

CTEI Working Paper

The Role of Domestic Administrative Law in the Accountability of Transnational Regulatory Networks^a

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1. Introduction

Cooperation amongst regulatory authorities, or “transgovernmental regulatory networks” (or “transnational” when in collaboration with private actors)¹ has been prevalent in the past two decades, in diverse areas such as finance, competition, and environmental issues. Despite the many benefits of such networking, a lot of the scholarly work on TRNs has been concerned with their accountability deficits, and various claims have been made. They have been said to lack transparency.² They have been criticized for their “club-like” nature – dominated by the US and Europe while affecting third countries, particularly developing countries, which do not adequately participate in their procedures.³ Moreover, it has been argued that affected nongovernmental actors are not sufficiently involved.⁴ Another frequent charge against TRNs has been that they are networks of unconstrained technocrats, or “agencies on the loose”,⁵ the main concern being the lack of domestic political or legal control over the bureaucracy,⁶ and the shifting of the decision making away from accessible, accountable national government to international bodies that are inaccessible to citizens.⁷

While most of the accountability literature has focused on the accountability measures available at the global level,⁸ this paper seeks to expand the analysis by examining the role domestic law has to play in the accountability of TRNs (whether purely public or public-private). The paper focuses on the International Conference on the Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), and on US administrative law, and draws lessons from this case for the general debate on the accountability of TRNs. The ICH is a network of drug regulatory authorities and industry associations from the US, EU and Japan, that harmonizes drug registration rules. The ICH raises particular interest because while its harmonized rules were initially intended for member states, they have now become *de facto* global standards, adopted worldwide.

¹ ANNE-MARIE SLAUGHTER, *A New World Order* (Princeton University Press. 2004).

² ROBERT O. KEOHANE, *Global Governance and Democratic Accountability* (2002).p. 21

³ DAVID ZARING, *Informal Procedure, Hard and Soft*, in *International Administration*, 5 Chicago Journal of International Law 547(2004-2005)., p.595.

⁴ MARIO SAVINO, *An Unaccountable Transgovernmental Branch: The Basel Committee*, in *GLOBAL ADMINISTRATIVE LAW: CASES, MATERIALS, ISSUES. S e c o n d E d i t i o n* (Sabino Cassese, et al. eds., 2008)., p.69.

⁵ SLAUGHTER, *Agencies on the Loose? Holding Government Networks Accountable*.

⁶ BENEDICT KINGSBURY, et al., *The Emergence of Global Administrative Law*, 68 *Law and Contemporary Problems* 15(2005);id. at.; ROBERT O. KEOHANE & JOSEPH S. NYE, *Transgovernmental relations and international organizations*, 27 *World Politics* 39(1974). JAN KLABBERS, *An Introduction to International Institutional Law* (Cambridge University Press. 2002)., p. 339

⁷ LORI M. WALLACH, *Accountable Governance in the Era of Globalization: The WTO, NAFTA, and the International Harmonization of Standards*, 5 *University of Kansas Law Review* 823(2001-2002).p.833.

⁸ With several exceptions : R.B. STEWART, *The Global Regulatory Challenge to U.S. Administrative Law*, 37 *New York University Journal of International Law and Politics* (2005);P.H. VERDIER, *Transnational Regulatory Networks and Their Limits*, 34 *Yale J. Int'l L.* (2009);PIERRE-HUGUES VERDIER, *U.S. Implementation of Basel II: Lessons for Informal International Law-Making* (Draft Paper) (June 2010).

The question of accountability of such harmonization networks will become more prominent in the coming years: Aligning unnecessarily diverging technical or social regulations, or what has been termed “3rd generation barriers to trade,”⁹ is high on the trade liberalization agenda of market oriented economies. OECD and APEC members are explicitly encouraged to strengthen regulatory cooperation to harmonize standards,¹⁰ with many initiatives already underway (for example between the US and Europe,¹¹ or US-Canada-Mexico,¹² to name just a few.) Collaboration with the private sector to this end, is considered important too.¹³

This paper argues that domestic law is significant in establishing the accountability of TRNs towards internal stakeholders, and has some role to play, albeit limited, in offsetting the problem of disregard towards external stakeholders. Global accountability measures are critical for external accountability, but also important in improving the accountability towards internal stakeholders. Domestic and global measures are, accordingly, complementary, and TRNs should be designed with this in mind.

The paper is organized as follows. Section 2 sets out the analytical framework of this paper. Section 3 provides a short overview of the ICH and why it was set up as a public-private network. Section 4 concerns the role of domestic law in setting procedural rules for the network. Section 5 concerns the role domestic law has in maintaining the accountability of the FDA, and in turn the network in its entirety, towards internal stakeholders. To this end, it addresses the domestic law that regulates transnational harmonization (5A), the accountability mechanisms (5B) and “other responsiveness promoting measures” (5C). Section 6 concerns the role domestic law has to play in the accountability of the network towards external stakeholders. It distinguishes between domestic law in member countries (6B) and in non-member countries (6C). Section 7 concludes.

2. Defining the Analytical Framework for Accountability

Due to predefined length limitations, this paper does not go into the vast literature on accountability. It adopts as its analytical framework a broad definition, namely an actor’s “responsiveness”, or rather “disregard”, to the

⁹ Mauro Petriccione, *Reconciling Transatlantic Regulatory Imperatives with Bilateral Trade*, in GEORGE BERMAN, et al., *Transatlantic Regulatory Cooperation: Legal Problems and Political Prospects* (Oxford University Press. 2001).

¹⁰ Principle 6 in The OECD 2005 Guiding Principles for Regulatory Quality and Performance (2005); OECD-APEC Integrated Checklist for Regulatory Reform; APEC SUBCOMMITTEE ON STANDARDS AND CONFORMANCE, 6th Conference on Good Regulatory Practice: Report to the Sub Committee on Standards and Conformance (2011).

¹¹ Roadmap for U.S and EU Regulatory Cooperation and Transparency (2005). *INITIATIVE TO ENHANCE TRANSATLANTIC ECONOMIC INTEGRATION AND GROWTH*, (2005).

¹² Canada/United States/Mexico Security and Prosperity Regulatory Cooperation Framework.

¹³ CONFORMANCE.

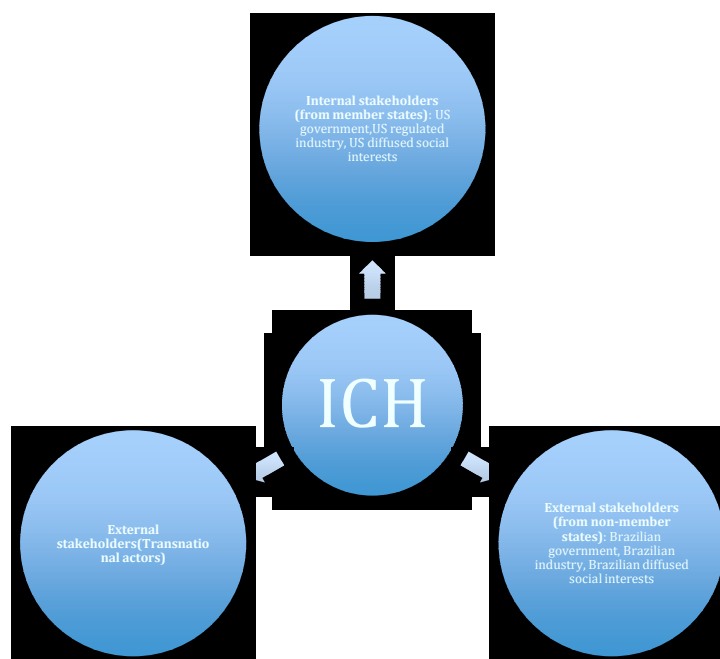
interests of others.¹⁴ As regards these “others”, or whom the actor should be accountable to, the paper presumes a distinction between the actors’ accountability towards “internal” and “external” stakeholders. The first is based on a principal-agent relationship, and is between the actor and those that authorized the actor’s activity. The second is between the actor and those affected by its actions.¹⁵ The paper further relies on the distinction between (i) decision rules (i.e., who are the voting members), (ii) accountability mechanisms (i.e., procedures whereby specified account holders have the authority to hold specified power holders to give account for their conduct and impose sanctions or secure other remedies for deficient performance or unlawful conduct), and (iii) other responsiveness promoting measures (in particular transparency, and non-decisional participation).¹⁶

In thinking about the accountability of the ICH, or generally harmonization TRNs, there are two main concerns: The first concern is the accountability of the network towards the *internal stakeholders*. The internal stakeholders are the governments behind the member regulatory authorities, and the companies behind the industry associations. Moreover, within each member country we have the businesses regulated by the networks’ output, and the individuals and other diffused social interests within the member country affected by the output. Based on a formal principal–agent model of democracy, and to maintain analytical clarity, the paper considers such nongovernmental stakeholders within member countries to be internal stakeholders. The second concern is of the accountability/disregard of the network towards its *external stakeholders*. External stakeholders are non-member countries that adopt a network’s guidelines. Business or diffused social interests affected by the network’s output fall into this category too. These may be from non-member states, and in some cases transnational actors (such as industry associations or patients organizations whose members come from both member and non-member countries).

¹⁴ Slaughter, RICHARD B. STEWART, *Accountability, Participation, and the Problem of Disregard in Global Regulatory Governance*, , Draft Paper (January 2008); JOOST PAUWELYN, *Informal International Law-Making: Mapping the Action and Testing Concepts of Accountability and Effectiveness. Project Framing Paper*, (July 2010).

¹⁵ RUTH W. GRANT & ROBERT O. KEOHANE, *Accountability and Abuses of Power in World Politics*, 99 *American Political Science Review* 29(2005).

¹⁶ STEWART, *Accountability, Participation, and the Problem of Disregard in Global Regulatory Governance*, PAUWELYN.



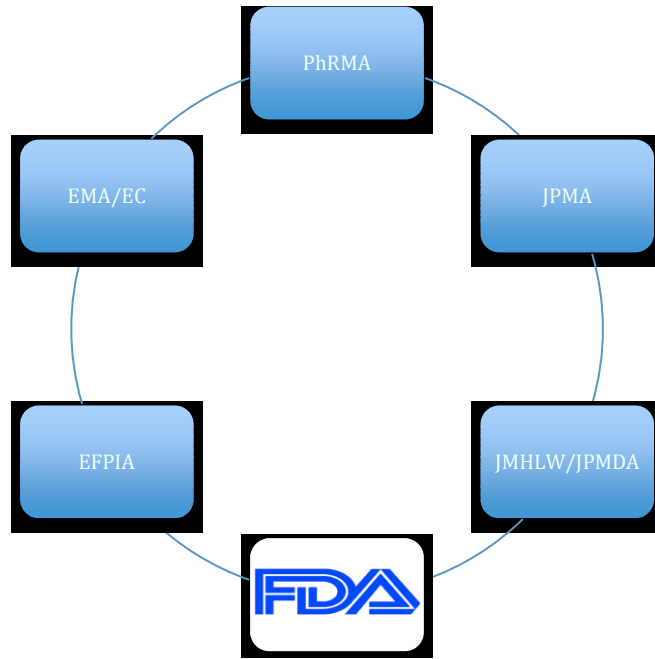
In dealing with these two problems, we can think of a TRN as an *actor* with a specific organizational form that can be contrasted with markets or hierarchies (say a treaty based intergovernmental organization),¹⁷ or we can think of it as *interconnected nodes* (in this case, of national regulatory authorities and industry associations). Most of the scholarly debate concerning the accountability and legitimacy of TRNs (or of other global actors in general) has focused on accountability measures at the “actor”, or the global level. Such an analysis is clearly relevant and important (and such an analysis of the ICH has been conducted in a previous paper¹⁸). The purpose of this paper, however, is to zoom in on the “node”, or the regulatory authority, and to check, empirically, the role domestic law is playing and can play in the accountability of the regulatory authorities, and in turn, of the network as a whole, towards its internal and external stakeholders.

Anne Marie Slaughter is the scholar to have made most notably the case of solving the accountability problems of TRNs through boosting domestic accountability procedures.¹⁹ Since TRNs are composed of regulators, which in turn are bound by domestic administrative law, this avenue of research indeed strikes as promising. This paper, accordingly, explores this possibility, focusing on the current legal situation in the US. While Slaughter’s work focused on purely transgovernmental networks, the question is equally relevant where regulators cooperate with private actors, such as in the ICH.

¹⁷ (Powell 1990, Kahler p.4-5).

¹⁸ See AYELET BERMAN, *The Accountability of Transnational Regulatory Networks : The Case of the International Conference on Harmonization* (26-27 November 2010).

¹⁹ SLAUGHTER.



Before proceeding with this analysis, the next section provides a short overview of the ICH and why it was set up as a public-private network.

3. The Public-Private Nature of ICH

The ICH was set up two decades ago, and is composed of drug regulatory authorities and R&D pharmaceutical industry associations (i.e. industry dealing with the development of *new* drugs) from the US, EU and Japan. The public parties are the US Food and Drug Administration (FDA), the European Commission, the European Medicines Agency (EMA), the Japanese Ministry of Health, Labor & Welfare (MHLW) and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA). The private parties are the Pharmaceutical Research & Manufacturers Association of America (PhRMA), the European Federation of Pharmaceutical Industries' Associations (EFPIA) and the Japanese Pharmaceutical Manufacturers Association (JPMA). Certain observers and private interested parties may attend too, such as the WHO, Swissmedic (the Swiss drug regulator) on behalf of EFTA countries, Health Canada, or the International Generic Pharmaceuticals Alliance (IGPA) (as well as other ad hoc observers). The Secretariat is run by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).²⁰

The purpose of the ICH is to harmonize drug registration rules concerning the quality, efficacy and safety of drugs between its member countries, but in practice they have become global standards adopted by a wide range of countries. It works in expert working groups (EWGs) and a Steering Committee, in which industry and regulators have an equal number of seats and decisions are reached by way of consensus. It issues legally non-binding guidelines, which are in most cases adopted as nationally legally non-binding rules (FDA “guidance document”/EMA “guidelines”), and in some rare cases as nationally legally binding rules.²¹

The ICH, set up in 1991, was the very first time drug regulatory authorities and industry ever met beyond the bilateral level on such a large and public platform,²² and it was the first time that the pharmaceutical industry engaged as a global political player.²³ Several political and bureaucratic developments generated this new kind of collaboration. First, with the European pharmaceutical harmonization project (the process which had begun in the 1970's) nearing its end, the European Commission (pharmaceuticals unit) sought to extend harmonization to its main trading partners — Japan and the US (together they held 95% of the market)—and initiated collaboration. Second, whereas prior to the mid-1980's, the FDA had been reluctant to collaborate with foreign regulatory counterparts or with industry,²⁴ European harmonization raised concerns about the competitiveness of the US pharmaceutical industry and the loss of FDA dominance in drug registration and brought about a change

²⁰ See BERMAN.

²¹ See *id.* at.

²² The Pharmaceutical Business News, 1991; David W. Jordan, International Regulatory Harmonization: A New Era in Prescription Drug Approval Notes, 25 Vand. J. Transnat'l L. (1992).494

²³ K. I. KAITIN, *Regulatory Reform at a Crossroads*, 36 Drug Information Journal (2002)., pp. 245-246.

²⁴ See AYELET BERMAN, The Public Private Nature of Harmonization Networks (17-18 March 2011).

in the FDA's attitude and greater openness towards FDA outsiders.²⁵ The FDA had also increasingly come under criticism for the "drug lag", and harmonization was among the reform proposals put forward.²⁶

The WHO was perceived by the parties to lack capacity to effectively lead such a project, and so the parties opted for another cooperation model.²⁷ The FDA and JPMDA lacked any previous experience in regulatory harmonization, and so the EC proposed to adopt the European harmonization model. This model was based on extensive interaction and open consultations between regulatory authorities and industrial partners, in particular EFPIA.²⁸ This hybrid model had proved very successful as it allowed to bridge the information imbalance between regulators and industry, inherent to the pharmaceutical industry. With 95% percent of research taking place in the industry, it is several years ahead of regulators on new scientific developments. Industry was also best informed about the regulatory differences that constitute obstacles to trade.²⁹ The FDA was persuaded by the efficiency of collaboration with industry, but insisted on the inclusion of procedural requirements (transparency, openness of guideline development process) in the network to be set up, so as to establish public interest safeguards.³⁰ After the ICH had proved to be successful, the public-private network model was copied in other networks involving the FDA during the 1990's. The first was the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products (VICH), then Global Harmonization Task Force (GHTF), and more recently the (International Cooperation on Cosmetics Regulation) ICCR (though industry are not equal members there).

To sum, this public-private cooperation is best explained by (i) the dependency of regulatory authorities on business for information, and (ii) by historical institutional theory, or path dependency theory,³¹ being a "copy-paste" exercise. In this sense, it is also an example of diffusion of European administrative practices to the international level.³²

In the following section we examine the role domestic law has in setting good administrative practices at the global level.

²⁵ See id. at.

²⁶ See id. at.

²⁷ Id. at.

²⁸ MARTIN BANGEMANN, *Welcome Address by Mr. Martin Bangemann, Vice President of the Commission of the European Communities*, in *Proceedings of the first International Conference on Harmonisation: Brussels 1991* (PF D'Arcy & DWG Harron eds., 1992). FERNAND SAUER, *Panel Discussion : The Way Forward*, at the First ICH (November 1991).

²⁹ See BERMAN, *The Public Private Nature of Harmonization Networks*.

³⁰ Id. at.

³¹ For a detailed overview explaining the events that led to the public-private structure of the ICH, VICH and GHTF, see id. at.

³² NICO KRISCH & BENEDICT KINGSBURY, *Introduction: Global Governance and Global Administrative Law in the International Legal Order*, 17 *European Journal of International Law* (2006).

4. Domestic Law and the TRN

In the US it has been a long-standing approach to encourage the participation of federal agencies in standard-setting activities outside of the government (whether domestic/international, or private/public). This approach was first set out in OMB Circular A-119 “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities”, that has been issued several times, dating back to the 1970s. The “National Technology Transfer and Advancement Act”, issued in 1995, codifies the Circular. Following and based on the Circular and NTTAA, the FDA issued three FDA-specific regulations and policies that regulate its participation in outside standard-setting activities and apply to its participation in the ICH. The binding regulation on “Participation in outside standard-setting activities,”³³ the “Policy on the development and use of standards with respect to international harmonization of regulatory requirements and guidelines,”³⁴ and the Staff Manual Guide 9100.1 “Development and Use of Standards.”³⁵

These FDA-specific rules set out, inter alia, minimum *procedural* requirements with which the *outside* standard setting activity must conform, in order for FDA employees to be allowed to participate. The regulation demands that a private standard-setting activity in which FDA employees participate, “(ii) will not be designed for the economic benefit of any company, group, or organization...and (iii) that the group or organization responsible for the standard-setting activity must have a procedure by which an interested person will have an opportunity to provide information and views on the activity and standards involved, without the payment of fees, and the information and views will be considered.”³⁶ The Policy similarly determines that the activity’s “development process for the standard is transparent (i.e., open to public scrutiny), comply with applicable statutes, regulations, and policies, specifically including §10.95 and OMB Circular A-119, and is consistent with the codes of ethics that must be followed by FDA employees”.³⁷ The Policy also sets out *substantive* requirements, such as that “(i) the harmonization activity should be *consistent with U.S. Government policies* and procedures and should promote U.S. interests with foreign countries, (ii) the harmonization activity should further FDA’s mission to protect the *public health*.”

While the US acknowledged the advantages attached to governmental collaboration with private actors in standard setting, it was equally understood that such collaboration raises concerns about regulatory capture and the necessity to safeguard the public interest.³⁸ These rules were hence introduced so as to encourage compliance with public interest safeguards, and to bring the

³³ 21 CFR sec 10.95

³⁴ 60 FR 53078 (11 October 1995) “International Harmonization; Policy on Standards”.

³⁵ FDA Staff Manual Guides, Volume IV- Agency Program Directives, Common Standards, Development and Use of Standards, 22 May 2007.

³⁶ 21 CFR 10.95 (d)(5)

³⁷ A(3)

³⁸ See generally, WALTER MATTLI, *Public and Private Governance in Setting International Standards, in Governance in a Global Economy: Political Authority in Transition* (M. Kahler & D.A. Lake eds., 2003). 200

FDA's (and other US agencies) outside standard-setting activities in line with national norms of transparency, participation and accountability. As noted above, when setting up the ICH, the FDA insisted on inclusion of safeguards in line with these rules. The idea underlying this demand was that transparency, participation, due process, ethics standards etc. would shield the process from inappropriate industry influence, and would guard the integrity of the scientific-based process. Moreover, the very fact that regulators participate was also considered a safeguard of the public interest.

To conclude, it is often claimed that networks fall in the cracks between domestic and international law.³⁹ But since US federal agencies may only participate in such outside standard-setting activities that comply with procedural requirements of transparency and participation, and in view of the FDA's dominance in drug registration, the FDA has the power to unilaterally impose good administrative practices on the TRN. Hence, while US law does not *de jure* apply to the network, it may do so *de facto*. This is a "bottom up" approach of extending US administrative law to global procedures.⁴⁰ Moreover, if other countries adopt similar rules, in particular powerful members such as EC/EMA, then such requirements will further impose themselves on the TRN. More generally, it can be concluded that a network may be *de facto* bound by the domestic legal requirements of its most dominant participants.

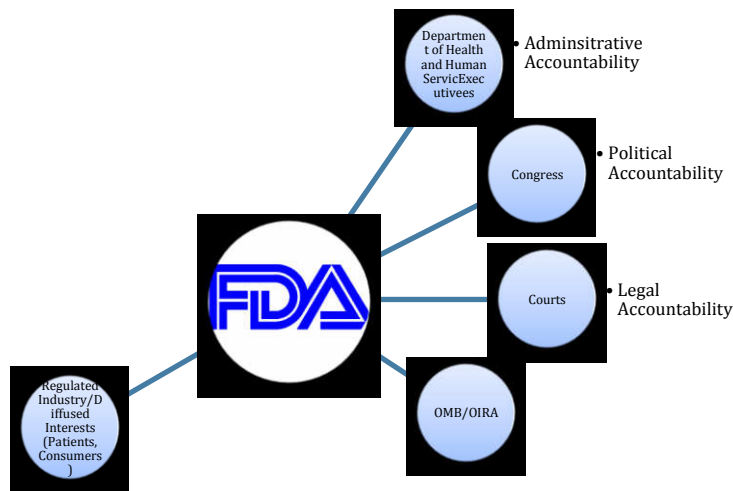
In the following section we explore the accountability measures available to internal stakeholders towards the FDA, and the consequence thereof, in turn, for the network as a whole.

5. Domestic Law and Internal Accountability

Regulatory authorities, in this case the FDA, have multiple internal stakeholders: the FDA leadership, the government (mainly, the Department of Health and Human Services, Congress, OMB and the courts), the regulated (pharmaceutical) companies, and the public whose interests in the safety, quality and efficacy of drugs the FDA must protect.

³⁹HILL, Tender Document: Democracy and Accountability in the Context of Informal International Public Policy-Making (2008);id. at.

⁴⁰ STEWART, *The Global Regulatory Challenge to U.S. Administrative Law*.753-754.



In this section the paper considers how domestic law regulates the accountability of the FDA towards its internal stakeholders, and what this effect has in turn on the network as a whole.

A. The domestic legal framework for transnational harmonization

For reasons that this paper, due to size limitations, does not cover, the FDA has made international alignment and harmonization of standards a high priority.⁴¹ Since 1997, with the enactment of the FDA Modernization Act, it is part of its formal mandate. Section 903(3) of the FD&C Act determines that it is among the FDA’s mission to “participate through appropriate processes with *representatives of other countries* to reduce the burden of regulation, *harmonize regulatory requirements*, and achieve appropriate reciprocal arrangements.”⁴² Section 903(4) further encourages that this mission be carried out with private parties, that is “in *cooperation* with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.” This authority is referred to in other provisions too.⁴³

Congress has, hence, authorized the FDA’s participation in public or public-private harmonization activities. The FDA leadership has consequently also embraced this principle, and encourages the participation of FDA employees/ centers in such activities in the series of FDA specific rules mentioned above.

In Section 1 we explored the ways in which these rules set procedural requirements for the network at the transnational level. But these rules also

⁴¹ For a detailed description of the background that led the FDA to embrace international harmonization, see BERMAN, *The Accountability of Transnational Regulatory Networks : The Case of the International Conference on Harmonization* ; and BERMAN, *The Public Private Nature of Harmonization Networks*.

⁴² 21 USC §393.

⁴³ For example, Sec. 803(3) of the FD&C Act

condition the participation of the FDA in transnational harmonization activities on the fulfillment of certain *domestic procedural* requirements. The Policy, for example, determines that the “... FDA’s input into international standard-setting activities should be open to public scrutiny and should provide the opportunity for the consideration of views of all parties concerned”.

More generally, the legal situation as regards public input into harmonization activities is fragmented in the US. While other agencies, such as the National Highway Traffic Safety Administration, EPA, or the Federal Aviation Administration (to name just some examples),⁴⁴ have also been obtaining citizen input regarding harmonization activity, so far there has not been issued a government-wide rule that specifically requires all agencies harmonizing domestic and foreign regulations, or that are cooperating with foreign regulators to ensure *domestic* public participation. Bodies such as the American Bar Association,⁴⁵ or the Administrative Conference⁴⁶ have made recommendations on the subject of international regulatory cooperation/harmonization, but a general rule has not been issued so far. In its most recent report to Congress, OIRA also recommended that “regulatory cooperation should be based, to the extent feasible and appropriate, on an open exchange of information and perspectives among the U.S. government, foreign governments, affected domestic and foreign stakeholders in the private sector, and the public at large.”⁴⁷ So far, however, these recommendations have not culminated into a formal government-wide rule.

B. Accountability Mechanisms under Domestic Law

[The section on accountability mechanisms needs to be further researched and developed]

As we have seen above, the FDA has been given statutory authority to collaborate with regulators and private parties on the harmonization of standards. It has also set out certain domestic procedural requirements, which the FDA must comply with. But what accountability mechanisms, if at all, oversee these transnational activities? Slaughter was among those most notably making the case that the accountability of TRNs could be improved by strengthening domestic accountability mechanisms.

⁴⁴ For further examples, see STEWART, *The Global Regulatory Challenge to U.S. Administrative Law*. 733-735.

⁴⁵ SECTION OF INTERNATIONAL LAW AND PRACTICE AMERICAN BAR ASSOCIATION: SECTION OF ADMINISTRATIVE LAW AND REGULATORY PRACTICE, GOVERNMENT AND PUBLIC SECTOR LAWYERS DIVISION, Recommendation “with respect to significant agency efforts to harmonize domestic and foreign regulations through international negotiations that may require new regulations or the amendment of existing regulations”.

⁴⁶(ADMINISTRATIVE CONFERENCE OF THE UNITED STATES), Recommendation 91-1, Federal Agency Cooperation with Foreign Government Regulators § 56 FR 33842 (24 July 1991). See also GEORGE BERMANN, *Managing regulatory rapprochement: institutional and procedural approaches*, in *Regulatory Co-operation for an Interdependent World* (OECD ed. 1994).

⁴⁷ OIRA, *Stimulating Smarter Regulation: OIRA 2002 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*. (2002).

As we shall see next, rather than setting up permanent, government-wide mechanisms to oversee the transnational activities of regulators (such as called for in 1991 by the US Administrative Conference), the US attitude has largely been to rely on the same accountability mechanisms which are in place to oversee purely domestic activities.

In the sections below, we focus on hierarchical, supervisory, and legal accountability mechanisms.⁴⁸

1. Supervisory Accountability

i. By Congress

Congress has various oversight mechanisms of agency actions, including hearings or informal meetings, reports or adoption of legislation. Calls for congressional oversight of transnational regulatory activities are longstanding.⁴⁹ In the past there had been proposals for specific reporting duties concerning international harmonization (including ICH and GHTF).⁵⁰ But since the inclusion of transnational harmonization/collaboration as part of its mandate in 1997, the FDA reports on its international activities in its regular annual report.

A search in the GPO database revealed that the ICH has never been the subject of any critical Congressional discussion. Similarly so for the General Accounting Office, Congress' investigative arm. In striking contrast, the implementation of the Basel Committee on Banking Supervision accords (II), have come under immense Congressional scrutiny, reflecting that Congress may impose significant constraints on the global activities of regulators.⁵¹

ii. OIRA/OMB overview

The Office of Information and Regulatory Affairs (OIRA), which is part of the Office of Management and Budget (OMB), an agency within the Executive Office of the President, reviews draft and final "significant" regulations and guidance documents under Executive Order 12866.⁵² "Significance" is determined by factors such as the monetary or economic effect of the rule, or whether it raises novel legal or policy issues. The question alone of whether it was a product of international or domestic deliberation is not a factor that justifies review. Nothing in the Executive Order or other memoranda indicates that guidance the source of which is global would be exempt from OMB review. Consequently, were an ICH guideline to fall within the definition of "significant", it would be subject to the same OMB review.

⁴⁸ STEWART, *Accountability, Participation, and the Problem of Disregard in Global Regulatory Governance*, .

⁴⁹ See BERMANN, *Managing regulatory rapprochement: institutional and procedural approaches*, (

⁵⁰ Senate Bill, S.3 (109TH CONGRESS 1ST SESSION);id. at.

⁵¹ See VERDIER, U.S. Implementation of Basel II: Lessons for Informal International Law-Making (Draft Paper).

⁵² On March 4, 2009, the Director of OMB issued Memorandum M-09-13, "Guidance for Regulatory Review," clarifying continued OIRA review of significant guidance documents.

iii. *Department of Health and Human Services (HHS)*
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2. Hierarchical Accountability

i. Within the FDA

The FDA Center for Drug Evaluation, the FDA unit that participates in the ICH, is subject to several levels of oversight within the FDA: All harmonization activities (including the ICH, but also GHTE, ICCR, Codex, PANDRH etc.) are coordinated by the “Harmonization and Multilateral Relations Office”. The Harmonization office is part of the FDA’s Office of International Programs (OIP). The later is located within the FDA’s Office of the Commissioner, and oversees the FDA’s international activities, which include, but are not limited to harmonization). The OIP’s mission is, inter alia, to assure that all FDA international interactions are “consistent with the US Department of Health and Human Services public health objectives.”⁵³ Within the FDA, hence, bodies that oversee the transnational activities of FDA centres and employees, have been set up.

3. Legal accountability mechanisms

Most of the ICH guidelines are adopted as FDA “guidance documents”. Whereas “rules” are subject to judicial review, guidance documents are subject to non-judicial appeals mechanisms as set out in the FD&C Act, FDA regulations, and the FDA’s Good Guidance Practices (GGP). Section 701(h)(4) of the Food, Drug and Cosmetics Act determines that: “The Secretary shall ensure that an effective appeals mechanism is in place to address complaints that the Food and Drug Administration is not developing and using guidance documents in accordance with this subsection.”⁵⁴ The GGP sets out the details of the appeals mechanism, that leads up to the FDA Chief Mediator and Ombudsman.⁵⁵ The FDA has stressed⁵⁶ that these procedures complement the FDA’s dispute resolution regulations on internal review of decisions,⁵⁷ or citizen petitions.⁵⁸ [*Further research would need to be conducted as to whether such appeals have ever taken place.*]

As regards cases brought before courts, while US courts have voiced in the past criticism regarding the use of guidance documents, US courts have never discussed ICH guidelines. [*Further research required on more recent US court cases regarding the use of guidance documents, in particular since OMB’s GGP was issued.*]

⁵³ « Vision and Mission », at

<http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofInternationalPrograms/ucm236579.htm>

⁵⁴ 21 U.S.C. 371(h).

⁵⁵ 21 CFR 10.115(o).

⁵⁶ 65 FR 56468, at p.56473.

⁵⁷ § 10.75

⁵⁸ § 10.30

C. Conclusion

Slaughter had called for the development of a concept of “dual function” for all national officials. That is, an assumption that their responsibilities will include both a national and a transgovernmental component, saying that they must be accountable to their national constituents for both categories of activity.⁵⁹ This dual function is already reality in the FDA’s case, as transnational activities are now formally part of its mandate. As regards accountability mechanisms, the US approach has been to rely on the existing ones (i.e., those that apply to purely domestic activities). The only exception appears to be within the FDA, where special offices have been set up to oversee international activities. Moreover, in practice, even though theoretically available, Congress and the courts have expressed minor interest in the ICH. Most oversight, in practice, is, hence, taking place internally, within the agency itself, and by public comments (which we address in the next section).

D. Other “Responsive Promoting Measures” under Domestic Law

1. FDA Administrative Procedure for adopting and implementing ICH guidelines.

The ICH guideline drafting procedure has 5 steps, and is characterized by step-wise consultation at both the transnational and domestic level.⁶⁰ A “Concept paper” put forward by one of the members or observers triggers the harmonization process. An EWG drafts a first guideline, and after its approval by the Steering Committee, the guideline leaves the ICH process and becomes the subject of regulatory consultation in the three regions.

The FDA usually adopts ICH rules as legally nonbinding “guidance documents”, (and the EMA too mostly adopts them as nonbinding “guidelines”). In some significant topics, such as on clinical trials or GMP, they may also serve as a basis for FDA regulations (or European legislation). In most cases, hence, the FDA’s regulation on “Good Guidance Practice” (GGP), which specifies the procedures for the development of guidance documents, applies at this stage.⁶¹ The GGP explicitly applies to guidance documents originating in ICH too.⁶² In cases where the guidelines are adopted as regulations, the APA applies.

According to the GGP, the draft guidance is subject to a notice and comment procedure,⁶³ which is very similar to the rule making procedure set

⁵⁹ ANNE-MARIE SLAUGHTER, *Disaggregated Sovereignty: Towards the Public Accountability of Global Government Networks*, 39 *Government and Opposition* (2004), 171, SLAUGHTER, *A New World Order*, p.218.

⁶⁰ For a detailed overview of the guideline development process, see BERMAN, *The Accountability of Transnational Regulatory Networks : The Case of the International Conference on Harmonization*

⁶¹ 65 FR 56468 (19 September 2000), 21 CFR part §10.115.

⁶² See 65FR 56475.(check). (Insert reference to ICH/VICH)

⁶³ 21 CFR 10.115 (g)(1)(ii)(A) and (B) and (C); See also “Notes on implementation in the three ICH regions”, at <http://www.ich.org/cache/compo/276-254-1.html>.

forth in the APA.⁶⁴ The FDA may also hold public meetings or workshops; or present the draft to an advisory committee.⁶⁵ Consultation not only takes place during the harmonization process, after the first draft has been issued, but also before the harmonization process. Any new topic is published in the FDA's "guidance document agenda", which is open for public input.⁶⁶ Moreover, *before* preparing a draft guidance document, the FDA can seek or accept early public input,⁶⁷ or conduct meetings or workshops.⁶⁸ [*Further research required whether this has been used in practice regarding the ICH*] Moreover, before any ICH meeting, the FDA issues a notice in the Federal Register and solicits public input prior to the meeting.⁶⁹ The literature has typically considered domestic notice and comment procedures to be ineffective as they come too late after the decisions have already been made at the transnational level, and an agency, having spent a lot of time negotiating and finally agreeing on a harmonized standard, is likely to be predisposed to adopt that standard.⁷⁰ In this case, however, the GGPs and the ICH introduce domestic consultation from a relatively early stage on,⁷¹ before the guideline becomes a *fait accompli*, and so benefits to stakeholders are not necessarily diminished or lost. That said, while public involvement is possible before ICH meetings or after a draft has been issued, stakeholders (beyond the recognized observers and interested parties) are not represented in the EWG's development process. Since the R&D industry is represented in those meetings, this raises a problem of unequal representation of interests.

After all comments are transferred to the EWG, a renewed consensus building process takes place. The regulators will exchange the domestic comments they have received in order to arrive at a single, harmonized guideline. This point is markedly different from normal national procedures for consultation on guidelines, as the interests of other countries will be taken into account. Once consensus is reached, the guideline will be adopted by the Steering Committee, and adopted as a harmonized guideline. Once adopted as final FDA guidance documents, they are published in the Federal Register, and are made available on the FDA website.

It should be noted that the adoption of ICH guidelines as guidance documents follows an existing trend in the past two decades, in US federal agencies, including the FDA, to increasingly set purely domestic regulatory policy

⁶⁴ TODD D. RAKOFF, *The Choice Between Formal and Informal Modes of Administrative Regulation* 52 *Administrative Law Review* (2000).168-169.

⁶⁵ 21 CFR 10.115(g)(1)(iii)(A) and (B)

⁶⁶ 65 FR 56468 (19 September 2000), at p. 56469.

⁶⁷ 21 CFR 10.115(g) (1)(i)

⁶⁸ 65 FR 56468 (19 September 2000), at p. 56470.

⁶⁹ For example, HHS FDA, Notice on Preparation for International Conference on Harmonization Steering Committee and Expert Group Meetings § 76 FR 20690 (13 April 2011);id. at. HHS FOOD AND DRUG ADMINISTRATION, Preparation for International Conference on Harmonisation Steering Committee and Expert Working Group Meetings in Tallinn, Estonia; Regional Public Meeting (13 April 2010).

⁷⁰ STEWART, *The Global Regulatory Challenge to U.S. Administrative Law*.

⁷¹ The quality of commentary is different if one participates in the initial drafting of the guideline or whether one reacts to a draft that has already been prepared. Peter Strauss article.

through guidance documents rather than binding regulations.⁷² In that sense, it is not an exception to domestic FDA practice. This practice is also widespread in other countries, such as by the EMA. The use of guidance documents had traditionally raised accountability concerns as it circumvented accountability measures (APA notice and comment procedures, judicial or OMB overview etc.).⁷³ Due to this criticism, Congress directed the FDA in the 1997 FDA Modernization Act,⁷⁴ to develop guidance documents with public participation (prior to implementation of guidance documents⁷⁵) and in a transparent manner.⁷⁶ The FDA GGP then went on to set out the specific requirements of guidance development.⁷⁷ It should be noted that reflecting this growing trend of federal agencies to rely on guidance documents, the OIRA issued in 2007 a “Final Bulletin for Agency Good Guidance Practices”, which establishes procedures for the development of significant guidance documents.

E. Assessment: Domestic Law and Internal Accountability

The FDA’s participation in TRNs is authorized under US law, and recognized as part of its mission. FDA-specific policies also set out certain domestic procedural and substantive requirements FDA must comply with in its transnational activities. The US attitude has been to rely on the existing accountability mechanisms and guidance development procedures of the US administrative system, and a special government-wide rule or unit to oversee transnational activities have not been developed. In practice, however, the particular ICH activities do not seem to have drawn much attention beyond the FDA, and Congress or the courts have not substantially dealt with it. Moreover, research so far indicates that comments have overwhelmingly come from the pharmaceutical industry, and very little on behalf of consumers and patients. (This is a well-known problem, which characterizes purely domestic procedures too.)

Subsequently, while in this case not all available accountability measures are taken advantage of, in principle, stakeholders within the US – the government, the regulated industry and diffused interests – have measures with which they can keep the FDA accountable for its transnational activities. The stakeholders have, in fact, the same accountability measures at their disposal as those that exist for activities of the FDA that are purely domestic in character – a situation that Stewart refers to as “parity”.⁷⁸

These limitations on the FDA potentially restrict the decisions it can take within the network. The FDA will not take decisions within the ICH, or

⁷² RAKOFF.165-166.

⁷³ For an overview of the problematic, see « Review of Problematic Agency Guidance » in Stimulating Smarter Regulation: OIRA 2002 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities.

⁷⁴ 21 U.S.C. 371(h). Section 405 of FDAMA added section 701(h) to the FD&C Act and establishes certain aspects of the 1997 GGP rule as the law.

⁷⁵ 701(h)(1)(C)

⁷⁶ 701(h)(1)(A)

⁷⁷ OECD, Regulatory Reform in the United States: Enhancing Market Openness through Regulatory Reform (1999).p.6,10

⁷⁸ STEWART, *The Global Regulatory Challenge to U.S. Administrative Law*.723

implement such decisions, that would not pass domestically. Since all ICH guidelines must be reached on the basis of *consensus*, limitations on the FDA, limit the network as a whole. If there is something the FDA can't agree to, the network as a whole can't either. This, accordingly may keep the ICH's output in line with the interests of US stakeholders that have prevailed in the domestic deliberation process. The same holds true regarding all other members that enjoy similar domestic accountability measures. It can generally be concluded that in principle, domestic accountability measures may limit the regulators (*de jure*), and in turn limit the network as a whole (*de facto*). Domestic accountability procedures are, consequently, a tool that may keep the network's output in check with the preferences that have emerged in the domestic deliberation processes of the member countries. Moreover, all of the member regulatory agencies, with their domestic processes, taken together, create a significant shield against undue influence of the industry. Finally, the public in member countries that lack domestic accountability procedures will suffer more disregard on behalf of the network than countries that maintain such measures.

That having been said, while in principle domestic measures may have a limiting effect, a separate question is, how meaningful they are in keeping the regulatory authorities in check with the interests of the US public. The literature, most notably Stewart, has doubted the power of domestic administrative law to provide meaningful accountability when domestically implementing global norms.⁷⁹ A central critique concerning international harmonization has been that procedures for harmonization are far less open to public scrutiny and participation than domestic regulatory decisional processes.⁸⁰ Another critique has been that the effective center of decision-making gravity lies outside of the agency, which in turn depreciates the value of domestic administrative law procedural requirements.⁸¹ As we have seen, the facts of this case suggest otherwise. The procedures for developing harmonized guidelines are equally open as those that apply to domestically developed guidance. Moreover, the *early* involvement of US stakeholders in the harmonization process, rather than only at the implementation stage, suggests that they participate in the effective part of the decision-making. On the other hand, however, this early involvement is not effective enough, as stakeholders may comment before the ICH meetings, and after a draft has been prepared, but they are not represented in the EWG proceedings. This is problematic, in particular given that the R&D industry *is* represented.

The decision to involve stakeholders during the EWG is a decision that would normally have to be made at the ICH level. This clearly points to the conclusion that while domestic measures are important, and contribute to accountability, they are not enough. In order to be more accountable, accountability measures at the global level (for example, that would allow for such involvement in the EWG) would be necessary. It is, hence a *combination* of both domestic and global procedures that will bring about better accountability.

⁷⁹ Id. at.723

⁸⁰ Id. at. 714

⁸¹ Id. at.719

Domestic and global administrative requirements should, accordingly, be regarded as complementary in achieving internal accountability.⁸²

Coming back to domestic measures, of course there are also additional concerns. For example, the fact that the FDA relies on guidance development procedures (rather than APA procedures) suggests that the accountability problem is enhanced. Whether these procedures and non-judicial appeals mechanism provide sufficient accountability is open to debate. Without the threat of judicial review, can demands on behalf of diffused social interests, such as by patients, have a limiting quality when confronted with other views at the global level? Moreover, even were the APA to apply, domestic procedures allow for *non-voting* participation of the public, whereas industry enjoys *voting-like* participation at the global level,⁸³ resulting in unequal representation of interests in the decision-making at the global level. Can regulators be trusted in such an unbalanced situation not to be captured by the industry's view, and to decide on the appropriate tradeoff between maximum achievement of national social interests (such as concerning the appropriate level of standards or level of protection) and maximum regulatory alignment?

The ability of domestic administrative law, accordingly, to control regulators (and in turn the network), has its limitations. But this problem of agency independence versus accountability is not something new, and is a central problem of any "regular" *domestic* democratic system,⁸⁴ and not one limited to regulators' transnational activities.

This then brings us to the question whether the particular characteristics of transnational activities/harmonization (being more removed than domestic processes,⁸⁵ the need to consider interests of foreigners and industry etc.) justify additional or specific domestic accountability measures beyond the existing ones, or what Stewart refers to as "parity plus".⁸⁶ In theory, or academically, that may be the case. In practice, as we have seen, there does not seem to be much concern in the US government. In other countries the approach seems to be slightly different. In Canada, for example, special requirements have been made. There, the *Guidelines on International Regulatory Obligations and Cooperation*⁸⁷ expressly acknowledge the concerns that international alignment of regulation raises, such as the lowering of standards or of the national levels of protection. The Guideline then says that in order to maintain public confidence in the national regulatory system that "analysis supporting regulations that pursue greater compatibility...should clearly demonstrate to decision makers the benefits, costs, and risks of these approaches."⁸⁸

⁸² See for a similar view *id.* at. 754.

⁸³ Distinction between voting and non-voting participation : see STEWART, *Accountability, Participation, and the Problem of Disregard in Global Regulatory Governance*, .

⁸⁴ See R.B. STEWART, *The reformation of American administrative law*, 88 *Harvard Law Review* (1975); JERRY L. MASHAW, *Structuring a "Dense Complexity": Accountability and the Project of Administrative Law*, *Issues in Legal Scholarship* (2005).

⁸⁵ STEWART, *The Global Regulatory Challenge to U.S. Administrative Law*. 728

⁸⁶ *Id.* at.723,728

⁸⁷ <http://www.tbs-sct.gc.ca/ri-qr/documents/gl-ld/iroc-cori/iroc-cori01-eng.asp>

⁸⁸ Section 3.1.2.

Finally, if compared with other global regulatory bodies such as treaty-based intergovernmental organizations, TRNs, thanks to being composed of regulators that are bound by domestic administrative law (as opposed to say diplomats active in intergovernmental organizations), allow for a much closer access of the public to the global rule making processes than would be available in diplomat-based discussions in say the WTO.

In the following section we explore the role of domestic law for external accountability.

6. Domestic Law and External Stakeholders

A. Defining the External Stakeholders

What role does and can domestic law play in the accountability of the TRN, or rather in offsetting its disregard, towards external stakeholders? Let us begin by defining the ICH's main external stakeholders: non-member countries, the generic drug industry and diffused interests (in non-member countries or transnational actors).

1. Non-member countries that adopt ICH guidelines

ICH guidelines are considered *de facto* global standards and are adopted by many countries that are not members to the network.

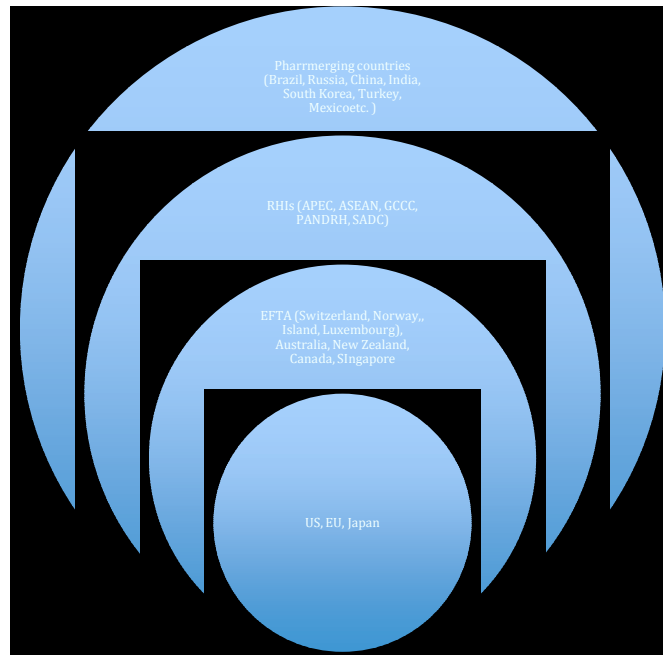
Within this group we can distinguish between three main sub-groups:

- (i) Developed countries, such as Switzerland, Canada or Australia. The pharmaceutical industry of these countries has traditionally been dependent and linked with that of ICH members. These countries have, hence, traditionally adopted ICH guidelines.⁸⁹
- (ii) With the shift of pharmaceutical production to emerging countries so-called "pharmerging" countries, such as China, Brazil, Russia and India, have been adopting ICH guidelines too.⁹⁰
- (iii) Regional harmonization Initiatives (RHIs) in APEC, ASEAN, GCC, PANDRH and SADC have been adopting ICH guidelines.⁹¹ Their members, including developing countries, have accordingly been adopting ICH guidelines too.

⁸⁹ For an overview of adoption of ICH guidelines by developed countries, please see BERMAN, *The Accountability of Transnational Regulatory Networks : The Case of the International Conference on Harmonization*

⁹⁰ For an overview of the pharmerging markets and their adoption of ICH guidelines, please see *id. at.*

⁹¹ For an overview of the RHIs and their adoption of ICH guidelines, please see *id. at.*



2. The generic drugs industry

While ICH guidelines were initially intended for *new* drugs, quality-related guidelines are now also regularly used for *generic* medicines. ICH guidelines, accordingly, now also affect the generic medicines industry. The generic industry is particularly important for developing countries since most generic drug production takes place there. Moreover, the main health concern of developing countries is the availability of essential drugs to its local population, and it relies to this end, on generic drugs. The concern has been raised that ICH guidelines, being a product of high-income countries, are unnecessarily high, that is not necessarily justified by safety concerns. These standards are too costly for producers of generic drugs in developing countries. Their adoption in developing countries may, hence, unnecessarily squeeze out local generic drug producers, with adverse effects on the availability of drugs to the local population.⁹²

3. Diffused interests of consumers, patients etc. in non-member countries.

XXXXX

The ICH has set up several “outreach” bodies that allow for communication with non-member countries, such as the Global Cooperation Group (bringing together the RHIs and drug regulatory authorities from pharmerging countries) or the Regulators Forum (bringing together regulators from pharmerging countries). The ICH has also welcomed them as non-voting participants in EWGs. The IGPA, an association of generic medicines manufacturers from the EU, Canada, US, Japan and India, has also been accepted as an “interested party”. Developed countries such as EFTA members and Health Canada have been observers since

⁹² WHO, Report of a WHO Meeting: The Impact of Implementation of ICH Guidelines in Non-ICH Countries (13-15 September 2001), p.2, 21-24.

the ICH was first set up. At the ICH level, hence, we see that responsiveness-promoting measures have been introduced.⁹³

But what does or should domestic law offer to improve the problem of disregard? One of the main criticisms against the use of domestic accountability mechanisms or procedures for strengthening the accountability of networks has been that this would not be able to solve the problem of the disregard of the interests of non-member countries.⁹⁴ Is that indeed the case?

B. Domestic Law in Member States

Notice and comment procedures in US rule making or guidance development are open towards “all affected parties outside of FDA”,⁹⁵ including foreigners.⁹⁶ Hence, foreign governments, companies or individuals (from any ICH non-member or member state), say from Brazil or Japan, could comment to the FDA during the ICH guideline development process. Foreigners would also have the legal or semi-legal accountability mechanisms (described above) at their disposal. While the claims are limited to the FDA’s conduct, in turn, as discussed above, they could have an impact on the network as a whole. In the ICH’s case, direct commenting to the ICH is possible, and so this may not be necessary. But in other networks that lack such a commenting option, this may be a tool for external stakeholders to voice concerns.

We see this approach of openness towards foreign stakeholders within the domestic administrative systems in many OECD/APEC countries. In fact, it is part of the regulatory reform many OECD and APEC countries are undergoing in the past decade. The “APEC–OECD Integrated Checklist for Regulatory Reform” (2005), a checklist of regulatory reform principles for the development of good regulatory governance principles, reflecting regulatory reform principles developed since the 1990’s in a series of OECD and APEC documents, requires that the development of rules, including non-binding guidelines, be transparent and accessible to foreign parties,⁹⁷ allowing them to comment,⁹⁸ including their access to appeal systems.⁹⁹ Moreover, agreements to this end have been concluded between countries such as the US and the EU,¹⁰⁰ or US, Mexico and Canada.¹⁰¹ And indeed, we find, for example, such rules in EMA’s Guideline Development Procedures,¹⁰² and in Canada.¹⁰³

⁹³ For a detailed overview, see BERMAN, *The Accountability of Transnational Regulatory Networks : The Case of the International Conference on Harmonization*

⁹⁴ See STEWART, *Accountability, Participation, and the Problem of Disregard in Global Regulatory Governance*, .p. 38

⁹⁵ 21 CFR 10.115 (c)(3).

⁹⁶ OECD. p.6, 10.

⁹⁷ Principle A6.

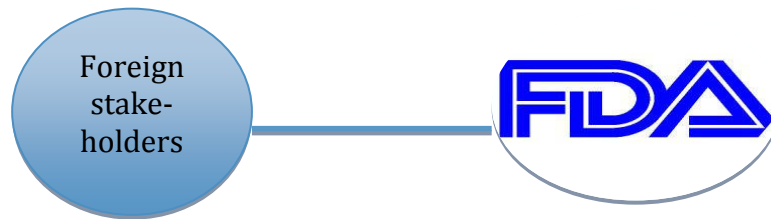
⁹⁸ Principle D5.

⁹⁹ Principle A11.

¹⁰⁰ TRANSATLANTIC ECONOMIC PARTNERSHIP, *Guidelines on Regulatory Cooperation and Transparency* (2002).(sec. 4, sec. 17)

¹⁰¹ Canada/United States/Mexico Security and Prosperity Regulatory Cooperation Framework.

¹⁰² Sec. 4.7 of the EMA Procedure on Guideline Development, “Collection and Treatment of Comments”.



To conclude, domestic law in the US makes certain “other responsiveness promoting measures”, and possibly a legal mechanism, available to external stakeholders.

C. Domestic Law in Non-Member States

It is this paper’s view that domestic administrative law within non-member states implementing harmonized guidelines may have a role in compensating for the problem of disregard taking place at the global level. This is the case in the ICH, but also more generally concerning any other TRN developing harmonized guidelines.

Domestic administrative procedures may serve here in two functions. First, they generate public input in non-member countries. Thanks to ICH procedural rules that allow comments by non-members, this input may be presented to the EWG and possibly taken into account. Second, domestic administrative procedures can allow countries to balance their domestic needs and interests, with the interest in adopting ICH guidelines. In this latter function, domestic administrative law serves as an umbrella within each non-member state to protect its national interests from undesired externalities of the network.

It is important to note that in both cases, domestic administrative law does not function as an accountability measure, as it does not have any relationship-supporting role between the non-members and the TRN. Further, because they are not members and their consent is not required for the consensus, their domestic administrative procedures don’t have the *de facto* power limiting power that members’ domestic measures may have (as discussed above), though clearly it will often be in the TRNS interest to take their considerations into account (a weak accountability measures nevertheless?).

Anyways, many non-member countries are indeed relying on domestic administrative procedures: In many developed countries such as in Canada and Australia, there are domestic administrative procedures (notice and comment, publication obligations etc.) in place that allow for public input during the harmonization process, and before adoption.¹⁰⁴On the other hand, Swissmedic does not conduct consultations, as it as a general rule does not conduct consultations for the development of guidelines. For the Swiss public, which are

¹⁰³ TREASURY BOARD OF CANADA, Guidelines for Effective Regulatory Consultations.

¹⁰⁴ DR LEONIE HUNT (OFFICE OF PRESCRIPTION MEDICINES AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION), Use of ICH Guidelines in Prescription Medicine Regulation in Australia;id. at. <http://www.ich.org/LOB/media/MEDIA5022.pdf>, p.6.

not ICH members, and also lack domestic accountability measures, the accountability problem is at its worst. China's State Food and Drug Administration, an emerging administration, has set up a "ICH research guideline group", whose goal is to study ICH guidelines, compare them with Chinese guidelines, and adapt the latter while maintaining local needs.¹⁰⁵

Regarding developing countries, this paper argues that domestic procedures may have a role to play in offsetting the problem of disregard: Developing countries do not have the resources to attain ICH standards. In such countries, the availability of affordable generic medicines is the most urgent concern, and so their public health needs justify a different risk/benefit balance than high-income countries (as reflected in ICH guidelines).¹⁰⁶ Since ICH guidelines are considered unnecessarily high (that is, not justified by safety/quality/efficacy concerns) for generic medicines, by adapting, or lowering, the standards.¹⁰⁷ local production of generic medicines, and in turn their accessibility, will remain possible.

That said, there are clearly several limitations in using domestic law as a tool to offset the problem of disregard. First, the market being dominated by ICH countries, in remaining globally competitive, guidelines of non-member countries may not be substantially different from ICH guidelines. Local adaptation of standards is, accordingly, not a significant option for *export* oriented countries/products (such as Canada or China), but rather concerns production for *local* needs. A second concern is that many developing countries have insufficient regulatory capacity, and poorly developed regulatory authorities, or no regulatory authority at all, making formal local adaptation unfeasible. The third and most significant concern is that in some cases, local adaptation could lead to double standards between "western" and "third world" standards,¹⁰⁸ or between standards for export-oriented products and products for local use. This raises ethical concerns that are beyond the scope of this paper. Sad as it is, in practice, this is anyways the case in many poor countries. In such countries the case will often be that the local drug regulatory authority will have formally fully adopted the international guideline, but with the standards being too high for local producers to comply with, will not enforce them. This is, for example the case in Tanzania, where local authorities formally adopt international standards, but for industrial policy purposes, support local producers by not enforcing international standards.¹⁰⁹ [*Further empirical work on what is happening in practice is required.*]

¹⁰⁵ DING JIANHUA, Introduction of ICH China Research WG (June 2010). at <http://www.ich.org/LOB/media/MEDIA6051.pdf>.

¹⁰⁶ VESNA KOBLAR (SLOVENIA), Impact of ICH on Non-ICH countries (2003);id. at.; WHO, *WHO Drug Information Vol 22, No. 3, 2008*, WHO Drug Information 2008 . 184

¹⁰⁷ Kourilsky

¹⁰⁸ (SLOVENIA).

¹⁰⁹ CHUKILIZO NDIRONDA B., Availability and Quality of Medicines in Low Income Countries: The role and opportunities for European manufacturers (2011).

This brings to the conclusion that in order to improve the TRNs accountability towards its significantly affected external stakeholders, their involvement at the global level is necessary.

7. Conclusion

The purpose of this paper has been to explore the role domestic law has to play in the accountability of TRNs. The paper has come to several conclusions.

First, domestic law may condition the participation of regulators in TRNs on the fulfillment of procedural or substantive requirements by the transnational networks. Where such rules are set by powerful member states, whose participation in the network is cardinal, the rules will apply *de facto* to the network as a whole. If more than one country imposes similar requirements, we can expect to see more TRNs (and global actors more generally) designed in accordance with good administrative procedures. Accountable administrative practices at the global level can, hence, be linked back to domestic legal requirements.

Second, domestic administrative procedures in TRN member countries has an important role to play in keeping the regulators, and in turn the network as a whole, accountable towards the interests of internal stakeholders. That is in particular the case when decisions in the network need to be reached by consensus. The extent to which it can keep the regulators accountable is, however, debatable, and we may need to consider developing “parity plus” domestic accountability measures. In any event, domestic law has its limitations and in view of achieving better accountability towards internal stakeholders, domestic measures must be complemented by global accountability measures. Only a combination of both will allow for meaningful accountability towards internal stakeholders.

Further, domestic notice and comment procedures provide the wide public in member states access to global processes – something that is lacking in the traditional diplomat-based international organizations, and provides an accountability “advantage” of TRNs over IOs.

As regards external stakeholders, domestic administrative law in the US (as well as in other countries) is opening up to external stakeholders, and provides an additional avenue for voicing concerns.

Further, domestic law in non-member countries allows external stakeholders to express their views at the global level. This too is possible thanks to a combination of domestic measures (notice and comment) and measures at the global level (openness to comments by non-members), and reflects the importance of accountability measures at both levels. Domestic law in non-members may also theoretically allow to adapt international standards to local needs. In this case administrative law does not serve as an accountability measure, but rather as an unilateral umbrella from network externalities. In practice, this approach comes across several problems.

Consequently, domestic administrative law as a base to solve external accountability, while not to be completely overlooked, has relatively little to offer. Non-member countries, industries or diffused interests that are significantly affected by network externalities are, hence, best off participating at the global level. This brings my conclusion closely to that of others that have argued that domestic accountability procedures do not solve the problem of the disregard of the interests of non-member countries.¹¹⁰

To conclude, domestic law is important in improving the accountability of TRNs towards internal stakeholders, and has some role, albeit limited, in offsetting the problem of disregard towards external stakeholders. Accountability measures at the global level remain important too. They are important in improving the accountability towards internal stakeholders, and are critical when it comes to external stakeholders. In designing domestic or global accountability measures, these purposes should be kept in mind.

It should also be kept in mind that while this paper has for analytical purposes distinguished between internal and external accountability, there are issues of overlap that affect both. For example, the ICH's joint regulatory authority-industry collaboration raises concerns regarding the integrity of the process, which in turn has effects on everyone. This is a topic that could be regulated under domestic law (with *de facto* imposition) or at the global level.

¹¹⁰ See STEWART, *Accountability, Participation, and the Problem of Disregard in Global Regulatory Governance*, .p. 38