding), valid incitements (eg non-mandatory guidelines), and valid propositions (eg established facts).

### *(b) Legal powers of informal law-makers*

Since it is issued in legal instruments, also IN-LAW is enacted law, that is to say, law that is valid by virtue of its having been declared valid. This means, however, that the parties that take responsibility for the declaration must have the legal capacity. One of the key issues is how such a capacity could be normatively grounded. We will return to this question in section F.

### *(c) Two ways of expressing legal norms*

We have concluded that informal international legal instruments can only include norms of certain types. This does not mean, however, that any international legal document expressing norms that are restricted to these types is a source of IN-LAW. Generally spoken, legal documents can express legal norms in two fundamentally different ways. As for the first way, we may imagine an international commission of experts proposing in a report on some subject matter a draft-regulation with the recommendation that nation-States promulgate the regulation expressed in the draft as uniformly formulated domestic law. The commission

report expresses norms in the first way. However, we would not term the draft a legal instrument, for it lacks one crucial feature: it has not been issued, that is, its content has not been declared legally valid by appeal to an international legal norm conferring on the commission the power to issue the regulation in question. In order to convey legal validity to the regulation use is made of power-conferring norms that enjoy legal validity within the legal orders of the nation-States. The second way in which legal documents can express legal norms is that of declaring them legally valid with an appeal to a power-conferring norm. The document becomes, then, an international legal instrument whose issuance is the performance of a legal act. Herewith, the question becomes: Is it true that, similar to formal international law, IN-LAW is also issued (enacted) by appeal to a power-conferring norm of international law?

### **E. An IN-LAW example: essential principles of safety and performance of medical devices (GHTF)**

#### **(1) In search of legal acts**

Under sub-heading (a) of the preceding provisional observations we argued that detailed investigations of existing informal international legal instruments in order to establish the types of norms appearing in them are in place. In the debate on IN-LAW the guidance documents of the Global Harmonization Task Force (GHTF) are frequently mentioned as prominent examples of informal international legal instruments.<sup>14</sup> It is, therefore, worthwhile to subject one of those documents to a brief investigation of this kind to test whether the answers we seek can be provided in this way. According to its own description, GHTF is a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the USA, Canada, Japan, and Australia. The GHTF has members of different types: founding members, regional members, participating members, and liaison bodies. Here we restrict ourselves to the founding members, that is, the regulatory authorities and industry representatives from the countries mentioned above. The founding members have declared that they will take the appropriate steps to implement GHTF guidance and policies within the boundaries of their legal and institutional constraints. Regulatory authorities agree to promote the GHTF documents within their own jurisdictions and, in the course of time, seek convergence of regulatory practices. Regulators hold the ultimate responsibility for this implementation. According to the GHTF, the primary way in which it achieves its goals is through the production of a series of guidance documents that together describe a global regulatory model for medical devices. These documents are prepared by study groups of the GHTF and approved by its Steering Committee. On 20 May 2005 the GHTF endorsed a final document, authored by GHTF Study Group 1, with the title *Essential*

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<sup>14</sup> A Berman, 'Informal International Lawmaking in Medical Products Regulation' (forthcoming 2012).

*Principles of Safety and Performance of Medical Devices* (hereafter: *Essential Principles*).<sup>15</sup> In the GHTF's own words: 'The document is intended to provide *non-binding* [italics by GHTF] guidance to regulatory authorities for use in the regulation of medical devices, [. . .]'. It is this document that will serve us as a case for testing the hypothesis that assessments of the contents of existing informal international legal instruments can be helpful in solving the fundamental problems facing us.

Since the document is intended to provide guidance to regulatory authorities, these are the primary addressees of the norms laid down in it. A regulatory authority (RA) is defined as a government agency or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal instruments. (Source—EU-Canada MRA.) The norms addressed to them take the form of requirements. These are subdivided in two categories, ie general requirements that apply to all medical devices (six requirements) and the design and manufacturing requirements of safety and performance, some of which are relevant to each medical device. The latter category is in turn divided into 11 subcategories: chemical, physical, and biological properties (six requirements); infection and microbial contamination (10 requirements); manufacturing and environmental properties (four requirements); devices with a diagnostic or measuring function (six requirements); protection against radiation (nine requirements); requirements for medical devices connected to or equipped with an energy source (seven requirements); protection against mechanical risks (five requirements); protection against risks posed to the patient by supplied energy or substances (three requirements); protection against risks posed to the patient for devices for self-testing or self-administration (three requirements); information supplied by the manufacturer (one requirement); performance evaluation including, where appropriate, clinical evaluation (two requirements). The manufacturer selects which of the design and manufacturing requirements are relevant to a particular medical device, documenting the reasons for excluding the others. The Regulatory Authority and/or Conformity Assessment Body may verify the decision during the conformity assessment procedure. Both the General Requirements and the Design and Manufacturing Requirements are drafted to a uniform pattern. We shall give an example taken from each (sub)category with references to the paragraph numbers in the *Essential Principles*.

*(a) General requirements*

'Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, when applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or safety of patients, or the safety and health of users, or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a higher level of protection of health and safety.' (5.1.)

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<sup>15</sup> Essential Principles of Safety and Performance of Medical Devices, Global Harmonization Task Force, Doc. GHTF/SG1/N41R9:2005, 20 May, 2005.

*(b) Design and manufacturing requirements*

(1) Chemical, physical, and biological properties

‘The devices should be designed and manufactured in such a way as to reduce as far as reasonable practicable and appropriate the risk posed by substances that may leach or leak from the device.’ (5.7.5)

(2) Infection and microbial contamination

‘Devices intended to be sterilised should be manufactured in appropriately controlled (eg environmental) conditions.’ (5.8.8)

(3) Manufacturing and environmental properties

‘If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should be safe and should not impair the specified performance of the devices. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use.’ (5.9.1)

(4) Devices with a diagnostic or measuring function

‘Where the performance of devices depends on the use of calibrators and/or control materials, the traceability of values assigned to such calibrators and/or control materials should be assured through a quality management system.’ (5.10.3)

(5) Protection against radiation

‘Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as practicable and appropriate.’ (5.11.3.1)

(6) Requirements for medical devices connected to or equipped with an energy source

‘Devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.’ (5.12.3)

(7) Protection against mechanical risks

‘Devices should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.’ (5.13.1)

(8) Protection against risks posed to the patient by supplied energy or substances

‘Devices for supplying the patient with energy or substances should be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.’ (5.14.1)

(9) Protection against risks posed to the patient for devices for self-testing or self-administration

‘Such devices should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in user’s

technique and environment. The information and instructions provided by the manufacturer should be easy for the user to understand and apply.’ (5.15.1)

(10) Information supplied by the manufacturer

‘Users should be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the internal performance, taking account of their training and knowledge. This information should be easily understood.’ (5.16.1)

(11) Performance evaluation including, where appropriate, clinical evaluation

‘All data generated in support of performance evaluation should be obtained in accordance with the relevant requirements applicable in each jurisdiction.’ (5.17.2)

(c) *‘Should’ instead of ‘shall’*

In all provisions cited above use is made of the term ‘should’ instead of ‘shall’, the latter being the grammatical form generally employed in statute law to express mandatory legal norms. Only in the following three provisions the term ‘must’ is used.<NL>

(1) General requirements

‘The benefits must be determined to outweigh any undesirable side effects for the performances intended.’ (5.6.)

(2) Infection and microbial contamination

‘Where a device incorporates substances of biological origin, the risk of infection must be reduced as far as reasonably practical and appropriate by selecting appropriate sources, donors and substances and by using, as appropriate, validated inactivation, conservation, test and control procedures.’ (5.8.2.)

(3) Manufacturing and environmental properties

‘Devices must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.’ (5.9.4)</NL>

We have found no reasons given for these exceptions to the general use of the term ‘should’, so that we assume that they are minor irregularities that tend to occur often in processes of collective drafting. If this assumption is correct, we may conclude that all ‘Principles of Safety and Performances of Medical Devices’ laid down in the GHTF document are given a non-mandatory form. In other words, they are not drafted with the objective of creating obligations. Accordingly, issuance of these norms cannot be conceived of as a performance of a self-obligating or an imperative legal act.

When we look at the preceding classification of legal acts and the corresponding typology of legal norms, the possibility presents itself of conceiving of the issuance of such norms as a performance of a purposive or a hortatory legal act in order to establish legally valid purposes or incitements. This possibility raises in turn the question which agents are able to perform such acts.

**(2) A crucial question: a legal instrument?**



The GHTF document can be interpreted in either of the two ways mentioned under section D(2)(c). If the sentences in the document that express the requirements for medical devices are interpreted as draft provisions, which are intended to be transformed into legal provisions of the domestic law of each of the countries participating in the GHTF, it follows that the GHTF does not intend the document itself to establish international law. It is then not a legal instrument. On the other hand, if the sentences are interpreted as legal provisions in their own right, it follows that the GHTF does intend the document to establish non-obligating international law. In that case we have to do with an exclusively committing legal instrument of the kind mentioned in the beginning of this Chapter.

Now, what may be the interpretation the GHTF has adopted? The passages quoted in section E(1) are ambiguous. The declaration of the Founding Members that they will take the appropriate steps to implement GHTF guidance and policies gives the impression that the GHTF is more than a mere supplier of non-committal draft-provisions. On the other hand, the declaration that the GHTF documents are intended to provide non-binding guidance to regulatory authorities for use in the national regulation of medical devices suggests that we have to do with a facilitating text, not with a legal instrument.

However, the employment of 'should' in the document only makes sense, if this is interpreted as a legal instrument that is intended to express non-obligating international law. We have seen that the GHTF produces its guidance documents with the explicit purpose that the participating national regulatory authorities will take the appropriate steps to implement them in their own domestic legal systems. Implementation takes place in the form of an obligating national regulation of medical devices. It is highly plausible that, if the GHTF had only the intention that its guidance documents would serve as facilitating non-committal model texts, it would have given the documents a mandatory form. This would have been achieved by replacing 'should' by 'shall'. On the other hand, employment of 'should' in the GHTF document is completely understandable, if we assume that the GHTF interprets its guidance documents as providing purposes or incentives addressed to the participating regulatory agencies, which are valid under international law and, therefore, urge the authorities in question formally to take the appropriate steps to transform these purposes and incentives into valid legal obligations within their respective national legal systems.

Let us for the sake of argument assume that the GHTF actually has the intention that its guidance documents do produce purposes or incitements that are valid under international law and thereby commit the international legal community to accepting them as social facts. This assumption leads immediately to the question of where the legal power of the GHTF to create such international legal norms would come from. This is probably the most important question to be dealt with here. We shall make an attempt at answering it starting from the current legal doctrine concerning the sources of validity of 'posited' mandatory international law.

## **F. Sources of posited mandatory international law**

As far as 'posited' ('written') mandatory international law is concerned, we might distinguish two kinds of legal sources: (1) treaties, and (2) decisions by organs of international

organizations. The validity of treaty law rests ultimately on the universal recognition of the rule *pacta sunt servanda*. The validity of obligating norms posited by decisions of organs of international organizations rests on treaty-based norms conferring on such organs powers to enact norms of the kind in question. They are at the same time the only kinds of sources for conveying validity to posited mandatory norms of international law. Since the guidance documents are no treaties and the GHTF is not an international organization, it is beyond any doubt that the GHTF lacks the legal power to issue mandatory international law. Must the same conclusion be drawn with respect to non-mandatory purposes or incitements?

This brings us to the question of what non-mandatory purposes and incitements exactly are. An answer to this question can be given with the aid of an analysis of obligations as peremptory or exclusionary reasons that is based on the respective works of the legal theorists Herbert Hart and Joseph Raz.

### **(1) Legally valid exclusionary and non-exclusionary reasons for action**

Obligations can be conceived of as special reasons for action. Hart explicates the difference between ordinary reasons for action and obligations by making a comparison between giving a command on the one hand and making a wish or giving a warning on the other. Making a wish or giving a warning serves to communicate a reason for action with the intention that this reason be included in the addressee's own deliberation on the action in question. By contrast, a reason for action as communicated by an act of commanding is intended to preclude any further independent deliberation from the side of the addressee. Accordingly, Hart terms obligations 'peremptory reasons'.<sup>16</sup> Raz provides a more intricate analysis of the 'intended peremptory character' of reasons of the kind that are conveyed by acts of commanding.<sup>17</sup> To that end, he introduces a distinction between first-order and second-order reasons for action. Making use of this distinction, Raz argues that an obligation is both a first-order reason to perform an act and a second-order reason not to act for conflicting reasons. In order to clarify what this exactly means, we must briefly pay attention to some basic notions used in Raz's analysis. Grossly simplifying, one might say that, to Raz, a first-order reason for action of a person is a fact that makes that he ought to act in a certain way. A first-order reason for action is not necessarily decisive, however, for there may exist conflicting reasons. Two first-order reasons for action conflict if one of them makes that the person in question ought to act in a certain way and the other makes that the person in question ought not to act in that way. First-order reasons have a dimension of strength, which means that in the case of conflict stronger reasons override weaker reasons. In the absence of second-order reasons for action, the principle for determining what action ought to be taken could be that one ought to do whatever one ought to do on the balance of reasons. However, second-order reasons for action do play an important role. A second-order reason for action is any reason to act for a reason or not to act for a reason. Of special interest for us is the last-mentioned subcategory: second-order reasons not to act for a reason. Second-order reasons of this category Raz terms

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<sup>16</sup> HLA Hart, *The Concept of Law* (Oxford University Press, Oxford 1982) 253.

<sup>17</sup> J Raz, *Practical Reasons and Norms* (Hutchinson, London 1990) 38 ff, 101; and DWP Ruiter, *Legal Institutions* (Kluwer Academic Publishers, Dordrecht Boston London 2001) 42–8.

‘exclusionary reasons’. Examples of exclusionary reasons given by Raz are a command of an officer to a subordinate and a promise of a husband to his wife. In either case there may be reasons against acting in the way indicated by the command and the promise, respectively. However, the command, as well as the promise serves as an exclusionary reason, that is, a reason that stands in the way of acting on the balance of all pertinent reasons.

On Raz’s analysis, a certain individual’s legal obligation to take a certain course of conduct is a valid reason on account of which the individual ought not only to take the course of conduct in question but also to refrain from weighing this reason against reasons for not taking the course of conduct.

Raz’s analysis of obligations provides a point of departure for a characteristic of non-mandatory purposes or incitements. To him the mandatory character of obligations is equivalent with their being exclusionary reasons for action. This involves that non-mandatory legal norms, such as legally valid purposes and incitements, are similar to obligations in so far as they constitute legally reasons for action but differ from obligations in so far as they do not constitute reasons for not acting for conflicting reasons. This leads to the following characteristic of non-mandatory purposes or incitements:

A legally valid purpose or incitement of persons to take a certain course of conduct is a legal norm on account of which the persons ought to take that course of conduct, provided that there are no other reasons for them not to take that course of conduct.

## **(2) The nature of GHTF requirements**

Returning to the GHTF, we noted that it lacks the legal power to issue mandatory international legal norms. It is unclear, however, whether or not it also lacks the power to issue certain non-mandatory international legal norms. Actually, this is exactly one of the questions to be dealt with in the IN-LAW project.

Raz’s conception of a legal obligation as a legally valid combination of a first-order reason to take a certain course of conduct and a second-order reason not to refrain from taking it for conflicting first-order reasons makes it possible to distinguish legal obligations on the one hand and legal purposes and incitements on the other in such a way that the implications of according a legal power to issue non-mandatory international legal norms to the GHTF can be determined more precisely. In order to do so, we take as an example the above quoted Design and Manufacturing Requirement 5.12.3: ‘Devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.’

We have seen that the Founding Members of the GHTF, that is regulatory authorities or industry representatives from Europe, the USA, Canada, Japan, and Australia, have declared that they will take the appropriate steps to implement GHTF guidance and policies within the boundaries of their legal and institutional constraints. Furthermore, regulatory authorities have agreed to promote the GHTF documents within their own jurisdictions. Imagine the situation that in one of these countries requirement 5.12.3 has been implemented in the form of the statutory legal norm: ‘Devices where the safety of the patients depends on an external power supply shall include an alarm system to signal any power failure.’ This norm is addressed to manufacturers of medical devices as an exclusionary reason for them to include the indicated

alarm systems. In other words, manufacturers are given a legally valid reason to include alarm systems in combination with a legally valid reason to disregard any reason not to include alarm systems. At the same time, the norm is addressed to the regulatory authority of that country as an exclusionary reason to apply it in conformity assessment procedures, which means that the authority is given a legally valid reason to declare devices without alarm systems unfit and to reject any reason brought forward for omitting such systems.

Recall that we have assumed that the GHTF intends the requirements in the guidance document to constitute valid norms of international law. Given this assumption, the example makes clear that the requirements take the form of reasons for action that are non-exclusionary under international law but are fit to be rendered exclusionary under national law by competent legal authorities of participating countries. The key question then becomes: How can the legal power of the GHTF to issue non-exclusionary reasons for action enjoying validity under international law be founded?

### **(3) In search of a foundation**

Our search for an answer to this question starts with an investigation of what ‘giving a first-order reason for action’ means in ordinary terms. In everyday parlance giving a first-order reason for action takes place in two main forms. The first main form is that of giving a first-order reason for one’s own future action(s). Examples are: planning and threatening. The second main form is that of giving a first-order reason for the action(s) of others. Examples are: advising, recommending, and warning. Performances of speech acts of both main forms produce reasons for action that, together with eventual concurring reasons, are to be weighed against conflicting reasons, so that the final decisions on the course of conduct to be taken is made, as Raz puts it, on the balance of reasons.

When speech acts, performances of which produce first-order reasons for action, are performed in a purely linguistic way, they result in everyday communications, such as, for the first main form, plans and resolutions, and, for the second main form, warnings, advices, and recommendations. However, speech acts of both main forms may also take a declarative shape, for example, that shape of purposive or hortatory legal acts.

We saw that self-obligating as well as imperative legal acts are productive of legally valid exclusionary reasons for action. The difference between the two kinds of legal acts is that performances of legal acts of the former kind establish legally valid exclusionary reasons for action by the performers, whereas performances of legal acts of the latter kind establish legally valid exclusionary reasons for action by others. In like manner, both purposive and hortatory legal acts are productive of legally valid non-exclusionary reasons for action with the difference that performances of legal acts of the former kind establish legally valid non-exclusionary reasons for action by the performers, whereas performances of legal acts of the latter kind establish legally valid non-exclusionary reasons for action by others. Legally valid exclusionary reasons for action are termed ‘legal obligations’. Accordingly, we propose to term legally valid non-exclusionary reasons for action ‘legal exhortations’.

It is the intention of the GHTF that the requirements it has issued serve as non-exclusionary reasons for action to be used in designing and manufacturing medical devices. Hence, manufacturers of such devices are the primary addressees. This means that the

question investigated can be rephrased as follows: How can a legal power of the GHTF to produce legally valid exhortations of manufacturers of medical legal devices be grounded on international law? At the same time the requirements are addressed to the national medical device regulatory authorities in order that they be applied by them in conformity assessment procedures. This means that here the question can be rephrased as follows: How can a legal power of the GHTF to produce legally valid exhortations of medical device regulatory authorities be grounded on international law?

In order to answer these questions it is worthwhile to compare the function of legal obligations on the one hand and that of legal exhortations on the other. A legally valid obligation puts an end to the freedom of its addressee to choose between taking or not taking a certain course of conduct. By contrast, a legally valid exhortation does not alter the freedom of choice of its addressee, but aims to decrease the effort the addressee has to make in justifying his choice in favour of one of the options. On the one hand, a legally valid obligation of a manufacturer to include an alarm system excludes his option to omit it and thus puts an end to his freedom of choice. On the other hand, a legally valid exhortation to include an alarm system does not affect the manufacturer's freedom of choice, for he can still omit the alarm system, but it offers a ready-made reason for justifying the costs of including it. The justificatory function of legal exhortations becomes even more manifest, when we recall that GHTF requirements are also addressed to medical device regulatory authorities in order that they be applied by them in conformity assessment procedures. A legally valid exhortation addressed to them that they require from manufacturers that alarm systems be included, while not impairing the authorities' discretion, forms an important reason justifying negative conformity assessments of devices lacking an alarm system.

The justificatory function of legal exhortations leads to the heart of the question of how a legal power of the GHTF to perform hortatory legal acts with medical device manufacturers and regulatory authorities as their addressees can be founded. For to be fitted to justify a choice between taking or not taking a certain course of conduct, an exhortation must rest on the recognized knowledge and expertise of the performer of the hortatory legal act producing it. For instance, the authority of a formal advice of a medical examiner to declare a person disabled depends above all on his recognized knowledge and expertise as a specialized physician and only derivatively on his formal position as a medical officer. It seems that the authority of all formal advices, recommendations, and the like are in the final analysis reducible to their foundations in forms of special knowledge or expertise that addressees do not have themselves but need for making proper choices. In advices and recommendations coming from advisory boards the notion of personal knowledge and expertise is replaced by that of consensus on the best available knowledge and expertise where a difference of opinions proves to be possible.

Here we touch possibly on the key term indicating the answer to the question of how to found a legal power of the GHTF: consensus on the best available knowledge and expertise. For where can we find the best available knowledge and expertise for designing and manufacturing medical devices? The answer is: within the professional community consisting of the medical device manufacturers and regulatory authorities themselves. And how can consensus be reached? We may answer: that was what the GHTF was created for. However, attractive as this direction for finding a solution to the key problem dealt with in this Chapter

may appear to us, we are well aware of the fact that these two positive answers are still a far distance from really grounding a legal power of the GHTF to issue exhortations that are directly valid under international law.

## **G. Implications**

The tentative outcome of our analysis is that consensus within an international professional community on the best available knowledge and expertise can offer a foundation for legal powers to issue exhortations enjoying validity under international law.<sup>18</sup> Acceptance of this idea would, however, have implications that require further investigation. In the first Chapter to this book a useful distinction is made between three kinds of informality of international lawmaking, namely, output informality, process informality, and actor informality. The present Chapter concentrates on output informality. However, acceptance of our basic idea would at once raise pertinent questions concerning process and actor informality. In conclusion, a few examples are mentioned. When is an international professional community so distinctly organized that it can be considered to be capable of expressing consensus on the best available knowledge and expertise? Which parties are to be included in the group of persons and organizations invited to participate in processes of consensus seeking? What kinds of procedures ought to be followed in such processes? Does the 'status' of the body matter and can it also be created and ultimately accepted informally (leading perhaps to a fourth dimension of informal international lawmaking: institutive informality)?

It is perhaps preferable to leave all these difficult questions unanswered as long as the basic idea is still awaiting broader discussion.

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<sup>18</sup> M Barnett and M Finnemore, *Rules for the World: International Organizations in Global Politics* (Cornell University Press, Ithaca, London 2004) 24.