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Legitimacy, credibility and responsibilities of the (big) European third-party certifiers

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Abstract

This paper's first aim is to put the light on a specific and understudied category of European experts, the so-called notified bodies, which are involved in the regulation of industrial products markets and risks; and to focus on the few ones among them which grew dramatically since a few decades so to become "big third party certifiers", and transnational regulatory intermediaries (Levi-Faur, Starobin, 2014). The question of the responsibilities of these bodies came out recently, when one of them, the renowned German certifier TÜV Rheinland, has been sued by victims in the French breast implants PIP scandal framework, and sentenced by a French (civil) Court for "having failed in its obligations of vigilance and caution". In the paper, I analyze the Tribunal de Commerce de Toulon enquiry and ruling so to point out two complementary research issues. On one hand, French judges, as they had to understand as precisely as possible the certification procedures they had to judge, put the emphasis on the need of deeper scholarly investigations inside certification "black boxes", - the role of subsidiary companies inside certification processes for example. On the other hand, I would argue simultaneously that the PIP case should be analyzed with a more holistic approach: not only the big third party certifier, but also other rule-intermediaries (accreditation bodies), or rule-makers themselves could *a priori* be considered as partly responsible of this multilevel regulation failure.

Introduction

The construction of Europe has led to the emergence of a large population of regulatory intermediaries (Levi-Faur, Starobin, 2014) – the so-called notified bodies – involved in the opening up of markets to industrial products. These bodies are responsible for issuing certificates of conformity with the "essential safety requirements" that industrial products must meet in order to obtain the CE marking needed in order to enter the Internal Market. In the first section of this paper, I will summarise how the notified body category was created and outline the complex regulatory architecture that grew up within this framework. In a

second, shorter section, I will attempt to characterise a specific subcategory of notified bodies and show how the “notification system” has helped some private certifiers to becoming what I call the “big European third-party certifiers”, entities that can accurately be described as transnational regulatory intermediaries. In the third section of this paper, I will focus on the French Poly Implant Prothese (PIP) scandal – involving thousands of victims all over the world – which hit the headlines in January 2012 because of what was gradually revealed as a failure in CE marking processes, in this case in the “medical devices” sector. This case is particularly worth studying because the notified body/big third-party certifier which issued compliance certificates for PIP was sued by victims and ultimately sentenced by a French court for having failed in its “obligations of vigilance and caution”. This was the first time a third-party certifier, as a notified body, was found liable for a failure to meet its obligations. I will argue that the trial itself has provided valuable insight into certification procedures, and into the transnational European regulatory process that has been in application for decades for the marketing of European industrial products. Not only does it demonstrate the potential liability of certifiers, it is also a first step towards a wider review of the possible responsibilities of numerous other actors. In this respect, therefore, the PIP case may be seen as symptomatic of a global regulatory failure.

1- The European “New Approach” and the “notification system”

The “notification system”, which has been in use for several decades, was a means of overcoming the consequences of the historical difficulties encountered by Member States and the European Commission in genuinely opening up the European market to industrial products. The original problem was that, until the 1970s, during the early days of the Common Market project, Member States would ban foreign European industrial products from their own markets on the grounds of safety factors embedded in existing national systems of standardisation. In consequence, differences between these national systems became “technical barriers to trade” that had to be removed. After a few unsuccessful attempts, the Commission devised a very specific response to this “practical” problem, a solution approved by a vote of the European Council: the New Approach to Technical Harmonisation and Standardisation (1985) was greeted as a method that both removed these technical barriers to trade and ensured the safety of products entering the Internal Market. Industrial products would be admitted across Europe if and only if they met “essential safety requirements” set out in sector-specific European Directives. Producers could choose whether

or not to rely on “harmonised (European) standards”, drawn up by the European Committee for Standardisation, in order to demonstrate that their products met the compulsory “essential safety requirements” set out in the corresponding Directive. This distinctively European solution – a two-level approach combining compulsory regulation and voluntary standards – has been extensively studied and discussed by scholars (Egan, 1998, Frankel & Höjbjerg, 2007, Schepel, 2005, Cafaggi & Janczuck, 2010). However, an important aspect that has received less scholarly attention is that, under certain directives and in the case of some specific safety requirements, producers are obliged to refer products to third-party certifiers. This second aspect – the requirement on producers in certain “sensitive” sectors to employ third-party bodies to assess compliance with certain essential safety requirements (by testing and inspecting products or production) – had been another source of conflict between Member States in the 1980s. Some Member States would not recognise the competence of third-party bodies from other Member States, with the result that producers had to submit their products to a new set of tests and inspections every time they wanted to sell in a “new” country, with the result that the original conflicts between Member States were simply displaced (Egan, 2001, p 126). This secondary problem gave rise to a rather complex “notification system”, set out in the so called Global Approach (¹), which reflects the political relations between Member States and the European Commission (Galland, 2013):

- When a new “New Approach” Directive (X), in an industrial sector to be liberalised, is adopted by the Council and the Parliament, each Member State draws up a list of bodies (in its own territory) that it considers competent to assess whether the products corresponding to this Directive comply with the essential safety requirements relating to it. Then each Member State *notifies* this list to the Commission and the other Member States (hence the expression “notified body”)
- The Commission simply combines these different national lists into one, which becomes the list of Directive X “European notified bodies” and is published in the Official Journal of the European Union and on the Commission website.⁽²⁾
- Every producer which needs a third-party certifier, under Directive X, for a product conformity assessment, may call on any notified body on the European list for this service; so, for example, a French producer may call on a German, British, or now a

¹ Council Resolution (December 1989) on the Global Approach: Conformity Assessment and Council Decision (July 1993) on Modules Conformity Assessment Procedures and CE marking used in Technical Harmonisation Directives.

² This website is called NANDO: New Approach Notified and Designated Organisations.

- Polish notified body, provided that its name figures on the Commission's list. Directive X has therefore opened up a (new) European market for certification.
- Once a producer has received the required conformity certificates from the notified body for a given product, that product may be marked "CE" and sold on the European market.
 - Member States must guarantee the competences of the bodies notified to the Commission, both at the time of original designation and over time, in the course of their day-to-day activities. This is a point constantly reiterated by the Commission, which has also tried to convince Member States – or "Notifying Authorities" in the New Approach jargon – to set and adopt common criteria for these purposes.
 - Observing that, in the main, this was not happening, and still with the aim of harmonising practices between Member States, the Commission increasingly recommended that notified bodies should be accredited by an independent accreditation body. This recommendation became quasi compulsory in 2008 ⁽³⁾, when the Parliament and the Council, following discussions, ruled that each Member State should have a single accreditation body ⁽⁴⁾.

See "Recapitulative Schema" (annex)

The "notification system" established in Europe is an interesting and distinctive example of the Tripartite Standard Regime (TSR) model (Loconto, Busch, 2010). On the one hand, it is a very specific and even borderline example of this model, because it mixes public and private regulations and the activities of voluntary and compulsory entities: producers and certifiers are free to decide whether or not to use "harmonised standards" to show the conformity of products with "essential requirements", but assessment by the notified bodies, if needed, is compulsory. On the other hand, the three components of the TSR model are clearly present here: the drafting of "essential safety requirements" and possibly of harmonised standards to satisfy them; the creation of a European certification market for each sector or Directive; a specific method of organising accreditation, with the establishment of a single national

³ Decision (EC) of the European Parliament and Council on a common framework for the marketing of products, July 9, 2008, 768/2008.

⁴ Regulation (EC) of the European Parliament and Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Council Regulation (CE) No. 339/93, July 9, 2008, 765/2008.

accreditation body within each Member State and the requirement for notified bodies to be accredited by “their” national accreditor.

Although the New Approach and its sequels affect a significant proportion of trade within the European Union (⁵), and is ultimately the primary means whereby markets and risks are regulated in Europe, the “notification system” has until now received little scholarly attention. Only one academic publication (Cetik, 2010) has sought to describe and classify the now large population of European notified bodies (⁶). Such a classification is hard because, since they are initially designated by Member States, the origins and (domestic) legal status of notified bodies may be very disparate. Some are public bodies, some private, others a mix of public and private; some are very small and operate within a single sector, others much bigger and operating across several.

2- The big European private third-party certifiers

Within the large population of notified bodies, a few have become big third-party certifiers. Although this phenomenon has not yet been systematically studied, I would argue that the notification system itself – together with the decisions of a few Member States within this framework – has contributed to the dramatic growth of certain notified bodies in recent decades. The story of this enlargement can be summed up as follows.

Before the construction of Europe, many European States used to rely on domestic private bodies to help them enforce national regulations, which were too technical for national civil servants to oversee directly (e.g. the lift or cableway sectors). When those sectors were liberalised at European level through New Approach Directives, Member States naturally designated and notified their old technical subcontractors as their best experts. Very quickly, those with expertise in multiple domains took advantage of the notification system to become notified by their respective Member States for a growing number of sectors and Directives. In the 1990s, the strongest of them set up subsidiaries and/or bought up small local notified bodies in other European Member States, either in order to diversify their certification portfolio or to reduce competition. They also used their status as notified bodies to sell other voluntary certifications (ISO 9000, or “green” certifications) to producers they met in their

⁵ Around 30 directives covering a large array of sectors (toys, construction products, lifts...) have so far been passed.

⁶ Some 1800 across all sectors.

CE marking role ⁽⁷⁾. This is how a few private technical bodies, embedded in their respective Member States, have expanded to European scale since the 1980s.

Today, however, the “playing field” for the big European private third-party certifiers is not just Europe. Here again, some of them have used the “notification system” to grow, this time at global level. One example is the “pressure equipment” sector, where the French Government has helped France’s biggest third-party certifier, Bureau Veritas, to develop its activities in China and in other Asian countries.

Under Directive 97/23 ⁽⁸⁾ which defines and liberalises this sector, pressure equipment covers a wide variety of industrial products, ranging from pressure cookers to pipes and steam generators used in industrial and nuclear plants. This is a big and lucrative market for producers and certifiers alike: in this high-risk sector, conformity assessment procedures require pressure tests and resistance trials, which are costly. Europe used to be a big producer of pressure equipment, but in recent years the majority of world production has been in Asia, specifically China. However, when Chinese pressure equipment producers want to export to Europe, how do they obtain the compulsory conformity certificates they need to be able to mark CE their products ⁽⁹⁾

Like other big private European certifiers, Bureau Veritas operates in China through a subsidiary with a local workforce. When it comes to CE marking for pressure equipment, BureauVeritas China cannot itself become a notified body because, legally, it is a Chinese company. However Bureau Veritas Group and the French Government found a solution. Following a recent decision by the Minister of Ecology ⁽¹⁰⁾, Bureau Veritas China staff are allowed to “work under” the French notified Bureau Veritas Group in the pressure equipment sector, subject to procedures set out in the above-mentioned *arrêté ministériel* (ministerial order). The results of the audits or tests carried out by Bureau Veritas China staff in Chinese factories must be sent to France, so that it is Bureau Veritas France, as a French notified body, which decides whether or not to issue a certificate of conformity. In this case, the *arrêté ministériel* also includes a specific requirement that this certification body should be audited

⁷ These assumptions are based on interviews of notified bodies (2012)

⁸ The Pressure Equipment Directive (PED) was initially passed by the European Parliament and Council on May 29, 1997 (N° 97/23/EC)

⁹ At this point, we would remind the reader that a CE marked product does not need to have been manufactured in Europe; it only has met the essential safety requirements set out in the relevant New Approach Directive. However, some essential safety requirements have to be checked by a (necessarily European) notified body.

¹⁰ Ministerial order of 22 March 2012, in application of amended Decree No. 99-1046 of 13 December 1999, providing authorisation of a body relating to pressure equipment. This ministerial order concerns not only BV China, but also other BV subsidiaries in Japan, India, or Malaysia.

by the French Accreditation body, COFRAC (¹¹). COFRAC not only has to verify the quality of the information exchanged between Bureau Veritas China and Bureau Veritas Group, but also has the task, if necessary, of auditing Bureau Veritas China *in situ*.

The “notification system”, sometimes with the encouragement of certain Member States, has contributed significantly to the growth of some European third-party certifiers. These technical bodies, which were and still are anchored in different European Member States, have grown dramatically in recent decades, both by diversifying their portfolios and by expanding, through subsidiaries, not just across Europe but worldwide (¹²).

Generally speaking, they have retained or developed a wide range of activities that they exercise either with public authorities or with private producers (inspection, control, advice). However, the increasing preponderance in these activities of certification relating either to voluntary standards or compulsory regulations – as in the case of the New Approach and CE marking – makes them transnational regulatory intermediaries, whose legitimacy, credibility and perhaps responsibilities need to be questioned and assessed.

Recently, a scandal that began initially in France but quickly spread worldwide, provided an opportunity for such questioning to be undertaken.

¹¹ Comité Français pour l’Accréditation (founded in 1994)

¹² Let us quote a few of the best-known of them: Société Générale de Surveillance (SGS), which originates in Switzerland – paradoxically not in the EU – has around 30 subsidiaries/notified bodies in various Member States, and a worldwide workforce of around 80,000; Bureau Veritas (France), around 25 subsidiaries/notified bodies in other Member States, more than 60,000 staff worldwide; TÜV Rheinland (Germany), 55 subsidiaries/notified bodies in Europe, around 20,000 staff worldwide. All the figures given have been estimated by the author on the basis of internet websites.

3- The PIP crisis: a chance to open the certification “black box”

3-1 The scandal in the media

The “PIP scandal” burst in the French media very early in 2012. Journalists found out and reported that the French company Poly Implant Prothese (PIP), located in La Seyne-sur-Mer, near Toulon (France), had for years been selling very poor quality breast implants, in France and all around the world, though these products carried CE labelling. More specifically, the owner and director of PIP had acknowledged that, for decades, he had been substituting a “home-made” silicone for the compulsory CE-compliant product in the day-to-day manufacturing of PIP breast implants. As a result, a significant number of women had suffered problems with their PIP breast implants: implants either burst or leaked, resulting in irritation and inflammation, and in many cases ultimately requiring removal (¹³). This was a serious scandal for two other reasons: first the number of possible “victims” was high, around 30 to 40,000 in France but probably 10 times more in Europe and worldwide (particularly in South America); second, the industrial products had been granted CE marking on the basis of conformity certificates issued by a (big) German third-party certifier, TÜV Rheinland.

As regards this second point, the French mainstream media began by accusing the French pharmaceuticals regulator AFSSAPS for failing to inspect PIP (¹⁴), which led to a public statement by AFSSAPS that, although it was responsible for the safety of medicines in France, it was not directly responsible for the safety of “medical devices”, a sector that includes breast implants, which in Europe are regulated through other, less familiar mechanisms (the New Approach).

3-2 The medical devices sector in Europe

In fact, since 1993, the medical devices sector in Europe has been regulated by a New Approach Directive (¹⁵). The Directive itself defines medical devices as “any instrument, apparatus, appliance, software, material or other article,..., to be used specifically for diagnostic and/or therapeutic purposes and necessary for their proper application, intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap; investigation, replacement or modification of the

¹³ A possible link to cancer was suggested by the media at the time, but has not been confirmed since.

¹⁴ Agence Française de Sécurité Sanitaire et des Produits de Santé, which became (2012) Agence Nationale des Médicaments et des Produits de Santé (ANSM)

¹⁵ Several to be precise, the main one concerned here being Directive 93/42 on Medical Devices.

anatomy or of a physiological process; ...”¹⁶), and implicitly distinguishes medical devices from pharmaceuticals, which are regulated through a network of public agencies, either European¹⁷ or national¹⁸), which issue pre-market authorisations (PMA) for pharmaceuticals before they are allowed to enter the European market.

This distinctive European approach – the difference in regulation between pharmaceuticals and medical devices – has long been highlighted (Altenstetter, Permanand, 2007; Lobmayr, 2010; Altenstetter, 2013) by scholars and criticised by some practitioners, especially as it is a distinction not made everywhere in the world: in the USA, the Federal Drug Administration (FDA) is responsible for issuing PMA for both pharmaceuticals and at least the most sensitive medical devices.

Nevertheless, as ever with a New Approach Directive, Directive 93/42 spawned a series of notified bodies (around 80 at this time in Europe), notably responsible for conducting conformity assessments for essential safety requirements on “sensitive or “risky” medical devices, such as breast implants or pacemakers. It is worth noting briefly here that the activities of the notified bodies in this sector have long been a matter of debate and controversy – more than in any sector liberalised under a New Approach Directive – but this is a point to which we will return later. For the moment, we will remain with the PIP affair.

3-3 Origins of and main responses to the PIP crisis

The PIP problem did not emerge for the first time in January 2012, when reports appeared in the French and worldwide media. As various investigations (journalistic, administrative and judicial) gradually revealed, questions about the quality of PIP breast implants – and about the viability of the company itself – were not new. Among other things, there is the fact that the FDA, after an unannounced inspection of PIP in the year 2000, had banned the distribution of its breast implants in the United States (¹⁹); that since 2005, several individual French and British victims had sued PIP’s director for supplying faulty implants; and that the final alarm had been raised in France in March 2010, when AFFSAPS decided to remove PIP breast implants from the market, both because of an unusual rate of device failure in patients and because AFFSAPS itself had observed the silicone substitution, following an inspection they had carried out at the company. In the meantime (March 2010), PIP, which for a time had been the world’s third largest exporter of implants, went into liquidation.

¹⁶ Council Directive 93/42 concerning medical devices, June 14, 1993, Art. 1.

¹⁷ European Medicines Agency (EMA)

¹⁸ Such as AFFSAPS

¹⁹ Not at this stage because of silicone substitution, but for other reasons (lack of competence of PIP staff)

Following this – and as these facts gradually emerged in France and around the world – victim groups began to institute proceedings against PIP owner and director, Jean-Claude Mas. These actions resulted in a number of trials (beginning in 2010 or 2011), in France and in other affected countries. For the media, the principal action was the criminal trial at the Tribunal Correctionnel de Marseille, where JC Mas was ruled to have deliberately substituted the silicones and in 2013 was sentenced to a four-year prison term for fraud ⁽²⁰⁾. It should be added that, at this same trial, the German certification agency, TÜV Rheinland, lodged its own action, alongside that of the victims, arguing that JC Mas had systematically deceived its auditors by providing false information.

Among the many different proceedings and trials associated with the PIP scandal, in France and elsewhere, one – relating to another set of questions also raised by the media – stood out: even if J.C Mas was a crook, how could he have fooled his own auditor/certifier so easily and for so many years? If a fraud on this scale is possible, what is the purpose of the certifier? And if a notified body/certifier has a purpose, what exactly are its duties and responsibilities? In the next section, I will concentrate on a civil trial at the Tribunal de Commerce de Toulon, which took place following proceedings instituted both by a number of breast implant distributors ⁽²¹⁾ and by some 1700 women from France and abroad who had received PIP breast implants. This action was taken against the certifier, and more specifically against two linked enterprises: TÜV Rheinland France and TÜV Rheinland Germany.

3-4 **The Tribunal de Commerce de Toulon: enquiry and ruling**⁽²²⁾

I will begin at the end: in its ruling of November 14, 2013, the Tribunal de Commerce de Toulon held the German certifier TÜV Rheinland liable for having “failed in its obligations of vigilance and caution” in the PIP affair. It imposed on TÜV a fine of some €3000 per victim, amounting to a total of around € million. TÜV immediately appealed against the sentence, so another trial is expected to take place in the coming years. This was the first time a certifier, as a notified body, had been brought to court, and of course the first time it had been sentenced.

²⁰ Some other high-level PIP employees (all PIP employees were more or less aware of the systematic fraud) were also sentenced and (or) fined.

²¹ One Italian, one Brazilian, and one Bulgarian importer/distributor of PIP breast implants.

²² This section is largely based on the analysis by the author of « Jugement du 14 novembre 2013, Société GF ELECTRONICS & société EMI IMPORTACAO E DISTRIBUCAO LTDA & société J & D MEDICALS et autres intervenants volontaires contre SAS TÜV RHEINLAND FRANCE & société TÜV RHEINLAND LGA PRODUCT », Tribunal de Commerce de Toulon, 3^{ème} chambre, 146 p.

Beyond this sentence, what is particularly interesting about the Toulon ruling on the TÜV-PIP case is that the judges had to understand as precisely as possible what the duties of the notified body actually were in this case and to assess how those duties differed from what TÜV Rheinland had actually done. In other words, the formal necessity of reaching a judgement forced the French judges to conduct an in-depth technical investigation into how the conformity assessments on PIP should have been carried out, and how they were carried out in reality. In short, they had to try to open the “certification black box”.

The first difficulty the judges encountered, when they tried to initiate investigations into TÜV Rheinland, was that the German certifier disputed the competence of the Tribunal de Commerce de Toulon to rule on certificates that had been issued in Germany. The notified body chosen by J.C Mas, under Directive 93/42, was TÜV Rheinland Germany⁽²³⁾, so TÜV argued that if the quality of those certificates was to be discussed or assessed, this could only be done by a German court. However, the French judges soon discovered that the regular audits at the PIP site were carried out by not TÜV Rheinland Germany, but by TÜV Rheinland France, a subsidiary of the German company, and also a French notified body which had no specialised expertise in medical devices⁽²⁴⁾. Regular audits and inspections were conducted by TÜV Rheinland France staff on the PIP site, and the results sent to TÜV Germany. TÜV Germany, as the official notified body appointed by PIP, would then edit the certificates and send them back to PIP’s director in France. The discovery of this procedure, which was acknowledged by TÜV⁽²⁵⁾, led to an interesting dispute on the underlying nature of certification: the French judges argued that the most important part of the certification procedure was in fact carried out by staff of TÜV France, in on-site audits at PIP, whereas TÜV claimed that this preliminary phase was only groundwork for the main part of the procedure, which was the writing of certification documents approved and issued in Germany. After these first skirmishes, the French judges raised further questions about the Medical Devices Directive itself and some of its requirements. Under Directive 93/42, breast implant producers may choose between different methods of inspection by notified bodies. JC Mas had chosen the so called “full quality assurance system”, which meant that the certifier’s job was essentially to audit PIP’s management system without having to inspect the breast implants themselves. TÜV argued, correctly, that Directive 93/42 therefore allowed them to deliver their conformity assessment certificates purely on the basis of “paper” inspections, i.e.

²³ The full name is TÜV Rheinland LGA Product GMBH.

²⁴ TÜV Rheinland France SAS, which is legally a French company, is notified by the French Government under the Low Voltage Directive.

²⁵ Judges could prove that TÜV Rheinland France was paid directly by PIP for its audits.

without even having to look at any breast implants manufactured by PIP. However, the judges argued that Directive 93/42 also required that “the assessment team must include at least one member with past experience of assessments of the technology concerned”⁽²⁶⁾, which was not the case when TÜV France’s auditors inspected PIP.

Another important subject of controversy was the interpretation of article 5.4 Annex 2 of the Directive, on unannounced inspections⁽²⁷⁾. TÜV defended itself by repeating that, as unannounced inspections were not compulsory under the Directive, they could not be accused of having failed to conduct any in more than ten years. However, the French court argued that, if TÜV had conducted only one unannounced inspection in all those years, with competent staff, PIP’s illegal practices would have been discovered.

In the end, and to summarise the general impression conveyed in reading the ruling of the Tribunal de Commerce de Toulon, the French judges ruled against TÜV not because of serious misconduct in its activities as a notified body. Instead, they sentenced it for having simply gone through the motions and for having done the minimum – indeed, even less than the minimum – that they were required to do by law. The judges compared this behaviour with the proud claims in advertisements on the TÜV website, aimed at industrial customers: “We are a notified body authorized to inspect your medical products and in vitro diagnostics and can assist you with the right conformity evaluation procedures for CE marks – meaning you can get your “driving license” for EU countries that little bit quicker”.⁽²⁸⁾ The judges argued that, if TÜV was indeed in the position of issuing “driving licenses” for any European producer to enter markets in Europe and beyond, TÜV should be aware of problem producers like PIP⁽²⁹⁾, and subject them to particular scrutiny.

On the one hand, this sentence constitutes a significant legal decision, and the enquiry and ruling by the Tribunal de Commerce de Toulon are an important step in making certifiers liable for their own obligations. On the other hand, however, the interest of the French judges in investigating this affair was confined to the certifiers’ legal responsibilities. As a sociologist, I cannot see this as the only problem. Beyond the judgment on the notified body’s liability, my interest is in looking at the PIP case as a global regulatory failure: there

²⁶ Directive 93/42, Annex 2, Chap. 3.3

²⁷ “The notified body may pay unannounced visits to the manufacturer”

²⁸ TÜV website, consulted 2014 June the 7th.

²⁹ For example, such a large and well-known certifier should at least have been aware of PIP’s problems with FDA.

are other, complex responsibilities that can and need to be analysed in exploring this case in greater depth.

3-5 Back to the Medical Devices Directive and the notification system

It is undoubtedly true that some of the arguments TÜV used in its own defense are correct. At present, the duties of a notified body under Directive 93/42 are not precisely defined: producers have extensive leeway in the way they choose, and notified bodies in the way they apply, the methods used in the delivery of conformity assessment certificates. The Commission is well aware of this situation and has been trying to overcome its consequences for years. Conscious that the practices of notified bodies differ widely across Europe, the Commission has long tried – in relation to New Approach Directives overall, but specifically in the sector of (sensitive) Medical Devices – to encourage Notifying Authorities and Notified Bodies to share their practices and discuss and promote best practices. Across the board, therefore, and specifically in the Medical Devices sector, numerous European working groups (of Notified Bodies, Notifying Authorities, producers, or any combination of these) have for years been producing Best Practice Guidelines, Codes of Conduct, and documents of all kinds that specify, in one area or another, how New Approach Directives should be implemented, in particular by Notified Bodies.

Nevertheless, it is questionable whether all this accumulated *soft law* really leads to a better allocation of legal responsibilities between the parties, or whether it simply serves to blur the lines of responsibility in the implementation of the New Approach Directives.⁽³⁰⁾ For example, the Commission has always reminded the Notifying Authorities that they remain guarantors of the capacities of the bodies they notify, even if this monitoring role has been outsourced to national Accreditation Bodies. Notifying Authorities and Accreditation Bodies, separately or together, do meet regularly in working groups to harmonise practices for the monitoring of “their” respective notified bodies. But if we go back to the PIP scandal, no one, not even the French judges themselves, considered the possibility that the German Notifying Authority and/or the German Accreditation Body could bear any liability in this affair. Yet one or other – or both – of these two institutions, was legally responsible for the competencies of the entity they designated as a Notified Body and were supposed to monitor. The same kinds of questions asked of certifiers can also be addressed to these “higher” level bodies: if

³⁰ The French judges did not take this body of soft law into account.

an Accreditation Body, for example, cannot be held at least partly responsible for the actual work certifiers do, or fail to do, in their day-to-day practice, what is it for?

Another important contextual factor is that Directive 93/42 has been under review since 2008. The Medical Devices Directive is partly under review because this is a highly innovative and dynamic sector, where new and increasingly sophisticated medical devices continually raise new regulatory questions. However, it is also because it is a “sensitive” sector with numerous problems that have long been under scrutiny by critics (Galland, 2013b). Some notified bodies, newer and much smaller than TÜV, are suspected of showing an accommodating attitude when delivering conformity assessment certificates (³¹); moreover, the cost of certification may differ significantly from one notified body to another, so that producers are inclined to practice “forum shopping” (Roy, 2009; Cohen & Billingsley, 2011). As suggested above, the idea of creating a European agency (or a network of national and European agencies, as in the pharmaceutical sector) has been put back on the table in recent years, but European and even North American producers have fought against it, arguing that the present European approach favors innovation much more than the North American way of regulating the sector (³²). The PIP scandal brought no essential change in the positions of the main actors, though the European Parliament seemed (2013) to disagree with the Commission on this issue (Hancher and Eva Földes, 2013). However, some of the questions highlighted by the PIP scandal were introduced into the debate on revising the Directive. For example, the question of whether unannounced on-site inspections by Notified Bodies should become compulsory, at least for highly sensitive medical devices, is now under scrutiny. This demonstrates – if such evidence were needed – that the 1993 Medical Devices Directive could have been drafted differently and less loosely.

This observation echoes initial warnings issued in the early days of the New Approach procedure, after long discussion of its general and innovative principles: the 1985 Council Resolution stressed that “essential safety requirements (should) be worded precisely enough in order to create, on transposition into national law, legally binding obligations which can be enforced”. In fact, as a former European Commissioner noted, “the bulk of directives adopted

³¹ Some of these notified bodies used to claim proudly on their websites that they usually achieve a “high level of acceptance” for the medical devices they are supposed to inspect under the CE marking process.

³² This claim is regularly “demonstrated” by experts, e.g. in the document “Regulation and Access to Innovative Medical Technologies, A comparison of the FDA and EU Approval processes and their Impact on Patients and Industry, The Boston Consulting Group, June 2012, 27 p.

under the New Approach involve essential requirements so generally and inexactly expressed” that these provisions would hardly be sanctioned under law (Previdi, 1998).

In the case of Medical Devices, we can say that the PIP scandal drew attention to the loose wording of the Directive, especially in its Annex, which specifies the essential safety requirements and the ways in which producers and notified bodies are supposed to show that products comply with them. To take the allocation of responsibilities a little further, it might be argued that the writers of the Directive, like the European institutions that voted for it, were also partly responsible for the regrettable PIP affair. It may be, however, that the loose wording of the current Medical Devices Directive is no accident: during the drafting process, producers (and notified bodies) undoubtedly lobbied to ensure that the Directive allowed a degree of leeway, as ever on the grounds of leaving room for innovation.

These controversies are far from over. As I write this article (June 2014), the European Parliament has closed its 7th session and has failed to vote through a new Medical Device Directive (or a stricter Regulation, as it is also considered), as previously expected. Battle will resume when the newly elected MEPs attend a new Parliamentary session.⁽³³⁾ Other important questions, less directly linked with the practices of notified bodies or certifiers – for example the complementarity between *ex ante* and *ex post* regulation, i.e. market surveillance (Marjolein Singh, 2013) – are also on the table.

The PIP scandal was and still is a good opportunity to investigate the notification system implemented under the New Approach Medical Devices Directive, and under New Approach Directives in general. The Toulon trial and ruling were a surprising but promising answer to some of the many questions raised in the media at the time, in particular about both the purpose and the liability of certifiers. In opening up the black box of certification involved in the CE marking framework, the French judges found a big third-party certifier guilty of day-to-day practices inconsistent with its legal obligations. On the other hand, it may be argued that the notified body in question was not the only actor responsible, both in this regrettable case but also within the framework of a rather complex and lax regulatory system. Moreover, it is to be wondered whether the multiplicity of actors in this case, all with different levels of accountability for obligations of one kind or another (notified bodies, notifying authorities,

³³ Elections were held in May 2014.

accreditation bodies), has led to a better allocation – or, on the contrary, to a blurring – of the lines of responsibility.

In other words, the European Medical Devices Directive is a fascinating example of the “multilevel regulation” employed in the European Union: “If we were to provide an overview of the regulatory space of marketing authorisation of medical devices, we would find that the primary activities of rule making and rule enforcement are being performed by multiple actors at both the European and national levels. Further, there is no specific authority for rule adjudication – unlike in the medicinal product sector – and this contributes to the non-hierarchical nature of relationships between these actors. Most importantly on the aspect of rule interpretation, there are various kinds of guidance documents that are being issued by different actors... Through their rule enforcement functions, both the competent authorities of Member States, as well as the notified bodies, have extensive rule interpretation authority. These characteristics make the regulatory space *prima facie* multilevel in nature... One of the most immediate problems that have arisen in this regulatory space... has been the lack of uniformity of enforcement and the fragmentation. ... Rise in regulatory uncertainty is a logical consequence of such fragmentation and lack of uniformity within this regulatory space. Regulatory uncertainty could adversely contribute to the lack of legal certainty” (Chowdhury & Wessel, 2012, pp 354-355)

Conclusion

As with other failures of regulation such as the Karachi fire disaster (2012), the PIP crisis “opens a window of opportunity that allows us to study, discuss, and analyse the role of intermediaries” (Levi-Faur, Starobin, 2014). And this latter case, as a result of the Toulon court ruling, also immediately raises important questions about the accountability, responsibility and liability of those intermediaries.

Although the PIP affair, which is not completely over at least in regard to consequences, needs further investigation, we can, on the basis of the short analysis above, reach a few general conclusions regarding transnational regulation and transnational regulatory intermediaries, which could be opened up for verification and discussion in relation to other contexts.

First, we saw that the Medical Devices Directive gave third-party certifiers and producers substantial leeway for interpreting rather loosely written rules. We also saw that the largest and most transnational of these third-party certifiers/notified bodies were often involved, along with others, in the production of soft law (e.g. guides to best practices) in order to “enhance” regulatory enforcement. Here, regulatory intermediaries can be seen adapting rules. However, there is more to be said about this. When we look closely at certification processes, whether in relation to Medical Devices or to the New Approach Directives in general, it is amazing how neat the fit is between the rules themselves (essential safety requirements, harmonised European standards that are supposed to fulfill them), and the complex way in which they are implemented by intermediaries (notified and accreditation bodies). Certification processes, for instance, are well suited to the worldwide organisation of the big notified bodies and their use of subsidiaries. Could it be that these intermediaries work alongside – or at least lobby – the “rule makers”, when transnational regulatory processes are being drafted, to ensure that they are well placed to take on the compliance role? ⁽³⁴⁾ This leads on to a more general question: to what extent can the intermediaries themselves be considered “rule makers”?

During the Toulon trial, TÜV argued in its defence that the existing global regulatory system for medical devices had not been designed to identify crooks. This is true. From the beginning, the New Approach and its sequels were designed to build trust at all levels: consumer trust in products through third-party certification, producer trust in certifiers through accreditation. At each level, however, compliance and inspection procedures rely primarily on declarations by the party being audited, in which the auditors have to place credence. With these methods, there is unquestionably no way to identify potential crooks, whether amongst producers or certifiers ⁽³⁵⁾. Within the New Approach framework, the Commission is always reminding Member States that they are responsible for post-market oversight, which might be a way of spotting crooked firms, but this does not answer the general question of whether or not the standard practices of transnational regulatory intermediaries lead or not to the discovery of possible criminal activity? Or is this goal systematically beyond the scope of their activity?

³⁴ As described above in the French Arrêté Ministériel on “pressure equipments” (note 10)

³⁵ Indeed, in the PIP affair, only the FDA and AFSSAPS, two national public agencies, were really able to spot cheating.

A third series of questions raised by the PIP affair can be summed up in the words accountability, responsibility and liability. Although the Toulon ruling was significant, and although the French judges did delve deeply into the certification black box, which is quite rare, further interdisciplinary (including specialist legal) research is needed in order to clarify more global questions, - why the liability of other actors was not even considered in the PIP case for example. To paraphrase Levi-Faur and Starobin (2014, p 26), the decentralised, transnational regulatory governance established under the New Approach has extended the chain of accountability, but also fragmented responsibilities for failure. For the moment, the multiplicity and fuzziness of these responsibilities seem to go unnoticed. One of our duties as social scientists is to bring issues such as the above ones into the light of day, so that global but specific lessons can be learned from regulatory failures, such as the PIP scandal.

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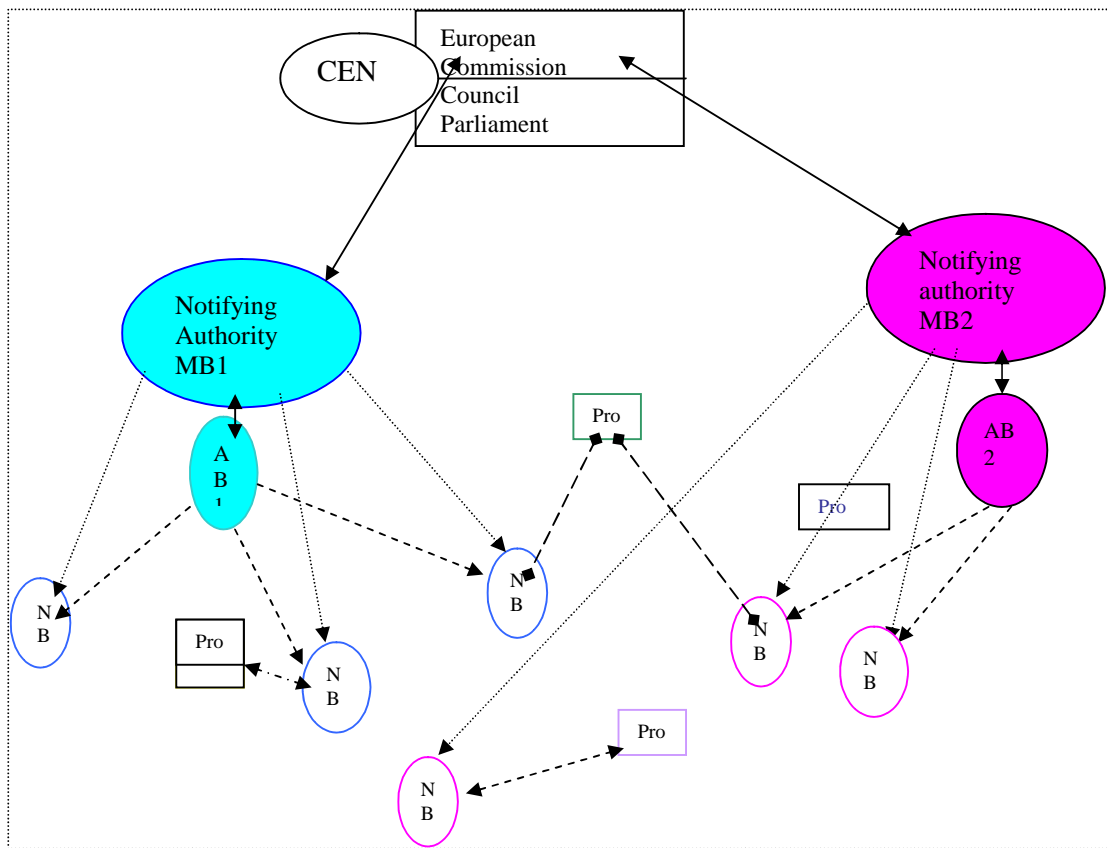
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Annex: Recapitulative schema



MB : Member State
 NB : Notified Body
 Pro: producers
 AB : (National) Accreditation Body