Can Elite Institutions Be Deliberatively Democratic? The Case of the European Medicines Agency's Public Hearing on Valproate

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Democratic innovations have been widely touted for over a decade as one of the best ways to improve the democratic quality of governance arrangements around the world (Smith, 2009). The Participedia website documents a range of practical examples employed by governments, social movements and municipal authorities the world over. Democratic innovations are particularly popular as they straddle the line between normative desirability and functional necessity. Government institutions need to govern – that is, they need to produce effective policies and regulations informed by systematic evidence, but they also need *legitimacy*. Legitimate governance is relies not only on the social acceptability or scientific quality of a policy or regulation, but also its *normative desirability*. While legitimacy can be claimed on the grounds of functional effectiveness or embeddedness within governance procedures, normative standards are important.

In the European Union, this latter point is particularly salient given the growth of 'politicisation' of the EU's institutions, and the recent surge of anti-EU populism in some parts of the Union. Scholars have argued the EU can no longer rely (if ever it did) purely on functionalist justifications and institutional designs to assure its continued support among member states. Since the early 2000s, EU-wide democratic innovations have been launched to more systematically address the 'democratic deficit' in the Union. For example, the European Citizens Initiative was launched in 2013 in an attempt to give citizens a voice in the European Commission. Such initiatives clearly have symbolic value as signals of democratic intent by the EU's core institutions. At a more everyday level, however, the agencies and committees of the EU have been slow to democratise. Stakeholder engagement initiatives have grown in light of the Commission's Regulation agenda of the late-2000s, and 'public' consultation processes are widespread at an everyday level. Generally, however, EU institutions have been slow in opening up their processes and procedures to involve the wider European public.

In 2017 the European Medicines Agency (EMA) sought to change this by staging not only a public consultation on a medicine whose safety had come under question – a common occurrence - but a *public hearing* involving representatives of patients and

testimony from those directly affected by the medicine. The EMA promotes public hearings as opportunities for 'working directly with people affected by [a] medicine', which have real impact on Agency decisions: 'Contribution(s) from the public at hearings will inform PRAC (Pharmacovigilance Risk Assessment Committee) decision making' (EMA, 2018, p.2). Public hearings are more ambitious than standard stakeholder engagement exercises. Any member of the public can apply to attend the hearing and individuals who have a specific interest in the policy issue being debated are encouraged to attend and report their experience in person.

This paper assesses the extent to which the EMA's public hearing was successful in achieving criteria for good democratic deliberation. Using the discourse quality index (DQI) to assess how deliberative the event was, I coded all four hours of a video of the hearing (https://www.youtube.com/watch?reload=9&v=CzeJSzkrygM#action=share). I complemented this with a qualitative analysis interpreting the value and limitations of the hearing. The core argument is that EMA's public hearing on Valproate enabled deliberative democracy to the extent that it facilitated equitable access and influence of patients and members of the public who had previously been excluded from decision making on the distribution of the drug. Specifically, the way the hearing was set up in the style of a court of law, with a democratic representative from the European Parliament present, and participants were allowed to use visual props to facilitate their argument. This allowed patients to tell profoundly powerful stories about the injustices they, and their families, had experienced. These stories compelled 'elite' actors, including industry and professional participants, to respect their demands and led to a transformation in how Valproate is regulated within the EU. The paper shows that elite institutions can gain from public hearings if they pay close attention to how those hearings are organised and the kinds of arguments that are permitted.

The paper proceeds in five sections. First, it outlines existing sceptical arguments about whether elite institutions can 'do' democratic/deliberative innovation. Second, it introduces the methods, details and justifies the Valproate case study. Third, it analyses findings from the quantitative application of the DQI to the public hearing. Fourth, it analyses my interpretation of the hearing video, highlighting three key determinants of why the public hearing was successful in transforming the regulation of Valproate. Fifth, the paper concludes by suggesting public hearings, despite their limitations, can be useful tools for elite institutions to respond to demands for democratic deliberation.

Democratic Innovations in 'Elite' Institutions

To what extent can democratic innovations 'innovate' democracy when they are introduced and embedded by political elites themselves? To what extent are those 'innovations' useful for pursuing democratic aims (and can they even be interpreted as doing so) in a context where those 'innovations' are explicitly designed and

promoted as achieving organisational functions that are not determined democratically (at least not directly)? Smith's definition of democratic innovations states that they must be institutionally embedded; 'new ways of engaging citizens in the *political decision making process*' (2009, p.2, italics added). However, existing research tends to deride democratic 'innovations' embedded within 'elite' institutions because they create a thin veneer of legitimacy for a reality of political objectives pursued by elite actors. Caluwaerts and Reuchamps call this approach to democratic innovation the 'inside follower', and they are highly critical in their findings of a case study of this type:

> The inside follower is a *democratic wolf in sheep's clothes*. It is often perceived as an alternative to politics as usual because it uses new ways of involving citizens and it gives the public the perception that it is listened to. In reality, however, the inside follower risks becoming a straw men set up by governments to deflect attention from the real democratic problems. Inside followers merely tinker at the edges and create the perception of legitimacy whereas nothing is actually changing to bridge the gap between power and the people (2016, p.24, italics added).

This critical approach is particularly pertinent at the transnational level, where attempts at 'stakeholder engagement' have been riddled with accusations of elitism. As Arras and Braun (2018) show, stakeholder engagement at a transnational level tend to privilege professionalised non-governmental organisations, industry and academia, rather than the wider public. Attempts at democratic innovation in the EU abound, but tend not to be directly linked with formal decision making (Smith, 2013). Smith's analysis of these projects is summarised in Table 1, below. Projects like EuroPolis and Agora are face-to-face, forum-like initiatives set up collaboratively by Universities to test public opinion on the EU. EuroPolis uses the Deliberative Polling method developed by James Fishkin and colleagues, while Agora is a collaborative initiative with academics, policy-makers and non-governmental organisations aimed at synthesising views and contributing towards policy-making. Similarly, Ideal-EU was a project led by academics aiming at creating an online space for deliberation, in this case over energy and climate change, through a social media platform and subsequently simultaneous online meetings with.

Table 1 also shows democratic innovations that were initiated by central EU institutions. Funded by the European Commission, European Citizens Consultation (ECC09) aimed to 'give EU citizens a voice' through a multi-staged mini-public including online deliberations across 27 EU member states (https://participedia.net/case/4135). The Your Voice initiative seeks to embed this mass online consultation via opportunities on the European Commission website for the public to submit views on EU regulations as they go through the decision making process. Futurum was a similarly earlier attempt at democratic innovation based online, and initiated by the European Commission, with the aim of allowing citizens to interact with each other while accessing and debating information about EU policy (Wright, 2007).

In all of these cases, as Table 1 shows, the need for 'interactivity' with citizens was emphasised. Participants could interact with policy-makers, hearing their views and

challenging them. In all of these cases, however, there is a striking lack of outputs with impact. In EuroPolis a survey was produced, while ECC09, Agora and Ideal-EU generated collaborative proposals or reports to elite bodies, and Your Voice and Futurum provide a rich diversity of individual comments. None of these, however, had lasting effects.

Table 1: EU Democratic Innovations Mapped by Smith (2013)

Design	Selection mechanism				Form of polity		Language			Medium		In-teractive	Nature of output			Im-pact
	Open	Targeted	Random	CSO	National	Trans-national	One only	Multiple but separate	Multi-lingual	Face-to-face	Online		Individual comments	Survey individuals	Craft proposals	
ECC09	✓		✓		✓	~	~	✓		✓	✓	✓			✓	
Euro-Polis			✓			✓			✓	✓		✓		✓		
Agora				✓		✓	?		?	✓	~	✓			✓	
Ideal-EU		✓			✓	~		✓		✓	✓	✓			✓	
Your Voice	✓			✓		✓		✓			✓		✓			
Futurum	✓					✓			✓		✓	✓	✓			

Source: Smith, 2013, p.203.

These older initiatives were surpassed to some extent by the European Citizens Initiative, which had support from the European Commission and has had some limited success. The ECI essentially allows EU citizens to develop signatures on a particular campaign that must be initiated by a subset of citizens from at least seven EU member states. If the campaign receives over 1 million signatures, the European Commission has to issue a response detailing how they will address the concern in light of their legal and political responsibilities. To date, very few initiatives have gained sufficient ground to elicit a response, and none of the responses from the Commission have come close to a wholesale change in policy position.

Existing initiatives hence provide much justification for critical attitudes towards elite democratic innovations at an EU level – both innovations created by elite bodies, and those funded by them but carried out by well-meaning academics and NGOs. While they might provide systematic evidence of deliberation, diversity in terms of representation and explicit interaction with policy makers, they tend to bubble up and fizzle out, producing 'outputs' with little tangible long terms effects. This lack of 'results' creates an opening for those who believe (often with significant empirical support) that these engagement initiatives are simply tools of the powerful to generate enough short-term buy-in from relevant communities to legitimate decisions they have already arrived at, what Fung and Wright (2003, p.265) call 'participatory window-dressing'. This may have debilitating effects on public trust and confidence in the long-run. As Offe argues:

> if the participants [in democratic innovations] cannot rely on the expectation that what they do and come up with has at least some chance of 'making a difference' in public policy, and that their common efforts are recognised as valuable … their readiness to participate, to spend time on learning and understanding, and to properly deliberate will soon be exhausted (2011, p.469).

If citizens are not allowed meaningful and systematic input and deliberation, democratic innovations may therefore end up doing the precise opposite of what is intended – leading to deepened disillusionment with the possibility of democracy, especially at the transnational level.

Such scepticism may be especially warranted for innovations with pretensions to being deliberative in nature.[1] Deliberative (or 'discursive') democracy is a critical theory that demands 'authentic deliberation', which means 'the requirement that communication induce reflection upon preferences in a non-coercive fashion' (Dryzek, 2002, p.2). A key element is that deliberative initiatives – initiated by the state or civil society - facilitate equitable influence on decision making of all those affected by a particular policy (Beauvais, 2018). At the elite level in particular, institutions are not set up for mass empowerment. Mini-publics, one of the main tools used for facilitating deliberative democracy, have been found to be highly 'ambivalent' as tools for directing elite decision making (Curato and Böker, 2016, p.174). Instruments like public hearings and stakeholder consultations have been disparaged as non-deliberative tools for legitimating pre-formed elite opinions (Baker et al., 2005).

This article argues that public hearings can be important democratic innovations for facilitating deliberation to establish equitable influence on elite institutional decision making. It does so on the basis of an analysis of the EMA's public hearing on Valproate. This hearing was explicitly designed to be different. It was directly linked into a regulatory decision making process; the hearing was included as one phase of a process of re-evaluating regulatory requirements for a medicine whose safety had come under question. The EMA stated the hearing was intended to 'enrich the available scientific evidence' (EMA, 2018) and public hearings more generally are described as going 'beyond existing channels or stakeholder engagement' (EMA, 2019). Moreover, the hearing was designed to give patients directly affected by Valproate 'a voice' in the process going much deeper than standard written submissions. As such, it could be argued that the Valproate public hearing was a democratic innovation differing significantly from previous attempts by elite EU bodies, because of 1) its direct link to substantive regulatory decision making, and 2) the explicit attempt to 'add value' in terms of the depth of engagement of those communities who would not usually have a voice in EMA decision making.

Case Selection and Methodology

Single case studies of democratic innovation have been criticised for not being generalisable (Pogrebinschi and Ryan, 2018). As Pogrebinschi and Ryan argue, with only single cases 'we cannot give surety across cases as to whether participatory processes are only used to legitimate decisions made elsewhere' (2018, p.149). Hence,

[1] The relationship between what counts as a 'democratic innovation' and a 'deliberative democratic innovation' is a matter of contention. While I do not address the ambiguity at length here, deliberative democratic ideals may be said to be specific and highly ambitious democratic 'goods' that sit alongside non-deliberative democratic goods, albeit with a particularly rarefied or normatively desired status.

they suggest research on democratic innovations suffers 'from a methodological bias to favour case studies' and argue for moving towards a comparative agenda (see also Ryan and Smith, 2012). How does this article justify focusing on a single case study to understand the value of public hearings as elite democratic innovations? Firstly, the EMA's public hearing may be seen as a potential 'paradigmatic case' of a new approach to democratic innovation at the EU level, directly linked into regulatory decision-making. The Valproate hearing was the first attempt at institutionalising a democratic innovation within an established EU institution, with a self-professed direct impact on that institution's policy. Particularly distinctive in this case study is how most attempts at democratic innovation at the transnational level 'failed to have any effect on the decision making process' (Smith, 2013, p.211). From a traditional perspective on 'case selection', the Valproate hearing thus represents a 'critical case' (Flyvbjerg, 2006) of a transnational technocratic institution attempting to initiate a democratic innovation with real impact on policy decisions, whilst simultaneously being subject to all the administrative, social, economic and political factors that would make that innovation likely to fail. Investigating the intricacies of how this democratic innovation played out in detail will yield important insights into how democratic innovations designed to overcome the traditional limitations elite governance arrangements impose can be successful in overcoming those barriers, and the extent to which those barriers continue to impose formidable, arguably insurmountable, challenges.

Second, the Valproate case is relevant in particular because it provides a distinctive set-up that does not receive as much attention as more deliberative approaches: the public hearing. Commonly, public hearings are dismissed as providing only partial decision making access, or being only one element inputting into deliberative processes. However, Karpowitz and Mansbridge (2005) argue public hearings are 'deliberative in the minimal sense that they [represent] an opportunity for citizens to give public reasons for their opinions and to hear the opinions of others'. Full deliberation is not an aim within public hearings. Rather, it allows invited speakers representing a range of interested groups to have their views heard by powerful decision makers, enhancing transparency. There are important deliberative elements to public hearings – speakers can be questioned by, and respond directly to, elites, and they are given a protected, highly structured, space to elaborate their arguments.

Third, there are also pragmatic, data-driven reasons for choosing the EMA case. The Valproate hearing was live streamed by video link with multiple camera angles showing participants speaking and the layout of the room, and an official summary was made available along with written submissions. This is useful both in terms of reinforcing how significant the agency itself viewed the hearing as an innovative exercise, and in terms of providing a detailed data source from which to evaluate the innovation itself. Unlike many democratic innovations, it was possible to track and replay every minute of the hearing, and make detailed reflective notes. As such, the author watched and coded the full four-hour hearing, both quantitatively and qualitatively, and referred back to the hearing transcript for clarifications. EMA also provided several supporting documents with detailed analysis of the problem,

written feedback from 'standard' stakeholder consultation routes, and a detailed report of the PRAC's final regulatory recommendation.

I streamed the hearing via YouTube on two separate occasions. Once in January 2019, and again in June 2019. The first time I recorded quantitative ratings for the deliberative quality of discussion during presentation and discussion by each participant in the hearing, relying on the widely used Deliberative Quality Index (DQI) (see below). The second time, in light of reading and theoretical reflection, I recoded the hearing based on the DQI, but also qualitatively coded the hearing for a range of visual representations I had not observed during the first viewing. Many of the most interesting and important aspects of the hearing, which have analytical value for showing how public hearings can be effective democratic innovations, are not captured by the DQI. I made reflective notes that reveal my particular interpretation of the video, from which I identified key themes highlighting what elements of the public hearing supported or detracted from the quantitative evidence about the hearing's deliberative quality.

The Case: Valproate

Understanding the context of public controversy around the public hearing is crucial for further explicating the importance of the EMA's public hearing as a critical case of (deliberative) democratic innovation. As Dryzek (2002) argues, democratic innovations, particularly those with pretensions to being 'deliberative' in nature, must address substantive issues with implications for justice, equity and sustainability, particularly those that are potentially contentious and open to conflicting views. The case of Valproate is just such an issue, with substantial implications for fairness, justice and equity, particularly among those who take Valproate and their families.

Valproate is a medicine used to treat epilepsy, bipolar disorder and sometimes Migraine in European Union member states. For some patients with severe cases, there are no other treatments available other than Valproate and similar substances (valproic acid, sodium valproate, valproate semisodium and valpromide). Valproate is not a new medicine – having been available by prescription in France since 1967. It has been approved for prescription in all EU member states. However, Valproate become known during the 2000s for significant side-effects among pregnant women, leading to abnormalities in new-born babies, particularly severe learning disabilities. Despite knowing its side-effects, some doctors prescribed Valproate to pregnant women without informing them of the full implications of its use, and many continued using it because of no known alternative treatment. In March 2017, at the request of the French medicines regulator, the Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM), EMA began a Europe-wide review of Valproate and its effects, with the aim of strengthening regulatory guidelines for practitioners around the conditions under which Valproate can be prescribed.

The severe learning disabilities some Valproate patients found their children experiencing, and the impact on their lives, are serious issues of equity and justice. Campaigners have argued that pregnant women were not given enough information to make a balanced decision by doctors who knew of the likely consequences for their children. Moreover, the severity of learning disabilities often suffered by children born from Valproate patients has implications for the entire life of those children, their mothers, and their families. Nevertheless, the freedom of patients with severe bipolar disorder or epilepsy to take Valproate must be taken into account when deciding on whether to place restrictions, or an outright prohibition, on its prescription to pregnant women. Some women refuse to be taken off the medicine despite knowing its likely side-effects, because it prevents the severe pain they experience from epileptic attacks, bipolar episodes or migraines. Previous medical studies, for example by the US Food and Drug Administration, also suggested taking patients off Valproate suddenly (for example in the event of pregnancy) can also have serious health impacts (https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-children-born-mothers-who-took-valproate-products-while-pregnant-may). The EMA's consultation was thus conducted in a potentially highly contestable field, both ethically and scientifically. A democratic innovation was particularly apt here, because it was focused on a contestable issue with significant implications for equity and justice across the whole of Europe. EMA's work is also used as a template for other smaller countries globally, so its review could arguably be said to have implications for regulatory policies focused on Valproate around the world.

Assessing the Deliberative Quality of the Public Hearing

First, this article assesses the Valproate public hearing according to its deliberative quality using the discourse quality index (DQI). The DQI was developed by Steenbergen et al (2003) and Steiner et al (2004) to quantify how closely purportedly 'deliberative' discussions in political arenas got to the 'ideal speech situation' posited by Habermas. The DQI has been subject to criticisms about the criteria it uses and the assumptions it makes (Jaramillo and Steiner, 2014; King, 2009). On the one hand, it attempts to measure discourse against an 'ideal' that even Habermas himself argued could never be achieved, and indeed was not his intention to achieve in his original theory of communicative action. On the other hand, even if it were possible to quantify such an 'ideal' outcome, the DQI does not cover all of the criteria that would need to be covered for assessing a case. Hence, King (2009, p.4) argues 'Steenbergen et al's attempt to operationalise the theory produces conceptions that distort, reduce and omit vital notions of the ideals it aims to measure'. On balance, because it evaluates speeches within a 'debate' as individual units, Steenbergen et al.'s index has been shown to be a useful tool for evaluating set-piece political speeches in parliamentary settings (Lord and Tamvaki, 2013), but has proved more difficult for assessing small group debates with a highly dynamic and intersubjective element (Jaramillo and Steiner, 2014).

For our purposes of analysing a public hearing with a series of staged interventions highly regulated by a chair, the DQI is useful so far as it is explicitly set up to code (and thus privilege) the quality of individual speakers' contributions. Where the public hearing does not match up, in this respect, is the intersubjective element of deliberation whereby there should be room for intervention and participation by all participants in the room. In other words, as a democratic innovation, public hearings are 'minimally deliberative'. We would not, therefore, expect all discourse to conform to the highest levels of deliberation. The purpose here, however, is to analyse how normative elements of criteria for deliberation were present within the hearing.

I watched the Valproate public hearing twice in January and June 2019 and coded for each of the DQI indicators in each case. I followed Steenbergen et al's original coding scheme as closely as possible, but also adapted it to the public hearing context. For example, I left out their 'participation' indicator from coding as the highly structured nature of the public hearing makes equal participation by all in the room not only beside the point of the innovation, but would actively undermine its intended outcomes (although two unanticipated interventions occurred during the hearing, neither were objected to by the chair or other participants). Second, I tweaked the 'level of justification' indicator to make it applicable for the second round of coding. In the first round, almost all of the codes for this indicator were ranked at '3' (at least 2 complete justifications) purely because of the length of time speakers had to justify their claims (most speakers had about 10 minutes to present their case). Instead, I reframed the coding scheme to differentiate between 2 and 3 more clearly, changing 3 to 'strong link made in justification' and 2 as 'weak link made in justification'. 'Strong' links involve reference to clear empirical evidence, quantitative data, scientific studies or deep personal/familial experience and 'weak' links involve vague anecdotes and assertions. Third, I clarified the 'respect counter-arguments' indicator by specifying that 'counter-argument' is not necessarily an argument made by another participant in the public hearing, but instead is the recognition of one of the two possible arguments in the Valproate review (namely, that Valproate regulation should either be reformed and even outlawed for pregnant women, or existing arrangements should be largely reinforced or remain the same). The remaining indicators – content of justification, respect for groups and demands, and constructive politics – all remained the same as in the DQI coding scheme.

Results and Analysis (Discourse Quality Index)

Codes were applied to each 'speech' by a scheduled speaker in the public hearing. This included patients taking Valproate with epilepsy, bipolar disorder and migraine, victims of Valproate-related post-birth abnormalities, the pharmaceutical company Sanofi that sells Valproate, professional representatives including pharmacists, medical scientists and authors of prominent academic studies of Valproate's effects. Overall, there were 17 participants who were introduced as 'speakers' in the main part of the public hearing (3 hours 45 minutes). 2 participants spoke twice making substantively different 'demands' (as Steenbergen et al call them) and are thus coded

as separate 'speeches' within the 'debate'. Appendix A details all the speakers and their affiliations as described by EMA in its public documents. The coded speeches are not directly referenced for each participant to protect anonymity; however, these may be replicated by other researchers by coding the hearing manually using the project codebook (see Appendix B). Table 2 below provides summary statistics for the discursive quality of the public hearing.

Table 2: Summary Statistics for the Discursive Quality of the EMA's Valproate Public Hearing

All participants	**Mean score**	**SD**	**No. speakers coded**	**Min**	**Max**
Justification (0 = low, 3 = high)	2.526 (1.682)	0.678	19	1	3
Common good*	1.316	0.798	19	0	2
Respect groups	1.056	0.848	18	0	2
Respect demands	1.2	0.748	15	0	2
Respect counter-arguments	1.529 (1.018)	1.377	17	0	3
Constructive politics	1.579	0.815	19	0	2

* 2A/B given score = 2, overrides 0 score for interest-based demand.
Overall DQI Score = **1.307 (Max=2, Min=0)**

This study goes further than existing work quantifying a range of separate deliberations – for example Lord's study of over 800 debates in the European Parliament – because it creates a quantitative scale for each DQI item and an overall DQI 'score' on this basis. This achieves Steiner et al.'s (2004, p.60) suggestion that the elements of the DQI should be 'at least in principle, scalable' to provide a single score on which to rate the deliberative 'quality' of a particular initiative. Such a scale is only possible and meaningful because of the case-based nature of the study enabling close attention to the detail of each intervention. The Mean scores in Table 2 are based on adding together the coded scores for each participant (assuming, as Steenbergen et al do, that higher scores indicate 'better' discursive quality) and dividing by the total number of participants. For the items where the scale was 0-3, the Mean score has been compressed (multiplied by 2/3, the number in brackets in column 2) to produce a score on a 0-2 scale. The scores were then averaged with equal weighting to produce an overall DQI score on a 0-2 scale of 1.307. The figure can be used as a summary score to suggest that, overall, the public hearing was a 'successful' deliberation on the grounds set by the DQI.

Table 2 suggests this public hearing was especially good for high quality justification (1.682), references to the common good (1.316) and constructive politics (1.579). On the other hand, overall respect for groups, demands and counter-arguments was relatively low. The mean scores for each were roughly half the maximum score, and ranged significantly between the highest and lowest possible scores. Some speakers

had to be left out altogether from these latter indicators as their speeches were deemed not relevant to the indicators in question. This tells us something interesting about the public hearing as it relates to the DQI framework in particular, and deliberative democracy more generally. It is more difficult in a public hearing format to show explicit 'respect' for other groups, demands and arguments because the exercise is not intersubjective. While speakers were asked questions by the panel, and got a chance to ask the panel themselves questions at the end of the hearing for 30 minutes, there was no rigorous two-way debate as would be expected in a 'dynamic' deliberative scenario. While this is a significant limitation of the public hearing, the low scores might also be seen as to some extent indicative of some of the DQI's shortcomings, tailored as it is to use individual speeches and demands as a unit of analysis.

Another one of the key problems with elite public hearings, existing research suggests, is that they privilege educated elite speakers who are invited 'to the table'. The EMA hearing sought to overcome this by inviting members of the public and patients, who made up the majority of speakers. How did deliberation compare between the groups? Table 3 and Table 4 below compare the scores for patients and members of the public, with participants from industry and professional associations (see explanation of calculations above).

Table 2: Discourse Quality Index scores for patient/public participants in Valproate public hearing

DQI Criterion	Patients/public	N	Industry/professional	N
Sophisticated Justification (3)	36%	11	100%	8
Qualified Justification (2)	45%	11	0%	8
Inferior Justification (1)	18%	11	0%	8
No Justification (0)	0%	11	0%	8
Utilitarian common good (2a)	18%	11	25%	8
Difference principle common good (2b)	64%	11	0%	8
Neutral statement (1)	9%	11	50%	8
Sectional interests mentioned (0)	91%	11	25%	8
Explicit respect for groups (2)	20%	10	62.5%	8
Implicit respect for groups (1)	20%	10	37.5%	8
No respect for groups (0)	60%	10	0%	8
Explicit respect for demands (2)	0%	7	75%	8

Implicit respect for demands (1)	57.1%	7	25%	8
No respect for demands (0)	42.9%	7	0%	8
Counter-arguments valued (3)	18.2%	11	83.3%	6
Counter-arguments included - neutral (2)	9.1%	11	16.7%	6
Counter-arguments included but degraded (1)	9.1%	11	0%	6
Counter-arguments ignored (0)	36.6%	11	0%	6
Mediating proposal (2)	63.6%	11	100%	8
Alternative proposal (1)	0%	11	0%	8
Positional politics (0)	36.4%	11	0%	8

*** Calculated as percentage of all relevant coded speeches for particular variable**

The scores demonstrate stark differences in deliberative 'quality' between groups that are in line with existing research and theory about differential capacities to deliberate among individuals with high levels of education and income, and those without. Industry and professional groups score higher on all raw scores for the components of the DQI. The difference is particularly striking for standards of justification, where 100% of speakers in the industry/professionals group scored the maximum of 3, while only 36% of patients and members of the pubic scored the maximum value. Similarly stark are the differences between respect for groups and demands among industry/professionals (62.5% and 75% of speeches explicitly showed respect for groups and demands respectively) compared with the public and patients (20% and 0% respectively). Industry representatives and professionals consistently recognised positively the demands of public participants for improved communication between doctors and patients on the risks of Valproate, making labelling clear on boxes and introducing more mandatory controls to ensure patients are as informed as possible. By contrast, patients often 'degraded' (in the words of Steenbergen et al's (2003) framework) the efforts of industry, government officials and practitioners, suggesting they were at best negligent in explaining the drug's side-effects, and at worst actively hostile and profiteering. There are also clear differences in terms of 'constructive politics' – the extent to which participants attempt to compromise or suggest solutions. 100% of representatives from industry sought mediating proposals, such as improving communication through pharmacists and intermediary professional bodies. By contrast, the appeals by patients and members of the public were emotive and often uncompromising, driven by individual experience and hostile to public information programmes that had previously had little impact across Europe (Mean = 1.273).

Interestingly, the only indicator where patients and the public scored higher was in reference to the common good. Demands made by industry/professionals were couched in terms of the scientific evidence, best practice, complexities around different types of epilepsy and their differential effects, and the evidence base surrounding withdrawal from Valproate provision and its impacts on patient health. These arguments, while sympathetic to claims focused on equity and the interests of those taking Valproate, focused neither on asserting group interests, nor on conceptions of the common good (Rawlsian or utilitarian). Patients and the public, on the other hand, focused strongly and almost exclusively on both their interests as representatives of Valproate patients and victims, and most importantly issues of justice related to helping the disadvantaged in society. Speakers demanded mandatory clear pictures being displayed on packaging to ensure communication to parents about risk, and told detailed stories of their own struggles with Valproate as emotive context for the hearing (although, as one speaker put it, 'not evidential').

The above analysis suggests some interesting implications for the value of the public hearing as a democratic innovation in elite institutions. Firstly, and as existing research shows, the overall deliberative quality of exercises such as these can be high, but unequal between participants. In some respects, the way in which the hearing was set up could be interpreted as setting up members of the public to fail. Patients and public members often struggled to articulate themselves, clearly suffering with nerves from the occasion. One participant had to be reassured by the Chair that she was able to take her time as she repeatedly stumbled reading out her pre-prepared statement. By contrast, the representative from Sanofi was articulate and well-rehearsed, making a reasoned case for improved communication by government rather than enforcing new regulations and responsibilities on pharmaceutical firms.

In light of this seeming inequality, the data also provoke reflection about the value of different aspects of deliberation and the extent to which they ought to be valued in this context. For example, do emotive appeals carry weight within deliberation, and how could they be incorporated into DQI in a meaningful way? One study has sought to include a measure of appeals to personal story and narrative, albeit only as a binary yes/no variable (Steffensmeier and Schenck-Hamlin, 2008, p.28). What place do anger and cynicism have in deliberative processes, particularly where such cynicism might be understandable given the highly structured nature of the discussions?

Qualitative Analysis: Influence and empowerment, performative scepticism, storytelling and visual symbols

The quantitative analysis above suggests EMA's Valproate hearing fell into the same traps as many elite-driven forms of democratic innovation. Those who were supported by corporate pharmaceutical resources, or elite scientific education, were more articulate and contributed a 'better' discursive quality than members of the public and patients, who were emotional, openly disparaging of elite actors, and sceptical of the process. However, this paper argues that a quantitative analysis gives

a partial, and misleading, interpretation of the value of public hearings as elite democratic innovations. Specifically, if we agree elite institutions should seek to implement innovative forms of democratic practice, they should do so in a way that actively allows for non-deliberative, even *anti-deliberative*, internal critiques of the shortcomings of elite-driven policy processes.

Influence and empowerment

When we examine the outcomes of the EMA public hearing it becomes clear that this innovation defies more of the traditional problems associated with elite-driven democratic innovations. Consequentiality is a key determinant of good democratic innovation, and deliberative scholars have noted the need for consequential outcomes as an important indicator of meaningful deliberation. Dryzek foregrounds consequences as a key aspect of any democratic innovation worthy of the name 'deliberative', stating that ''. Such outcomes may be direct policy effects, but this can imply that deliberation must create demonstrable change in one form or another, with a pre-determined policy outcome, which is not the goal of deliberation. Deliberation can, however, also involve facilitating equity in the process of influencing outcomes that are decisive. This involves empowering those who have inadequate access to existing formal/policy processes and enabling them to exercise a potentially transformative influence upon the decision making process.

In this regard, the most powerful evidence of the hearing as a 'successful' deliberative innovation is that it helped shape an eventual policy outcome that transformed the regulatory controls over the provision of Valproate in a way that demonstrates (or at least heavily implies) the influence of those who had started out in the debate as disadvantaged and receiving injustice in its provision. In 2018, the PRAC announced its final decision to introduce stringent new controls on the provision and marketing of Valproate. These are summarised as follows:

- Where licensed for migraine or bipolar disorder:
    - In pregnancy - valproate must not be used.
    - In female patients from the time they become able to have children – valproate must not be used unless the conditions of a new pregnancy prevention programme are met.
- For epilepsy:
    - In pregnancy - valproate must not be used. However, it is recognised that for some women with epilepsy it may not be possible to stop valproate and they may have to continue treatment (with appropriate specialist care) in pregnancy.
    - In female patients from the time they become able to have children – valproate must not be used unless the conditions of the new pregnancy prevention programme are met.
- The PRAC has also recommended that the outer packaging of all valproate medicines must include a visual warning about the risks in pregnancy. In addition to boxed text, this may include a symbol/pictogram, with the details to be adapted at national level.
- A patient reminder card will also be attached to the outer package for pharmacists to discuss with the patient each time the medicine is dispensed.
- Companies that market valproate should also provide updated educational materials in the form of guides for healthcare professionals and patients (EMA, 2018).

The outcomes are fascinating because they impose new obligations upon pharmaceutical companies against the demands those companies made within the public hearing. Sanofi argued for more communication by governments in the medicine's provision, but demanded that Valproate not be banned for pregnant women with the relevant syndromes. The PRAC recommendation goes explicitly against this stated demand. Moreover, the demands articulated by patients and members of the public in the hearing have been met in full, particularly demands to introduce new visual warnings on packaging and to require pharmaceutical firms themselves to produce and disseminate educational materials about the effects of the products they are selling. These recommendations then become legally binding. PRAC's recommendations were validated by the Coordination Group for Mutual Recognition and Decentralised Procedures (Human) in March 2018, and then adopted in full by the European Commission to become law across the European Union.

This outcome was not only a result of the public hearing, nor was the result only an outcome of privileging the emotive arguments of patient representatives. The hearing was one part of a review encompassing 'written submissions, expert meetings, meetings with stakeholders including healthcare professionals, patients' organisations, patients and their families' (EMA, 2018, p.2). The PRAC's recommendation, moreover, could not *legally* have relied on patients' testimonies alone, but *had* to be justified on the basis of a balanced consideration of the range of evidence provided to come to a 'scientific' decision. However, crucially from our perspective, the hearing allowed representatives of those suffering from Valproate to exercise a particular kind of *influence* within the process that would not have been possible otherwise. One of the key requirements of the deliberation is that participants should exercise 'equal (or fair) influence over the outcomes of discourse' (Beauvais and Bächtiger, 2016, p.2). In this case, we can see the influence of patients and members of the public by tracking how their demands from the hearing are reflected in the final recommendation, while those of other, more powerful actors with multiple lines of influence on EMA decision making, were not. How was this influence enabled in this particular instance? My interpretation of the hearing video identified three aspects in particular: reflexivity, storytelling and visual symbols.

Reflexivity

Hammond (2018) argues that deliberative democracy ought to be 'an innately inclusive, itself reflexive and self-reflexive project' rather than 'a theory to be implemented'. As such, attempts at creating innovations of the type conducted by EMA must be conducted in a way that allows and appreciates the shortcomings and contradictions in these processes. The first moment during the discussion where contradictions are acknowledged is in the introductory remarks by EMA Head of Public Engagement, Juan Garcia Burgos, who notes that there is 'no time for the specific debate' during the hearing, and that the aims are constrained to allowing the PRAC to hear participants' evidence and ask 'clarification' questions.

The process itself allowed reflexive remarks about participants' scepticism about whether the hearing was simply a talking shop. As the first participant in the hearing wryly noted, 'if nothing comes from this the whole hearing will have been a waste of everyone's time'. At several points during their speeches, patients directly sought to expose power relations within the process. Two patients noted the presence of a Sanofi representative in the room and called on them to stop 'profit-making' activities. One patient noted sarcastically that if Sanofi had been marketing a new drug, they would be enthusiastically giving information out for the public to hear, while others used their speeches to berate national governments for 'doing nothing' and that 'neither Sanofi, nor anyone else, has been held accountable'.

While these statements were only tangentially related to the matter at hand, by allowing them to take place the PRAC enabled reflexivity during the public hearing in a way that exposed and allowed reflection on the shortcomings of the proposal. In response to patients, the Chair of the PRAC mentioned on several occasions that the panel were 'listening very carefully' to their recommendations and reiterated the purpose of the hearing as enabling those who do not 'usually' have a say in such processes to have their 'voice heard'.

Storytelling

Storytelling has occupied an increasingly vital role within deliberative democratic theory in particular, and deliberative innovations research more generally. Where disadvantaged communities are given a 'stage' from which to tell, in detail, the extent and intensity of their suffering, this can have powerful effects on the deliberative process. Elite actors are forced to respond to the basic human tragedy they tell, and put themselves in the positions of those who experience suffering. Theoretically, this is explicated in deliberative democracy through the conception of 'mutual justifiability':

> The term "mutual justifiability" … opens the door to storytelling and the non-cognitive evocation of meanings and symbols that can appeal to actual or imagined shared experiences. Stories can establish credibility, create empathy, and trigger a sense of injustice, all of which contribute directly or indirectly to justification (Mansbridge et al., 2010, p.67).

In the EMA's Valproate public hearing, patients and victims of the drug's malign effects were given the floor right from the start of proceedings and enabled to tell their stories. One patient told of how she and others she knew had received their medicine in a plastic bag with no information or warnings on it. She described how because she was not made sufficiently aware of the risks of taking the drug, and that because she was not made sufficiently aware, her children suffered:

> **Behind the statistics are real human stories, and mine is that I am a mother of three adult children [states names], who have all been affected by the exposure of Valproate. We are living evidence of the risks and devastating impact of this drug. Two of my three boys require lifelong care and will never be able to have a normal life. They will never be able to**

> **get married. They will never be able to have children. They have been robbed of all the joys of life (author's notes).**

Her story was responded to appreciatively by the Chair, who stated that the PRAC 'greatly appreciate your courage in bringing your own [long pause] issues into a situation of constructive proposals'. A young speaker with Valproate syndrome told the story of her family's experience dealing with her disease: 'As a family we have been through hell. Called liars. Told we are fabricating our daughter's condition. It's ridiculous. The ignorance surrounding the rare disease is as bad as the disease itself'. The Chair again responded to the speech by thanking her for 'courageously sharing your thoughts which are extremely valuable to us'. Another woman with bipolar disorder related her own problems with taking the drug and its effect on her mental health:

> I stand here as an individual woman with bipolar who has not received any input from any organisation. My thoughts are mine and mine alone and aren't evidential. As a woman with bipolar I battle with feelings of shame, inadequacy and guilt, therefore I was terrified of getting pregnant while taking Valproate due to its proof of toxicity … I have always had a strong desire to have children and continue to express this to my mental health teams. However, for a number of years I had an unsympathetic psychiatrist who refused to stop providing Valproate despite my concerns and requests. I was actually told "perhaps, given your illness, you shouldn't have children", although I have never been detained under any mental health act (author's notes).

This story about the unsympathetic psychiatrist had a visibly powerful effect on the rest of the room. Other women in the audience behind the speaker can be seen shaking their heads, and at the end of her speech the room breaks into applause, despite there not being any applause for previous speakers. The Chair praised the speech as 'tremendous and very altruistic'.

These stories exercised power in at least two ways. First, their rhetorical force demanded recognition from subsequent professional speakers from industry and academia. I noted down twice whilst watching the video how speakers later in the hearing seemed to spontaneously make reference to, and express deference towards, the experiences of the patients quoted above at the start of their own speeches. In the DQI, this creates the image that industry and professional speakers made more of an effort at recognising other groups and demands than other participants. Interpreting their speeches carefully, however, suggests that by recounting the injustices they faced, the patients *forced* recognition of injustice in a way that may not otherwise have happened. In this respect, it could be argued that allowing a space for storytelling *contributed directly* to the deliberative quality of the hearing by pressurising other, elite, speakers to recognise other groups and demands. Of course, we cannot know the counter-factual here, whether if patients had not recounted their stories the industry/professional speakers would not have recognised the importance of their experiences. Based on my interpretation of the video – the way subsequent speakers framed and made reference to those speeches - it seems unlikely.

Second, the power of the stories in question was enhanced by the Chair of proceedings from PRAC giving recognition to the stories and testimony of participants. By praising the impact of their stories and their 'courageous', 'brave' and 'altruistic' motives, the Chair not only reinforces the rhetorical power of those stories, by breaking out of the role of being a neutral receiver of the arguments in question, she emphasised the relevance of the stories to the PRAC's overall assessment and the functional and epistemic demands it must also fulfil. This observation is in line with existing research showing the importance of 'facilitation' in deliberative exercises. Facilitators, who can range from trained conveners of mini-publics to moderators of online deliberative forums, play a crucial role in determining the internal quality of deliberation. In this instance, the PRAC Chair did so by elevating the importance of personal stories and projecting their value to the decision making process as a whole, thus counter-acting any bias towards statistical data and academic studies. Given the make-up of PRAC is almost exclusively trained medical scientists, this is a crucial mediating role.

Visual symbols of power

Enabling the influence of marginalised and vulnerable groups in elite institutional arenas is a delicate and difficult process, particularly enabling them to recount powerful stories of deeply personal injustice. What processes and practices helped enable those who gave personal stories to the PRAC, present them in such a compelling way? My interpretation of the video was that *visual symbols* enabled the expression of these powerful stories. I identified three in particular: the layout of the room, the presence of a democratic representative, and the use of visual props. All four are symbols that generated and expressed power in the hearing and enhanced the equitability of the decision making process.

First, my primary interpretation of the hearing was that the layout of the room created a powerful atmosphere of a law court. The 'robust argumentative capacity and privileged perspective' of law courts, particularly constitutional courts, gives them significant authority in the public imagination (Mendes, 2013, p.2). The video shows a long room (it is described by one elite actor at the start as making things seem 'a bit far away') with EMA officials at one end, members of the PRAC sat at adjacent tables with a space in the middle of the room, leading to a plinth to which speakers were called. A translator sat alongside participants, translating for non-English speakers, and helping to pour speakers' water. Behind speakers there are several rows of chairs where both other speakers and members of the public were sat. The seats were mostly full for the entirety of the hearing. This testimonial, set piece, atmosphere, can be both daunting and facilitating for deliberative quality. On the one hand, non-elite patients in particular struggled with nerves for the occasion. However, the way in which this set-up gave a feel of participants being called as 'witnesses' created a feeling of drama and importance to the occasion. There is an impression within the room, particularly at the start of proceedings, of the audience hanging on the words of participants as they 'testify' to their views and experiences. The court-like atmosphere is reinforced by the line-up of participants. Eleven public and patient demands were presented

first, before eight industry and professional opinions were presented. This programme, which one professional representative lamented for only allowing him limited space because he was 'twelfth on the bill', presents a 'prosecution versus defence' scheduling common in court rooms. The patients and public representatives are framed as those 'on the attack' while industry and professional representatives as frames as giving mitigating circumstances.

Second, I also interpreted the hearing as being an empowered space because of the presence of democratic representation. Specifically, an elected Member of European Parliament, Linda McAvan, was sat at the front of the room next to the PRAC Chair, and explained at the beginning of the hearing how it had come about through EP legislation designed to require regulatory reviews in the field of medicines to be conducted via engagement with the public, and that she was there to report back on its effectiveness. This gave the hearing a clear rationale – that it had been sanctioned, and was being monitored, by a directly elected democratic institution. McAvan's presence was never directly referred to as an indicator of the democratic legitimacy of the exercise, but there were several points where her presence was noted in relation to the process as a whole. One participant noted they were glad McAvan was present given the work of her EP committee in the area of health, and several other participants expressed hope that the hearing might have implications for practice on the basis that it was a 'serious' decision making venue.

Third, and finally, allowing participants to use visual symbols can be interpreted as enhancing the power particularly of patients and members of the public during the hearing. One French participant who led a campaign to introduce visual warnings on the side of Valproate packaging spoke via a translator, but showed PRAC members an enlarged version of the warning sign (a black outline of a pregnant woman in a red circle with a cross through). Another participant held up a plastic bag for PRAC members to see, that she claimed was one of the unmarked bags she had received her medication in, with no description on the side of usage guidance or health warnings. I interpreted these as powerful symbols because they became objects of sustained questioning by PRAC members. They asked the speakers to elaborate further on the points the symbols were used to illustrate, and then returned to them in questioning industry and professional participants. As the final recommendations to include clear visual markers on packaging to indicate risk suggest, they may also have stuck in the minds of PRAC members as they went away to discuss their final recommendations privately.

Conclusion

Public hearings get a bad reputation as democratic innovations in elite institutions, because they are only minimally deliberative in nature and are tightly stage managed, not allowing for open and free-flowing deliberation between anyone who wishes to participate. Authorities hear the views of a select group of individuals and then go away to discuss the issue in private. Often scholars suggest this is only democratic

'window dressing' for elite decisions driven by elite interests. This paper has examined a case study of the EMA's public hearing on Valproate in 2017 to show 1) public hearings can have a significant deliberative quality; 2) at face value they do perpetuate and showcase unequal capacities for deliberation, but 3) they can enable equitable influence within a decision making process by empowering disadvantaged actors through the equitable deployment of instruments of symbolic power.

In this case, my interpretation of the video recording of the hearing was that point 3 was enabled specifically by the way in which the hearing was staged as a trial-like event, with witnesses giving testimony of both personal experiences, and those of their families. The layout of the room as equivalent to a court hearing, the presence of Linda McAvan, a Member of the European Parliament in a monitoring role, and allowing participants to use visual props to make relevant demands, created an equitable space that gave patients and members of the public the chance to influence the process through the power of storytelling. In short, it gave them a 'stage' that is particularly pertinent where elite institutional decision making is concerned. EMA did not pretend the hearing would have singular impact on its decision regarding Valproate (as, by law, it could not). Rather, as the PRAC Chair indicated, the proceedings would be 'taken into account' and used her position to extend personal support to those who clearly found the process daunting, emphasising the importance of their stories to PRAC's decision making. What are the implications of this study? I believe there are two relating to public hearings and their value, and one to the DQI methodology.

First, as Beauvais and Niemeyer (2016) argue, 'not every civic forum needs to achieve every deliberative goal simultaneously'. Which deliberative goals may be given preference depends on the type of outcome envisaged, who is running the deliberation, and how 'maximally deliberative' the forum needs to be. In this case, I have argued that public hearings can have a deliberative democratic function to the extent that they facilitate equitable participation in elite institutional decision making processes in which authoritative outcomes arise from a process in which individuals were able to give public reasons for their opinions and hear the reasoned opinions of others. Their role is to facilitate equity within the process, and this is achieved by empowering and giving a platform to those

Second, this article suggests that elite democratic innovations are not destined to be merely tools for public legitimation. Indeed, in this case, one could hardly see how the EMA received any public legitimation for the hearing at all. As of 3/8/2019 the YouTube video of the hearing has only been watched 1,631 times worldwide in just short of two years since it was first uploaded on 29/9/2017. While EMA went on to hold another hearing in 2018 on a similar medicine safety review, public coverage of the debate has been, as with many EU institutional processes, minimal. It could be argued to this extent, then, that the hearing was relatively removed from any ambitions EMA had to improve its public reputation. One may go further to argue, contentiously perhaps, that EMA's public hearing was even a 'critical' exercise in

deliberative democracy, because it 'promote[d] emancipation against domination' (Hammond, 2018) to the extent that the outcome of the hearing was to introduce:

a) new burdensome requirements upon those with power (the pharmaceutical company Sanofi) to invest resources in;
b) providing those without power (pregnant women with epilepsy or bipolar disorder without knowledge of the adverse side effects of the drug they are reliant upon) with important relevant information about its use, and;
c) introduced mandatory requirements upon mediating authorities (national governments) to bar any exercise of non-legitimate domination through the continued prescription of Valproate to pregnant women who were being harmed by taking it without their knowledge or active consent.

Again, it is difficult to think of the counter-factual here; whether the PRAC would have recommended something different, and more suited to the demands of Sanofi, had patients not had the opportunity to testify. Nevertheless, the EMA case should offer pause for thought for those insistent that elite bodies cannot do 'meaningful' deliberation.

Third, and lastly, there are methodological implications for using the DQI for analysing public hearings. The empirical analysis points to some of the limitations of Steenbergen et al's (2003) framework, which have already been highlighted by others. The DQI framework needed to be adapted, as in other studies, to the particular context, and even then it missed important aspects of what made the hearing deliberative in nature. I found coding, for example, on respect for groups and demands to be difficult in this context, not least because details in the original coding guidelines developed by Steenbergen et al (2003) and Steiner et al (2004) were difficult to interpret precisely. The qualitative analysis picked out how the structure and framing of the hearing empowered patients and the public, despite the DQI seemingly showing they scored 'lower' on deliberative quality than the industry and professional participants. The study hence suggests weaknesses in the DQI even when focusing on innovations where the framework should be strong – a structured public hearing with individual speakers rigidly separated. Future research might look into how the DQI could be explicated in more detail and guidance developed for its application to different deliberative arenas.

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APPENDIX I – Participants

Patients and affected families

• Intervention 1 − Catherine Cox, Fetal Anti-Convulsant Support Association, UK − Janet Williams, Independent Fetal Anti-Convulsant Trust (In-FACT) & FACS Syndrome Association, UK

• Intervention 2 − Marine Martin, Association of Parents of Children with the syndrome anticonvulsant (APESAC), France

• Intervention 3 − Karen Keely, FACS Forum, Ireland

• Intervention 4 − Clare Pelham, Epilepsy Society, UK − Philip Lee, Epilepsy Action, UK

• Intervention 5 − Nathalie Raemdonck, Belgian Association of Victims of Valproate Syndrome (ABVSV/ BVSVS), Belgium

• Intervention 6 − Martin Brodie, International Bureau for Epilepsy (IBE)

• Intervention 7 − Josephine Tapper, Patient, member of Bipolar UK

• Intervention 8 − Joanne Cozens, Organisation for Anti-Convulsant Syndromes (OACS), UK − Emma Friedmann, FACSAWARE.NET, UK − Branwen Mann, Patient representing Anti-Convulsant Syndrome, OACS Youth Trustee

Pharmaceutical industry

• Intervention 9 − Eric Teo, Sanofi Healthcare professionals and academics

• Intervention 10 − Jurate Svarcaite, Pharmaceutical Group of the European Union (PGEU)

• Intervention 11 − Helen Cross, European Reference Network for Epilepsy (EpiCARE) − Timothy Barrett, University of Birmingham, UK − Daniel Hawcutt, Royal College of Paediatrics and Child Health (RCPCH), UK

• Intervention 12 − Torbjörn Tomson, International League Against Epilepsy (ILAE) (CEA)

• Intervention 13 − Anthony Marson, European Academy of Neurology (EAN) − Philip Smith, Association of British Neurologists (ABN) − Sanjay Sisodiya, Epilepsy Society, UK − Dyfrig Hughes, Centre for Health Economics and Medicines Evaluation, Bangor University, UK

• Intervention 14 − Paolo Martelletti, European Headache Federation (EHF), Department of Clinical and Molecular Medicine, Sapienza University, Italy

• Intervention 15 − Kim Morley, Epilepsy specialist midwife/ nurse practitioner, UK

• Intervention 16 − Angelika Wieck, European Psychiatric Association (EPA)/ Greater Manchester Mental Health NHS Foundation Trust

APPENDIX II – Coding Scheme

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. A single such complete inference already qualifies for code.
(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: We use this code 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: I use this code 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 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.