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ARTICLE

Enhancing Vulnerable Groups' Participation in Medicines Risk Regulation: The Case of the European Medicines Agency's Public Hearing on Quinolone Antibiotics

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Abstract

What is the value of including vulnerable people in risk regulation decision-making in the European Union (EU)? This article examines a distinctive approach employed by the European Medicines Agency (EMA): public hearings integrated within safety reviews of medicinal products. The article presents findings from a case study of the EMA's public hearing on Quinolone antibiotics, which was included by the EMA as part of a review process that led to significant tightening of regulatory restrictions on the prescribing of this class of antibiotics. The article argues that the public hearing enabled a group of patients who had been victims of a debilitating toxicity syndrome associated with Quinolone antibiotics to criticise the existing scientific evidence base around the safety of Quinolone. Deploying the quantitative Discourse Quality Index and an interpretive analytical approach, the article shows how patients challenged the evidence base in a manner that was efficacious in advancing knowledge in this area of risk regulation. When physically staged alongside interventions by professional experts, the article argues that patients facilitated a process of "negotiation" of expertise, leading professional representatives to propose methods of coordination in order to integrate the patients' qualitative evidence of their suffering with the toxicity syndrome. Ultimately, this process led to the EMA proposing more stringent future guidelines for the prescription of Quinolone antibiotics in the EU.

Keywords: epistemic injustice; European Union; health inequalities; regulation

I. Introduction

Stakeholder engagement has been a growing theme within the study of regulatory governance.[1] This is particularly the case in risk regulation, where stakeholder involvement and consultation have been highlighted by both practitioners and academics as tools "supposed to serve responsive, effective and legitimate regulation"[2] in order to manage risk "responsively".[3] Stakeholder engagement can contribute valuable external expertise, identify and monitor risks in industry and facilitate risk management with key private-sector

[1] C Braun and M Busuioc, "Stakeholder engagement as a conduit for regulatory legitimacy?" (2020) 27(11) Journal of European Public Policy 1599–611.

[2] S Arras and C Braun, "Stakeholders wanted! Why and how European Union agencies involve non-state stakeholders" (2018) 25(9) Journal of European Public Policy 1257–75.

[3] C Koop and M Lodge, "British economic regulators in an age of politicisation: from the responsible to the responsive regulatory state?" (2020) 27(11) Journal of European Public Policy 1612–35.

actors and non-governmental bodies. However, at the same time critics have noted the limited scope regulators have to include a broad range of stakeholders.[4] Others worry that stakeholder engagement can be tokenistic and generate only a surface-level impression of including all relevant stakeholders.[5] More worryingly still, groups among the general public that are vulnerable to the highest burden of exposure to regulatory risks (eg health or environmental risks) feel that business organisations dominate regulatory consultation processes.[6]

Nevertheless, vulnerable groups among the wider public may make important contributions to regulatory decision-making when they are considered as important stakeholders. Their lived experiences provide a source of data and evidence about how regulatory risks manifest in everyday life and the *efficacy* of regulatory coordination 'on the ground'. This evidence shows the extent to which regulatory coordination garners authority and legitimacy with relevant communities.[7] Ignoring the experiences of sections of the public whose vulnerability to regulatory risks sheds important light on their causes and responses can lead to blind spots and crises.[8] Failing to recognise the valuable qualitative data and evidence vulnerable groups hold can make regulatory failure and injustice more likely.[9] More positively, including vulnerable groups in the collaborative co-design of regulatory rules can contribute to effective regulatory processes.[10]

How can European regulatory institutions integrate vulnerable groups as stakeholders in regulatory decision-making? Given the transnational scale at which European Union (EU) risk regulation operates, this is a difficult task. Stakeholder engagement at an EU level commonly takes place through consultation, with advocacy organisations representing vulnerable groups alongside other stakeholders from industry, Member States and other EU bodies.[11] Regulatory decision-making, particularly in relation to product safety, involves the highly technical consideration of datasets pertaining to the health and physical risks associated with medicinal, food, chemical and other products in the Single Market. These datasets are usually quantitative in nature and are provided by professional and industry bodies with the purpose of making reliable generalisations about product risks. They are intended to give regulatory decision-making agencies such as the European Medicines Agency (EMA), European Food Safety Authority (EFSA) and European Chemicals Agency (ECHA) sufficient scientific evidence to justify regulatory requirements on industry or occasionally to ban specific products outright across the EU. Including qualitative evidence in the form of the particular views of groups or individuals runs the risk of introducing subjectivity into the safety review process at the cost of generalisability and scientific credibility.

Despite these risks, this article argues that vulnerable groups can provide vital qualitative evidence when included within regulatory decision-making via structured public

[4] DP Horton and G Lynch-Wood, "Technocracy, the market and the governance of England's National Health Service" (2020) 14(2) Regulation & Governance 295–315.

[5] Y Papadopoulos, "Problems of democratic accountability in network and multilevel governance" (2007) 13(4) European Law Journal 469–86.

[6] S Yackee, "Participant voice in the bureaucratic policymaking process" (2015) 25(2) Journal of Public Administration Research and Theory 427–49.

[7] VA Schmidt, "Democracy and legitimacy in the European Union revisited: input, output and 'throughput'" (2013) 61(1) Political Studies 2–22; ML Flear, "Epistemic Injustice as a Basis for Failure? Health Research Regulation, Technological Risk and the Foundations of Harm and Its Prevention" (2020) 10(4) European Journal of Risk Regulation 693–721.

[8] K Wegrich, "The blind spots of collaborative innovation" (2019) 21(1) Public Management Review 12–20.

[9] Flear, supra, note 7.

[10] R Weymouth and J Hartz-Karp, "Deliberative collaborative governance as a democratic reform to resolve wicked problems and improve trust" (2015) 17(1) Journal of Economic & Social Policy 62–95.

[11] I Pérez Durán, "Interest group representation in the formal design of European Union agencies" (2018) 12(2) Regulation & Governance 238–62.

hearings. Within public hearings individuals who experience the risks associated with products that are under safety review can provide valuable qualitative evidence that adds depth and meaning alongside quantitative datasets demonstrating product safety risks at a generalisable scale. Moreover, in the process of elite deliberation that characterises EU product safety reviews, interventions by vulnerable groups can provide an important corrective to the limitations and blind spots of elite-led deliberations.

To make this argument, this article presents new analysis of a public hearing held by the EMA during its 2018 safety review of Quinolone antibiotics. The public hearing included testimonial evidence from patients who had used Quinolone antibiotics and had experienced serious side effects. Their testimonies were given in advance of interventions from the product manufacturer, academics and other relevant stakeholders. This article presents an analysis of the public hearing, one of the first conducted by an EU regulatory agency alongside its internal product safety review procedures, using the Discourse Quality Index (DQI).[12] The DQI measures the "deliberative quality" of each intervention during the public hearing across nine indicators of quality deliberation. Interpretation of these data is conducted using the concepts of "negotiated expertise" and "boundary work" from the literature on deliberative and epistemic diversity in policy-making. As a result of this interpretation, the article argues that the patients' interventions in this public hearing challenged the boundaries of accepted professional knowledge on Quinolone. Their interventions elicited responses from professional representatives that advocated coordination to expand the scope of regulatory requirements in line with newly accepted boundaries of knowledge. The public hearing achieved this by situating the vulnerable group (patients) *in negotiation* with the professional experts.

The article proceeds as follows. First, it reviews the limitations of elite deliberations over regulatory risk and the role of qualitative evidence and deliberative innovations in the risk regulation of medicines. Second, it introduces the case study of Quinolone and the EMA's public hearing and safety review. That section also outlines the DQI measure and interpretive methodology. Third, the article presents the findings from the applications of the DQI to an analysis of four hours of audio-visual data covering the public hearing, accessed via YouTube. Fourth, it presents an interpretive analysis of the data, drawing in an iterative manner from the concepts of "negotiated expertise"[13] and "boundary work" in arm's length agencies[14] to make sense of the value of public hearings in EU regulatory governance. Finally, the article concludes that public hearings can improve the efficacy with which epistemic and deliberative diversity is facilitated within safety review processes.

II. Stakeholder engagement, elite deliberation and "epistemic diversity"

Existing research on stakeholder engagement in European regulatory governance demonstrates the diversity of engagement, but also its "elite" dynamics. Moreover, as this section argues, the engagement of mainly "elite" actors in EU risk regulation is not surprising. It is in conformity with the mission of EU regulatory agencies and networks to achieve "output" legitimacy, including regulatory effectiveness based on credible evidence.[15] This focus

[12] M Wood, "Can independent regulatory agencies mend Europe's democracy? The case of the European Medicines Agency's public hearing on Valproate" (2022) 24(4) British Journal of Politics and International Relations 607–30.

[13] E Krick, "Negotiated expertise in policy-making: how governments use hybrid advisory committees" (2015) 42(4) Science and Public Policy 487–500.

[14] J Boswell, "Keeping expertise in its place: understanding arm's-length bodies as boundary organisations" (2018) 46(3) Policy & Politics 485–501.

[15] FW Scharpf, *Governing in Europe: Effective and Democratic?* (Oxford, Oxford University Press 2009).

on effectiveness comes at the expense of "input" legitimacy, which refers to control of regulatory decision-making by the public and politicians, and "throughput" legitimacy, which refers to a focus on inclusiveness, openness, transparency and accountability within regulatory decision-making processes.[16] However, it is important to understand the limitations of elite deliberation for including relevant evidence-based decision-making and the value of "epistemic diversity" for regulatory reflexivity and risk management. This, in turn, provides theoretical grounds for expecting that the inclusion of qualitative testimony from vulnerable groups will provide "added value" for regulatory decision-making around product safety in the EU; or what Vivien Schmidt calls "throughput legitimacy".[17]

Existing literature on stakeholder engagement shows how stakeholders engage both with EU institutions in general and by specific regulatory agencies who are designing regulatory standards. Coen and Katsaitis' research shows "élite pluralism and preponderance of business interests in lobbying the European Commission".[18] When the Commission conducts consultations, representatives of business primarily organise to make evidence submissions and take part in stakeholder discussions. This is in the form of in-house lobbying units or via law firms and similar professional consultancies. Moreover, they show that Commission Directorates General (DGs) with a higher interest in regulatory effectiveness ("output legitimacy") place a higher value on expertise and are more likely to prioritise engagement with such business representatives.

The central role of business representatives in risk regulation is reinforced by recent research on stakeholder engagement by EU agencies via consultations, stakeholder bodies and representation on agency boards.[19] This evidence shows that agencies with a regulatory remit (eg on medicines, food and chemicals) are highly reliant on stakeholders for technical information in the relevant sector and highlights that stable patterns of inclusion and exclusion exist, with business representatives being included more prominently. This finding on the central role of business is given nuance by Pérez Durán, who finds considerable variation in the representation of interest groups across regulatory agencies.[20] Agencies with a stronger regulatory role tend to include more formalised representation for a balanced range of groups representing industry, trade unions and citizens. Arras and Beyers also show that the diversity of stakeholders increases at earlier stages of the policy process when consultations are more open.[21] Nevertheless, their systematic study of a range of EU agency consultations concludes: "Even in the most diverse consultations ... 69% of consultees represent regulated industries."[22]

The reliance on elite business interests and the emphasis on their ability to provide technical information and evidence is not particularly surprising. It is a key function of the European Commission and regulatory agencies to achieve "output" legitimacy and basing policy recommendations and regulatory decisions on credible evidence. Such information is often held by industry bodies such as pharmaceutical, chemical or food manufacturers, as well as other industry actors in supply chains. Regulatory agencies have legal obligations to also consult with consumer organisations, as deemed appropriate according to task and issue.

[16] Schmidt, supra, note 7.

[17] ibid.

[18] D Coen and A Katsaitis, "Chameleon pluralism in the EU: an empirical study of the European Commission interest group density and diversity across policy domains" (2013) 20(8) Journal of European Public Policy 1104–19.

[19] Arras and Braun, supra, note 2

[20] Pérez Durán, supra, note 11.

[21] S Arras and J Beyers, "Access to European Union agencies: usual suspects or balanced interest representation in open and closed consultations?" (2020) 58(4) JCMS: Journal of Common Market Studies 836–55.

[22] J Beyers and S Arras, "Who feeds information to regulators? Stakeholder diversity in European Union regulatory agency consultations" (2020) 40(4) Journal of Public Policy 592.

In this context, what value may specific procedures for engagement with vulnerable groups have for EU regulatory bodies in particular and risk regulation more generally? This article theorises that such engagement may enhance regulatory decision-making based on addressing two limitations of closed elite deliberation: epistemic and deliberative inclusivity. First, it is important to recognise that risk regulation at the transnational level already proceeds through intensive deliberation about a range of scientific evidence.[23] Studies of EU decision-making set out the burgeoning regulatory rules and processes for ensuring effective "use of science" within the Commission and regulatory agencies.[24] Regulatory agencies including the EMA, EFSA, ECHA, European Centre for Disease Prevention and Control (ECDC) and others draw on extensive in-house expertise from relevant professions and scientific expertise, institutionalised within a range of Committees for considering regulatory rules.[25] Moreover, the Commission's Joint Research Centre provides a range of scientific services and expert advice for the DGs.

However, despite longstanding promises by the Commission to include the widest range of evidence, the way in which scientific evidence is used within EU regulatory deliberations is not always clear. There is sometimes a conflation of the form of "evidence" needed to make Impact Assessments and product safety reviews (data on effectiveness) and the balance of expert perspectives needed to inform broader regulatory decisions. Schrefler and Pelkmans find in an informal SWOT (strengths, weaknesses, opportunities and threats) analysis of the use of science in EU policymaking that there is a "partial ... use of scientific evidence in some cases without corrections governed by guidelines".[26] Moreover, they find an "absence of clear criteria to establish what scientific evidence is needed and when it is sufficient to assess risks". This lack of clarity in when expert evidence is used and why runs the risk of political contention. As Schrefler and Pelkmans also note, EU risk regulation processes are vulnerable to a "perceived lack of transparency in the wider policy community", despite the EU's transparency rules being among the most stringent for a transnational regulatory authority.[27]

How can these risks of a perceived lack of transparency be managed? My argument is that the explicit inclusion of vulnerable people within regulatory decisions can channel deliberation over contentious political issues related to risk regulatory governance in a way that adjusts "elite" deliberative processes. This is because such inclusion adds two important elements to the EU's risk regulation process: mitigating "epistemic injustice" and "agonistic provocation". First, the experiential evidence that vulnerable people possess of the negative effects of products ought to be given special consideration to avoid what Fricker terms "epistemic injustice".[28] Epistemic injustice occurs where individuals who have direct knowledge of the safety risks of particular products do not see their knowledge included within political decision-making. This in turn leads them to evaluate negative outcomes from regulatory rulings as a "failure", a construction that is reinforced by other political groups, due to the perceived *injustice* of the lack of inclusion of the knowledge they have gained through lived experience within regulatory decision-making processes.

[23] E Krick and Å Gornitzka, "Tracing scientisation in the EU Commission's expert group system" (2020) Innovation: The European Journal of Social Science Research 1–21.

[24] M Wood, "Europe's New Technocracy: Boundaries of Public Participation in EU Institutions" (2021) 59(2) Journal of Common Market Studies 459–73.

[25] C Ossege, "Driven by expertise and insulation? The autonomy of European regulatory agencies" (2015) 3(1) Politics and Governance 101–13.

[26] L Schrefler and J Pelkmans, "Better use of science for better EU regulation" (2014) 5(3) European Journal of Risk Regulation 314–23, 319.

[27] ibid.

[28] M Fricker, *Epistemic Injustice: Power and the Ethics of Knowing* (Oxford, Oxford University Press 2007).

Mitigating epistemic injustice requires that people who directly experience regulatory outcomes – those who are vulnerable to the effects of negative personal outcomes "on the ground", particularly in the domain of health – are given close attention within regulatory processes. Personal experiences of negative health impacts have value not only as datapoints within statistical datasets, but also as qualitative evidence in the form of written or audio data. Such "close attention" to lived experience is only possible through giving priority to such qualitative data alongside consideration of statistical and quantitative datasets of product safety. Moreover, it is not sufficient that such attention be given by Committee members in deciding on regulatory risks. It is vital that the experiences of vulnerable communities are *seen to be included by those groups*. Regulatory decision-makers need to *visibly* include vulnerable groups' experiential data on an equal footing to other sources of data. This is because epistemic injustice and the way in which it links to perceptions of regulatory *failure* are matters of social *construction*.[29] As Flear argues: "reliance on a narrow discourse of technological risk in the regulatory framing of harm may contribute to epistemic injustice, *and that this may underlie harm and in turn lead to the construction of failure*".[30]

Second, the quality of deliberation can be strengthened by *diverse deliberative* interventions from groups who are usually marginal to regulatory decision-making. Although the literature on deliberative policymaking emphasises that regulatory decisions ought to be based on reasoned discussion by all affected interests over relevant evidence, it cautions that "reason-giving" is not always the best way to present evidence within deliberative processes.[31] Particularly where important evidence is held by individuals who are emotionally "close" to that evidence or value it in a personal capacity, the evidence may be best presented not in a "reasoned" and neutral way typical within scientific research, but rather in the form of a rhetorical provocation or narrative.[32] Moreover, where evidence may be ethically or morally troubling or difficult to process on a personal level for the audience, it may be inappropriate to present it in a "reasoned" manner that gives an impression of dispassionate detachment from its implications. Such interventions have been advocated in theoretical debates by "agonists" who argue that deliberation cannot proceed through privileging the giving of reasons, as expected by (some) deliberative democrats.[33] Rather, they argue, rhetorical provocations that expose both the evidence and the (negative) emotion of the individual towards others (as in the presentation of contending arguments in a criminal trial) can be more appropriate. These "agonistic" arguments have found traction in the area of legal scholarship on decision-making in courts but may also be relevant for deliberations in other regulatory arenas.[34] While regulatory Committees already value deliberation over diverse evidence, diverse deliberative "interventions" and types of evidence that are valued less in technical or scientific arenas may strengthen the robustness of deliberative decision-making by "troubleshooting" blind spots in technical regulatory decision-making.

Both of the benefits of including vulnerable groups outlined above may be applicable to a variety of processes and procedures. Vulnerable groups may be included via specialised forums through which they may discuss the regulatory risk in question, with the evidence from these discussions then being forwarded onto the "main" regulatory committee – a

[29] Flear, supra, note 7.

[30] ibid, 695, emphasis added.

[31] SA Ercan, CM Hendriks and J Boswell, "Studying public deliberation after the systemic turn: the crucial role for interpretive research" (2017) 45(2) Policy & Politics 195–212.

[32] E Beauvais, "Deliberation and non-deliberative communication" (2020) 16(1) Journal of Deliberative Democracy 4–13.

[33] C Mouffe, "Deliberative democracy or agonistic pluralism?" (1999) 66(3) Social Research 745–58.

[34] R Mańko, "Judicial Decision-Making, Ideology and the Political: Towards an Agonistic Theory of Adjudication" (2021) 33 Law and Critique 175–94.

process often termed "enclave deliberation".[35] Alternatively, qualitative evidence of the experiences of vulnerable groups may be sourced via focus groups, direct observation or interviews. These can then be considered alongside other evidence sources by the committees. Although these approaches clearly provide qualitative evidence and an element of "visibility", they are at one step removed from Committee members and the regulatory process itself. Both of the criteria of overcoming epistemic injustice and enabling non-deliberative interventions require that vulnerable groups' evidence can contribute in a way that *empowers* the individuals in question to contribute this evidence. This requires *adjustments* by other groups to enable vulnerable groups to contribute their evidence in dialogue with other forms of evidence.

III. Case study and method: the European Medicines Agency's public hearing on Quinolone

This article presents evidence from a case study of the EMA's public hearing during its safety review of Quinolone. A case study approach is useful because it gets beneath surface-level appearances of the inclusion or exclusion of vulnerable groups. Some studies statistically map the range of groups involved in a range of consultation processes, but these analyses are limited in their ability to appreciate the way in which vulnerable groups' needs and the knowledge they provide are included in substantive discussions about regulatory change. A case study approach appreciates the particular contextual dynamics of the regulatory and political processes in and through which vulnerable groups' evidence comes to be discussed in regulatory decision-making. Various contextual details including the technical details of the product, the particular harm that arises from excluding vulnerable groups and the value their perspectives add to decision-making can only be appreciated through a case study approach that pays carefully attention to the ways in which contextual details shape how vulnerable groups' knowledge claims are included or excluded.

As the regulatory agency for pharmaceuticals in the EU, the EMA is responsible for the "centralised procedure" through which pharmaceutical firms receive regulatory approval for their products in the European Single Market. If concerns arise about the safety of medicines after their approval, the EMA can launch post-authorisation safety reviews and recommend changes. The Pharmacovigilance Risk Assessment Committee (PRAC) is the dedicated Committee in the EMA for the design and evaluation of post-authorisation safety studies.

In 2018, the EMA reviewed the safety of Quinolone, which refers to a class of antibiotics ("fluoroquinolones") contained in medicines commonly administered to treat serious illnesses, where standard antibiotics have not proved effective. The safety review came in light of mounting evidence that Quinolone is linked to serious disabling side effects on muscles, tendons or joints and the nervous system, a condition termed "fluoroquinolone toxicity syndrome". The review was initiated on 9 February 2017 at the request of the German medicines authority (Bundesinstitut für Arzneimittel und Medizinprodukte; BfArM) under Article 31 of Medicinal Products Directive 2001/83/EC.

The EMA had trialled the use of a public hearing during a safety review of the medicine Valproate. Following the success of this trial, the EMA integrated a public hearing within the safety review process for Quinolone. The PRAC ran the public hearing as part of its stakeholder consultation process.[36] The PRAC had been empowered to hold public hearings via Article 107j of Medicinal Products Directive 2001/83/EC as part of safety review

[35] K Grönlund, K Herne and M Setälä, "Does enclave deliberation polarize opinions?" (2015) 37(4) Political Behavior 995–1020.

[36] Wood, supra, note 12.

procedures under Article 20 of Regulation (EC) No 726/2004 and Articles 31 or 107i of Directive 2001/83/EC. Article 107j states: "Where the urgency of the matter permits, the Pharmacovigilance Risk Assessment Committee may hold public hearings, where it considers that this is appropriate on justified grounds particularly with regard to the extent and seriousness of the safety concern." The PRAC also has latitude to organise the hearing as it sees fit: "The hearings shall be held in accordance with the modalities specified by the Agency."[37]

1. Research methodology

This research employed a mixed methodology including quantitative and qualitative analysis to show how the Quinolone public hearing impacted dynamics of elite deliberation and facilitated epistemic diversity. Mixed methodology is common in case study research where the aim is to investigate a process of interest using as many sources of data and research tools as possible. Here, we need to know the quality of discussion and the epistemic diversity of viewpoints, and we have transcripts and audio-visual data available, so the research drew on methodological tools that allowed for the measurement of the quality of discourse based on a quantitative assessment of available transcripts and allowed for the interpretation of the impacts of different speakers on the discourse, accounting for the context in which they spoke.

With these criteria in mind, following existing research on regulatory public hearings,[38] the research employed the quantitative DQI to assess the quality of deliberation by all contributors to the public hearing. The research also employed visual observation of the hearing on YouTube and conducted an interpretive analysis of these data. This enables the article to demonstrate the value of the "performance" of a public hearing in a way that facilitates epistemic and deliberative diversity.

a. The Discourse Quality Index

The DQI is a statistical measure used by researchers studying deliberative democracy empirically to evaluate the quality of forums that are intended to be deliberative. In its first iteration, the DQI sought to operationalise the classical features of "good" deliberation as conceptualised by Jürgen Habermas and (to a lesser extent) John Rawls.[39] The DQI features seven attributes, which are summarised in Appendix 1, including details of their measurement. A key point to note is that these features stick rigidly to the so-called "ideal speech situation" conceptualised by Habermas and have been subject to criticism. King argues: "Steenbergen et al's attempt to operationalise the theory [of deliberative democracy] produces conceptions that distort, reduce and omit vital notions of the ideals it aims to measure."[40] Nevertheless, the DQI has proved popular in empirical research, particularly on deliberation in legislative chambers and other arenas with relatively structured interventions by speakers rather than dynamic interplay within a group (eg in a mini-public). This makes the DQI well suited to application in the analysis of a public hearing.

In a revised version of the DQI, Gerber et al add two further dimensions: storytelling and questioning.[41] These refer to personal stories told by participants that are of relevance to

[37] Art 107j Directive 2001/83/EC.

[38] Wood, supra, note 12.

[39] MR Steenbergen, A Bächtiger, M Spörndli M et al, "Measuring political deliberation: a Discourse Quality Index" (2003) 1(1) Comparative European Politics 21–48.

[40] M King, "A critical assessment of Steenbergen et al's Discourse Quality Index" (2019) 1(1) Roundhouse: A Journal of Critical Theory and Practice 1–8, 4.

[41] M Gerber, A Bächtiger, S Shikano et al, "Deliberative abilities and influence in a transnational deliberative poll (EuroPolis)" (2018) 48(4) British Journal of Political Science 1093–118.

the deliberation and to the questioning of assumptions that underpin the rationale of the debate – for example, that it is even possible to resolve the issue within the confines of institutional rules and norms. These are not elements of "classical" deliberative qualities, but they have been added by participatory and agonistic theorists in an expanded list of normative qualities of discourse to promote a more inclusive theoretical approach to deliberation. Deliberative qualities are not only related to the quality of reasoning that is "other-regarding" (ie only the internal validity of argumentation and sophistication of communication in relation to the subject of deliberation), but also to rhetorical interventions and emotional critique aimed at disrupting hierarchical dynamics of power that structure closed deliberative forums. The research informing this article incorporated Gerber et al's additional dimensions to enable a nuanced assessment of deliberative qualities of participants in the public hearing.[42]

b. Visual observation

Alongside the quantitative measurement of deliberative qualities, the research also included qualitative visual observation of the YouTube recording of the hearing. Visual observation assumes that how regulatory innovations are physically staged and organised matters. Who sits where, when people speak and the tone in which they speak are important in terms of "symbolic meaning" for the way in which different types of evidence are considered and valued within the regulatory process. I also read the written transcript and accompanying written documentation submitted by participants and included in the EMA's documentation concerning the safety review of Quinolone.

Following a method established in previous research on the EMA's first public hearing on Valproate medicine,[43] I made written notes of the Quinolone public hearing recording and identified a set of themes linked to the conceptual focus of the research – in this case, deliberative and epistemic diversity. Interpretive analysis was conducted on the audio-visual content of the hearing so as to develop an explanatory narrative of the hearing's power in shaping epistemic and deliberative diversity.[44] I returned to relevant literature on "boundary work" and diversity in expertise in the public sector[45] to contextualise the importance of the themes identified for the dynamics of deliberation identified by the DQI. The themes were then linked together in a narrative that explains the power dynamics in the hearing that facilitated epistemic and deliberative diversity. This enables the research to explain how the staging of the public hearing shaped epistemic and deliberative diversity and increased the efficacy of the hearing in facilitating inclusion for vulnerable groups.

IV. The deliberative quality of the European Medicines Agency's Quinolone public hearing

The DQI analysis shows how the EMA's public hearing was characterised by deliberative diversity. In particular, it shows how patients and professionals (including industry representatives and academics) differ in the deliberative quality of their interventions. Table 1 sets out the results of the DQI analysis, and this is elaborated upon below.

Table 1 shows the DQI scores for thirteen patient and eight professional representatives. The results show significant differences in some deliberative qualities and

[42] ibid.

[43] Wood, supra, note 12.

[44] M Bevir, "How narratives explain" in D Yanow and P Schwartz-Shea (eds), *Interpretation and Method: Empirical Research Methods and the Interpretive Turn* (New York, M. E. Sharpe) pp 281–90.

[45] Krick, supra, note 13; Boswell, supra, note 14.

Table 1. Discourse Quality Index scores for participants in the European Medicines Agency Quinolone public hearing.

	Patients	Professionals
Sophisticated justification (3)	9 (69%)	6 (75%)
Qualified justification (2)	4 (31%)	1 (13%)
Inferior justification (1)	0 (0%)	1 (13%)
No justification (0)	0 (0%)	0 (0%)
Utilitarian common good (2a)	3 (23%)	1 (13%)
Difference principle common good (2b)	7 (54%)	0 (0%)
Neutral statement (1)	1 (8%)	6 (75%)
Sectional interests mentioned (0)	2 (15%)	1 (13%)
Explicit respect for groups (2)	3 (23%)	7 (88%)
Implicit respect for groups (1)	8 (62%)	1 (13%)
No respect for groups (0)	2 (15%)	0 (0%)
Explicit respect for demands (2)	0 (0%)	7 (88%)
Implicit respect for demands (1)	10 (77%)	1 (13%)
No respect for demands (0)	3 (23%)	0 (0%)
Counterarguments valued (3)	0 (0%)	2 (25%)
Counterarguments included – neutral (2)	1 (8%)	6 (75%)
Counterarguments included but degraded (1)	9 (69%)	0 (0%)
Counterarguments ignored (0)	3 (23%)	0 (0%)
Mediating proposal (2)	9 (69%)	7 (88%)
Alternative proposal (1)	0 (0%)	1 (13%)
Positional politics (0)	4 (31%)	0 (0%)
Storytelling (1)	12 (92%)	0 (0%)
No storytelling (0)	1 (8%)	8 (100%)
Questioning (1)	2 (15%)	3 (38%)
No questioning (0)	11 (85%)	5 (63%)

Note: See Appendix 2 for a table of scores for each participant (data anonymised to protect direct personal association of participant and score).

similarities in others. There are significant similarities in three respects: the level of justification for views, making of mediating proposals and the questioning of procedures and processes of the hearing. First, regarding the level of justification offered by both patient and professional representatives for their views, 75% of professionals and 69% of patients offer sophisticated justifications for the views they expressed. By contrast, a significant minority (31% of professionals and 25% of patients) were coded as offering either a qualified or inferior justification of views. Second, in terms of mediating proposals, a majority of both patient and professional representatives (69% and 88%, respectively) made a mediating proposal. "Mediating proposal" refers here to a suggestion for alternative regulatory decisions that balance the preferences of different groups. Third, on the questioning of procedures and processes of the hearing, a majority of 85% of patients and 63% of

professionals scored 0, referring to "no questioning" of the hearing's processes and procedures. A minority of patients (15%) and professionals (38%) scored 1, indicating that they did question the processes and procedures of the hearing.

While these similarities are interesting and relevant (see the interpretive analysis below), there are more indicators in which the patient and professional representatives diverge. Patients and professionals substantially diverged on five indicators. In terms of their consideration of the common good in their interventions, most patient representatives (54%) were coded as justifying their views using a version of Rawls' "difference principle" – that is, with reference to helping the least advantaged in a society. By contrast, no professional representatives were coded as justifying their views in these terms. A total of 88% of professional representatives were coded as justifying their views with a neutral statement, or only as statements of sectional interests, compared to only 23% of patient representatives.

There was also clear divergence in terms of respect for groups and demands. For both indicators, professional representatives were overwhelmingly coded as showing explicit respect for other groups and demands – seven out of eight for both indicators (88%) – and one out of eight professional representatives were coded as offering implicit respect for other groups and demands. By contrast, most patient representatives were coded as offering only implicit respect for other groups (62%) and demands (77%). A minority of patient representatives were coded as showing explicit respect for other groups (23%), and no patient representatives were coded as showing respect for other demands.

Divergence was most clearly evidenced in how representatives spoke about potential counterarguments to their own views and in terms of their propensity for "storytelling". First, while every professional representative was coded as recognising potential counterarguments to their own position – 75% implicitly and 25% explicitly were coded as doing this – only one patient representative (8% of the total) was coded in either of these categories. By contrast, 92% of patient representatives were either coded as including counterarguments but degrading them (69%) or ignoring counterarguments altogether (23%). The starkest division, however, was in storytelling. All eight professional representatives were not coded as including personal stories about Quinolone in their interventions, whereas all but one of the patient representatives (92%) were coded as including personal stories in their interventions.

The evidence from the DQI hence shows significant divergence between patient and professional representatives in the deliberative qualities of their interventions. This does not mean that one group is "less deliberative" than another. The coding suggests that both groups made sophisticated justifications for their arguments and suggested alternative proposals to mediate on disagreements. Scoring high on both aspects means we can say that the hearing was focused closely on evidence-based arguments about Quinolone and its effects. It was also analytically productive, in the sense that the PRAC received a series of diverse alternative proposals for how to regulate Quinolone.

Yet the analysis also suggests that professional and patient groups have different deliberative strengths. Patients are strong on storytelling and appeals to the common good, while the professional representatives score higher on showing explicit respect for other groups and demands and valuing and including counterarguments. The scores suggest that these groups have distinct approaches to deliberation, emphasising some qualities over others. For patients, personal stories and their connection to a common good argument – couched as wider argument in favour of achieving the justice for those who are the worst off in society – were preferred. By contrast, for professionals, respectful argumentation and the consideration of possible objections and alternative viewpoints are privileged. These might be viewed in terms of diverse ways of presenting deliberative argumentation and evidence either as an exercise in "claims-making" from an individual or group perspective or as a rational consideration of systematic clinical trials data. The following

section builds on these insights to show how the way in which the public hearing was "staged" allowed for diverse forms of deliberation and consideration of evidence within the regulatory process.

V. Challenging and shifting knowledge boundaries

This section interprets data from the Quinolone public hearing interventions using relevant concepts from the literature on evidence, knowledge and arm's length regulatory decision-making to facilitate an understanding of the value of a public hearing as enhancing the efficacy with which vulnerable groups are engaged within these processes. As argued above, if vulnerable groups are only given minimal formal opportunity to engage with risk regulation, their valuable perspectives can be in effect excluded, entailing a form of "epistemic injustice". The efficacy with which they are included is therefore of critical importance. The section argues that the Quinolone public hearing enabled the *challenging and expansion* of the boundaries of accepted professional knowledge within the PRAC's safety review of Quinolone antibiotics by putting vulnerable patients who experienced fluoroquinolone toxicity syndrome in negotiated dialogue with professional representatives.

1. Challenging knowledge boundaries

First, differences in deliberative quality measured by the DQI do not exist in a vacuum: deliberative qualities interact and play off each other; they are not static and uniform across each participant. It is crucial to understand how differences in deliberative quality are *produced* by participants; the way in which their interventions are scripted, staged and performed, in interaction with each other and the audience.

Theoretically, we can understand how the public hearing enabled the expansion and diversification of knowledge within the EMA via work on the diversification of knowledge in policymaking. Eva Krick's work is particularly helpful here because it theorises the role of citizens as experts within regulatory governance systems.[46] Her work conceptualises how advisory committees with hybrid membership offer *negotiated expertise* between scientific experts and other "lay" sources of knowledge within their procedures and processes.[47] For Krick, advisory committees like PRAC can provide ideal conditions for integrating lay citizens' perspectives as forms of knowledge. This negotiation does not need to be completely transparent. Indeed, Krick suggests that a relatively closed institutional context with limited media coverage allows for focused and rigorous discussion of the evidence.[48] Within this structured environment, citizens can be included *as experts* alongside figures from industry, academia and civil society and their views taken seriously alongside more "traditional" sources of expertise. Moreover, the connection to formal institutional sites of decision-making empowers these "citizen experts" to communicate their knowledge alongside and in interaction with the traditional experts. In doing so, their knowledge is treated as "expertise" because the traditional experts have to respond to their claims in an institutional environment within which scientific and medical evidence is considered.

Storytelling foregrounds patient experiences in a way that reveals qualitative data about access to medicines and difficulties with diagnosis that are not available through

[46] Krick, supra, note 13; E Krick, "The epistemic quality of expertise: contextualized criteria for the multi-source, negotiated policy advice of stakeholder fora" (2018) 12(2) Critical Policy Studies 209–26; E Krick, "Dealing with the epistemic-democratic tension in policy-making. Institutional design choices for multi-layered democratic innovations" (2021) 3(1) Political Research Exchange 1893608.

[47] Krick, supra, note 13.

[48] ibid.

quantitative datasets. For example, one participant in the Quinolone hearing highlighted his struggle in obtaining a diagnosis for fluoroquinolone toxicity syndrome:

> Of course I visited more than 10 different doctors. I belong to a family of sanitary professionals and I got to visit the most prestigious doctors around. They test for everything. All these physicians had no idea of what was wrong with me. I told them how things happened, I gave them all the information, but they never associated my symptoms to the CIPROFLOXACIN I took before [the medicine containing Quinolone]. After the worst 3 months of my life I visited the Head of Infectious Diseases and Microbiology of Navarra Clinic. He had worked in the USA in the Mayo Clinic for 8 years and he was the only one that told me: "I think you are suffering from Fluoroquinolone Toxicity Syndrome". He had good information, the rest didn't.[49]

Alongside this evidence about his problems with securing diagnosis, the patient also communicated that he was a practising pharmacist, had a stable family and was previously extremely healthy, making his evidence all the more compelling. His story suggests an underestimation of the problem of fluoroquinolone toxicity syndrome at the practitioner end of risk regulatory processes – the sites at which Quinolone medicines are distributed and assessed for outcomes. By relaying the fact that he spoke to so many doctors who were unable to identify fluoroquinolone toxicity syndrome and highlighting his personal context that made this result all the more surprising, the patient provided compelling evidence that this syndrome was likely to be under-appreciated. The story is backed up by other patients who state, for example, that "I have seen several doctors, each of whom have been helpless with the various symptoms I experienced".[50] Another patient who worked in the medical profession recounted:

> Unfortunately, after [a] rather optimistic beginning of my medical condition being believed, I could not find one single doctor who was familiar with the symptoms of the delayed and long lasting side effects of the fluoroquinolone antibiotics. The above mentioned professor told me he couldn't help me. Not even a clinical pharmacologist specialized in side effects of medication had heard of these severe and lasting side effects. I had to refer her to a professor from the University of California to convince her my symptoms were real and caused by levofloxacin.[51]

The patient gave further details of the way in which general practitioners (GPs) failed to understand the symptoms. She stated:

> In total I visited at least 7 specialist[s] of 3 different top teaching hospitals in Amsterdam. None of them could help me, most could not believe my symptoms were due to taking levofloxacin. I remember once a GP asking me: "did you sprain your ankle?" This [was] because my ankle was very swollen and painful.[52]

The stories provide evidence of the limitations of existing knowledge and expertise within the regulatory network. Practitioners in primary and secondary care contexts failed to identify fluoroquinolone toxicity syndrome, assuming that negative side effects were

[49] European Medicines Agency, "Public hearing on quinolone and fluoroquinolone medicines: written interventions received from speaker requests" (2018) <https://www.ema.europa.eu/en/documents/other/public-hearing-quinolone-fluoroquinolone-written-interventions_en.pdf> (last accessed 29 May 2022; (hereinafter "EMA 2018"), 6–7.

[50] ibid, 17.

[51] ibid, 24.

[52] Ibid.

present mainly in elderly people. Patients hence sought different medical opinions – this is not necessarily unusual, but given the severity of the symptoms and the number of different practitioners approached, it is indicative of a deeply rooted problem in diagnosing the syndrome.

These stories demonstrate understanding of the boundaries of existing medical knowledge and practice. In telling their stories, the patients show that practitioners are not well informed about the side effects of Quinolone medicines. These stories are contextualised with information that the patients themselves were previously healthy, active and stable individuals. Several of them were medical practitioners when they contracted fluoroquinolone toxicity syndrome or had friends and family with relevant medical experience. This makes their stories more powerful because the evidence they provide is "controlled" in the sense that the most obvious objections to the validity of their stories (eg that their "lay" position meant they were unlikely to understand the complex professional standards applied in medicine) are headed off. Their evidence therefore challenges the boundaries of existing medical knowledge about Quinolone – it cannot be dismissed from the perspective of medical expertise as an *ex nihilo* opinion from an ill-informed lay patient.

Theoretically, patients' storytelling can be characterised in terms of the identification of "boundary problems".[53] In the context of boundary work within arm's length agencies, "problems" around the boundaries of scientific expertise emerge when the validity of a body of scientific knowledge drawn on by the agency is brought into question. In this case, patients can be viewed as problematising the extent to which medical professionals "know" about an unexpected toxic reaction to a medicine. They bring their own personal "cases" to bear to support their claims. Studies of boundary work in agencies tend to conceptualise agencies as policing the boundaries of knowledge contained within the agency.[54] However, in this case, we can see boundary problems being identified *within* the agency as opposed to outside it. This is the benefit to the agency of institutionalising a public hearing in which professional medical knowledge, which holds a privileged position within the EMA, is held up to critique by patients. In doing so, they push against the boundaries of institutionalised knowledge. Yet rather than treating patients' critiques as a threat, the EMA incorporates them within the PRAC's engagement process by situating those critiques as part of a "negotiation" of expert knowledge.[55]

2. *Shifting the boundaries*

Following the patients' critique of the lack of professional recognition of their fluoroquinolone toxicity syndrome, industry and academic figures were asked to respond during the hearing. The DQI analysis shows that these "professional" actors showed higher levels of recognition for alternative groups and demands and included counterarguments in their interventions. Again, we can frame this divergence as part of the "negotiation" process between diverse forms of expertise that the public hearing facilitates.

In its intervention, the representative of the pharmaceutical firm Bayer AG defended the scientific validity of the safety of Quinolone medicines by reiterating evidence from large-scale trials:

> The safety and efficacy of Bayer's ciprofloxacin and moxifloxacin [medicines containing Quinolone] have been demonstrated in clinical trials involving more than 90 000 patients and extensive experience in clinical practice among an estimated 800 million

[53] Boswell, supra, note 14; RL Korinek and S Veit, "Only good fences keep good neighbours! The institutionalization of ministry–agency relationships at the science–policy nexus in German food safety policy" (2015) 93(1) Public Administration 103–20.

[54] Korinek and Veit, supra, note 53.

[55] Krick, supra, note 13.

> patients. Ciprofloxacin and moxifloxacin are now generic and are manufactured and supplied in Europe by hundreds of companies.[56]

Despite quoting these statistics, Bayer's representative went on to state: "Clear communication about benefit and risk of treatment is essential to optimize the safe use of these products for the individual patient."[57] As such, the representative made an offer to the PRAC during the hearing that "Bayer sees an opportunity to collaborate with PRAC in working with patient groups and academic centers specializing in patient safety communication, to further improve the content and format of the PIL [Patient Information Leaflet for Quinolone], and to identify novel ways to distribute it".[58]

This alternative proposal can be viewed through the "boundary work" literature as an attempt at instigating "coordination" – that is to say, the acceptance of a problem within a particular knowledge domain and of the need for scientific activity to address the problem. Boswell notes that coordination in an institutional sphere refers to "practices of communication across spheres – engaging in dialogue and producing (or translating) artefacts that are digestible for diverse audiences".[59] The artefact in this case is a clearer PIL containing stronger messaging around the potential risks of Quinolone medicines. The Bayer representative's acknowledgment that it "is open to further clarifying the nature and duration of some of the adverse drug reactions in the prescriber information"[60] can be interpreted as an at least partial acceptance that the existing scientific evidence around adverse effects is unclear to all practitioners and that change within the regulatory network is necessary.

Other professional interventions similarly sought to communicate the results of large-scale experimental studies in defence of the effectiveness of Quinolone. The Pharmaceutical Group of the European Union (PGEU), for example, states that

> we have a preference for retaining access/option to dispense quinolones/fluoroquinolones in primary care with additional measures so as not to restrict the supply of potentially useful/helpful medicines from patients who would benefit from them.[61]

This intervention was also backed up by an academic representative from the Louvain Drug Research Institute. They emphasised Quinolone is "an important part in our armamentarium for the treatment of infectious diseases".[62] However, despite pushing back on the overall effectiveness of Quinolone, they also recommended similar changes in the communication of risks associated with the drug on packaging. The PGEU representative suggested "[p]op-up messages on dispensing software" for products and a "[p]atient card on the outside of packaging" as potential solutions. Other professionals recommended going further. For example, the representative of the European Union of General Practitioners suggested avoiding the use of Quinolone antibiotics in "first-line" treatments and potentially restricting their use to "specialised care" situations. A representative of the European Specialist Nurses Organisation stated unequivocally that there should be measures to "avoid use of quinolones and fluoroquinolones unless there are no alternative treatment options".[63]

[56] EMA 2018, 71.
[57] ibid.
[58] ibid, 72.
[59] Boswell, supra, note 14.
[60] EMA 2018, 71.
[61] ibid, 71.
[62] ibid, 82.
[63] ibid, 78.

The interventions can be interpreted as the professional response in the "negotiation" of an evidence-informed position that draws the boundaries around an appropriate expert-led decision. Some of the professional contributors, particularly the manufacturers, do cite clinical trial data indicating the effectiveness of Quinolone antibiotics. Yet they recognise, implicitly or explicitly, the stories provided by patients about the adverse effects. They therefore accept the premise of the third question structuring the public hearing: "In your opinion what further measures could be taken to optimise the safe use of quinolones and fluoroquinolones?" Some of the suggestions are more incremental (emphasising better communication of risk), while others are more systemic (advocating the partial or total prohibition of Quinolone antibiotics in primary and secondary medical settings or restricting their use to extreme cases).

To summarise, this analysis of the Quinolone public hearing interprets it as a site of negotiated expertise.[64] While the DQI suggests the patient and professional speakers have differing deliberative qualities and so on an aggregate level do not score high on all of the deliberative qualities, we see that they in fact operate in negotiated form as ways of testing or pushing the "boundaries" of scientific knowledge in a way that is consistent with other studies of "boundary work" within arm's length agencies such as the EMA. Patient representatives challenge the boundaries through their stories of the personal experiences they have of limitations in the professional knowledge of GPs. Professional organisations respond by asserting the scientific validity of clinical trials data but then acknowledging the limitations of existing professional practices and suggesting updates to regulatory arrangements. Rather than feeding their evidence in via separate committees, the PRAC included different types of expertise and evidence to stage a contest over the boundaries of existing evidence regarding a regulatory governance problem: the toxicity syndrome associated with Quinolone and its debilitating effects. By staging patient interventions alongside professional speakers, the EMA generated a regulatory environment in which it complemented the deliberative qualities associated with elite deliberation (considered judgments about the risks of particular products) with the deliberative qualities associated with "enclave" deliberation among minority groups (powerful storytelling revealing under-acknowledged evidence).

Why did the professional and patient groups differ so markedly in their discourse? A key explanation here can be found in the *interests* underpinning the positions of the interventions and the role of alternative *ideas* of expertise and evidence in the discourse of patients. The professional interventions come from individuals who predominantly are involved in the production of Quinolone antibiotics or are representative of the scientific community that has established evidence for the efficacy of this class of antibiotics. The socio-economic positions of these actors incentivises them to defend those interests, specifically the interest of maintaining the perceived integrity and reputation of existing scientific research institutions and the interest of maintaining the market position and profitability of the pharmaceutical firms invested in the production of Quinolone antibiotics. These pre-existing interests incentivise adherence to the existing evidence base and defence of the efficacy of Quinolone. Professional participants therefore referred to an existing "paradigmatic" evidence base, including statistical evidence based on accumulated evidence of clinical trials, to assert the efficacy of Quinolone.

Yet the way in which the public hearing was set up, in the context of a wide-ranging safety review into the efficacy of Quinolone, allowed for the expression of alternative *ideas* about what can and should be considered a legitimate form of evidence. It was in the interest of the patients in the public hearing to articulate these ideas in a way that would influence regulatory change. Patients articulated their personal experiences of the previously unrecognised severity of fluoroquinolone toxicity syndrome and uncertainty about

[64] Krick, supra, note 13.

medical practitioners' understanding of how to treat its severe symptoms. This evidence was presented as rhetoric, or as a form of storytelling, without the even-handedness common to paradigmatic medical science, as a *critique* of the basis of the paradigmatic scientific approach. Patients were therefore enabled to express their evidence not only *as evidence*, but as evidence framed in a way to *influence change* by questioning fundamental assumptions about what medical practitioners know about fluoroquinolone toxicity syndrome and how to treat it. It was because of the purpose of the patients to exert influence to change the central *ideas* underpinning regulatory practice that their discourse differed markedly from that of professionals.

VI. Conclusion: towards more efficacious stakeholder engagement?

This article has shown that the EMA's public hearing on Quinolone antibiotics included a vulnerable group – victims of fluoroquinolone toxicity syndrome – in a way that both empowered that group to influence an elite site of deliberative regulatory governance and improved the rigour of decision-making in a substantive field of regulatory risk by challenging the boundaries of accepted professional knowledge. Through application of the DQI and qualitative interpretation of the hearing transcript and video, this article shows how a vulnerable group can be substantively empowered within EU risk regulation processes, while also contributing towards the aims of high epistemic quality. This comes through placing purposefully chosen representatives of the vulnerable group in "negotiation" with professional representatives, resulting in both a *challenging* of the boundaries of professional knowledge about Quinolone and proposals for *coordination* to respond and integrate the revised professional knowledge into regulatory rulings on product risk.

The obvious parameter of this case study is that it applies principally to areas of regulation where the vulnerable group is easily identifiable: patients who have experienced fluoroquinolone toxicity syndrome and its associated side effects. In other regulatory arenas, vulnerable groups whose experience directly applies to a regulatory decision around risk or a safety recommendation are more difficult to identify. For example, in the case of aviation safety – a highly technical area of risk regulation – knowledge primarily rests with those who design the complex technologies behind modern aeroplanes and aviation systems. Nevertheless, with some work, aviation regulators may identify relevant vulnerable groups, such as passengers with disabilities who may suffer from inadequate wording of signage.[65]

The inclusion of vulnerable groups does already take place in EU stakeholder engagement processes. For example, the "Better Regulation" programme includes non-governmental organisations, consumer groups and trade unions that all represent relevant vulnerable groups with an interest in and knowledge about regulations. However, the more targeted way in which the EMA's safety review public hearing works provides a clearer structure that seeks and enables *efficacious* participation. Efficacy is important because regulatory procedures and processes do not come as "black boxes" – made to be filled with any democratic or deliberative functions.[66] Rather, they are already designed in a *purposeful way*, with the aim of facilitating the review of products in the Single Market in a manner that considers relevant evidence drawing from expertise. The key to enhancing the role of vulnerable groups in this system is to *integrate their involvement* in a way that embeds the knowledge that they have about the "risk" problem in question, treating it as *relevant and important*, but also recognising the way in which it is often treated as marginal within risk regulation processes.

[65] EASA, "Carriage of Special Categories of Passengers (SCPs)", Comment-Response Document 2014-01 (2014) <https://www.easa.europa.eu/sites/default/files/dfu/CRD%202014-01.pdf> (last accessed on 2 August 2022).

[66] Schmidt, supra, note 7.

In the way advocated by Krick, this method is effectively to re-conceptualise the role of vulnerable groups as stakeholders within risk regulation, as a *negotiation* between the knowledge and deliberative capabilities they have and those of more well-established stakeholders. By placing these groups in *physical dialogue* with the professional experts, as the EMA did in their Quinolone public hearing, the value of their expertise, which might otherwise be dismissed as merely anecdotal evidence, is revealed. It is revealed in contestation and challenge – but also in agreement and complementarity – with professional expert knowledge.

Competing interests. The author declares none.

Appendix 1. Coding scheme for the Discourse Quality Index

Level of justification
(0) No justification: A speaker only says that *X* should or should not be done, but no reason is given.
(1) Inferior justification: Here a reason *Y* is given as to why *X* should or should not be done, but no linkage is made between *X* and *Y* – the inference is incomplete. This code also applies if a conclusion is merely supported with illustrations.
(2) Qualified justification: A linkage is made as to why one should expect that *X* contributes to or detracts from *Y*.
(3) Sophisticated justification: Here at least two complete justifications are given, either two complete justifications for the same demand or complete justifications for two different demands.

Content of justification
(0) Explicit statement concerning group interests: If one or more groups or constituencies are mentioned in a speech, then a code of 0 is assigned.
(1) Neutral statement: There are no explicit references to constituency/group interests or to the common good.
(2a) Explicit statement of the common good in utilitarian terms: There is an explicit mention of the common good and this is conceived in utilitarian terms; that is, with reference to the "greatest good for the greatest number".
(2b) Explicit statement of the common good in terms of the difference principle: There is an explicit mention of the common good and this is conceived in terms of the difference principle; that is, with reference to helping the least advantaged in a society.

Respect for groups
(0) No respect: This code is reserved for speeches in which there are only negative statements about the groups.
(1) Implicit respect: This code is assigned if there are no explicitly negative statements, but neither are there explicit positive statements.
(2) Explicit respect: This code is assigned if there is at least one explicitly positive statement about the groups, regardless of the presence of negative statements.

Respect for demands
(0) No respect: This code is reserved for speeches in which there are only negative statements about the demand.
(1) Implicit respect: This code is assigned if there are no explicitly negative statements, but neither are there explicitly positive statements.
(2) Explicit respect: This code is assigned if there is at least one explicitly positive statement about the demand, regardless of the presence of negative statements.

Respect for counterarguments
(0) Counterarguments ignored: There are possible counterarguments but the speaker ignores these.
(1) Counterarguments included but degraded: This code applies when a speaker acknowledges a counterargument but then explicitly degrades it by making a negative statement about it or the individuals and groups that propose the argument. A single negative statement is sufficient to assign code 1, unless the speech also contains positive statements about a counterargument (in which case a code of 3 applies). If neutral statements accompany a negative statement (and there are no positive statements), a code of 1 also applies.
(2) Counterarguments included – neutral: This code applies if a counterargument is acknowledged and if there are no explicit negative or positive statements about it.
(3) Counterarguments included and valued: This code applies if the counterargument is acknowledged and is explicitly valued. We assign this code even if there are also negative statements.

Constructive politics
(0) Positional politics: Speakers sit on their positions. There is no attempt at compromise, reconciliation or consensus-building.
(1) Alternative proposal: A speaker makes a mediating proposal that does not fit the current agenda but belongs to another agenda. In such cases, the proposal is really not relevant for the current debate, although it may be taken up in a different debate.
(2) Mediating proposal: A speaker makes a mediating proposal that fits the current agenda.

Storytelling
(0) No: Participants do not use personal narratives or experiences.
(1) Yes: Participants use personal narratives or experiences.

Questioning
(0) No: The speech does not contain an informational or critical question.
(1) Yes: The speech does contain an informational or critical question.

Appendix 2. Coding of speaker interventions in the Quinolone public hearing

Speaker ID	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Level of Justification	3	3	3	2	3	3	2	3	2	3	3	2	3	1	3	3	3	3	2	3	3
Content of Justification	0	2b	2b	2b	2b	2a	1	0	2a	2a	2b	2b	2b	1	1	1	1	2a	0	1	1
Respect for groups	0	2	1	1	0	1	1	2	1	1	2	1	1	2	2	2	2	2	2	2	1
Respect for demands	1	1	1	1	0	1	1	1	0	0	1	1	1	2	2	2	2	2	2	2	1
Respect counterarguments	1	0	0	0	1	1	1	1	1	2	1	1	1	3	2	2	2	2	2	3	2
Constructive politics	0	2	2	2	2	2	2	2	2	2	0	0	0	1	2	2	2	2	2	2	2
Storytelling	1	1	1	1	0	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0
Questioning	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	1	1	0

Colour code: red = patient; yellow = professional.

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