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Who drafts better EU regulation?

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'Better EU Regulation' has been an important horizontal strategy of the Union and, in particular, the European Commission. Preceded by simplification programmes in the late 1990s, the introduction of regulatory impact assessment (RIA) and the emergence of the administrative cost model for calculating red-tape costs (and subsequently cutting them), the Better Regulation strategy was initiated in 2005. It is based on the seven principles of the Mandelkern report.[1] It is evidence-based, works with extensive and open consultation and requires all proposals to pass through a much-improved Commission Impact Assessment process. The latter has also come under the quality control of the Impact Assessment Board since late 2006, with public reports on draft RIAs, a further contribution to a more analytical and logical underpinning of EU regulation. In particular, the RIAs would seem to have narrowed considerably the scope and options for ideological approaches, or the discretion to allow or exploit regulatory 'capture' within the Commission. Ideally, it should also help MEPs to appreciate better what lobbyists tell them to adopt or reject, given the various options in every RIA and the empirical evidence and/or impact estimates for each one of them.

The new Barroso Commission is well advised to maintain a Better Regulation strategy and not to tinker with its core: Regulatory Impact Assessment. Indeed, in his first overtures, Commission President Barroso has hinted that he appreciates the importance of the strategy and that he will personally assume responsibility in this respect. In this light it was surprising to notice the announcement of a reshuffling of regulatory responsibilities among DGs in the Commission. Among the changes, the most conspicuous one was the shift of pharmaceutical regulation from DG Enterprise to DG SANCO (Health and Consumer Affairs). Portfolio reshuffling might be explained by at least four motives. One is the need to give meaningful tasks to each and every Commissioner, and there are 27 of them! Surely, this can hardly be the reason for the shift of pharma as DG SANCO has expanded its portfolio steadily over the last (say) ten years. Another reason can be the perceived need for a special Commissioner: this is certainly the case for Mrs. Maire Geoghegan Quinn, the new Commissioner for innovation. But it does not apply to the pharma case, since it is simply transferred from one existing portfolio to another existing portfolio. A third reason might perhaps be a perceived overload of DG Enterprise, but also that seems hard to

[1] Mandelkern Group on Better Regulation, Final Report, 13 November 2001. The seven principles – necessity, proportionality, subsidiarity, accountability, accessibility, simplicity and transparency – have all acquired operational significance in the meantime.

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accept since Barroso intends to pull the strategic aspects of Better Regulation closer to his direct control, reducing coordination work for DG Enterprise, whilst the shift of innovation to Mrs. Geoghegan Quinn should reduce the overload, if any. Fourth, some plain political bargaining around the appointment of new Commissioners might have played a role. One could imagine that the shift of pharma, which took many by surprise, resulted from a claim by a member state to accept the health portfolio only if pharma would be included. This fourth possible motive is hard to verify. All one can say is that, so far, no rumours to this effect have been heard.

So, what could explain the reshuffling of pharma regulation? And more importantly, why would the new setting serve EU regulation better than before?

The reshuffling would seem to express a sentiment that it matters *who* does the drafting of regulatory proposals in the Commission. But, of course, from the perspective of the EU Better Regulation strategy, the 'who' should not matter! It is all about the 'what' and the 'how' of proposals. If RIAs are properly prepared, it is the interservices IA group that is in charge, supported by studies (usually) and consultation (always). And the draft RIA is submitted to the Impact Assessment Board, which is independent (and has proven that it is, so far) and takes an analytical approach. Only when this system is not working properly, can one make a case that the leading DG drafting early versions might have preponderance. If one subsequently suspects that the relevant DG is 'captured', one might see a rationale in either improving the RIA system, or, in portfolio reshuffling. However, the latter would be a defeat because it is in the European public interest to improve the RIA system (in the Commission) as such! And a good RIA system should pre-empt or sterilise capture or its consequences.

In the case of pharma, one might take the view that, apparently, certain voices in the Brussels circuit regard DG Enterprise as assuming "too much" of an industrial approach to issues of, or related to, pharma. In other words, they seem to think that DG Enterprise has well developed relations with (here) the pharmaceuticals sector and is liable to be 'captured', making it presumably less responsive to a health care-driven perspective rather than the EU public interest would require. Implicitly, such voices discredit at least to some degree the current RIA system, in that the interservices IA groups (where the health care view is likely to be argued by DG SANCO), the studies (perhaps preceded by Green Papers and even White Papers), extensive public consultation and the IA Board do not add up to enough countervailing power to obtain the 'right' EU draft regulation. Empirical studies of the Commission RIA system (including a recent one to be published by the EU Court of Auditors) show that interservices RIA committees cannot fully remove the dominance of the drafting DG, either because the committee meets only a few times, or because it is the drafting DG that runs the hearings and other consultations, or because the technical expertise on detailed annexes is so specialised that it always confers an advantage, or, because it is the drafting DG that meets the IA Board and revises the RIA afterwards, or a combination of all these. Therefore, it cannot be excluded that undue dominance of one DG survives the RIA process. Nevertheless, given the continuous improvement of the Commission's RIAs and the processes generating them, it seems unlikely that a single DG can impose its preferences all the time. Altogether, these considerations might amount to a (weak) case in favour of reshuffling, as a second best to improving the RIA system directly. In the case of DG SANCO, the idea of reshuffling might also be welcomed in the light of its desire to be represented in the IA Board. The IA Board consists of five leading Commission officials, but not one of them is from DG SANCO (nor, conspicuously, from DG Markt). However, this desire suggests once again that it matters *who* does the quality control in the Board. But the idea of the IA Board is about the 'what' and the 'how' of the quality of RIAs, and the status of the five individuals is one of independence (protected against complaints inside the Commission by the President himself). Insofar as one believes that the Board's composition does matter, the blocking of membership might prompt a desire to go for reshuffling of portfolios instead.

In any event, it is better to tackle the internal RIA process so that the 'who drafts' issue becomes irrelevant. Reshuffling, as a second best, may not necessarily improve the situation; it might even mean the substitution of one dominant DG for another dominant DG. That would just be 'ad-hoc-ery'. The point is to prepare good EU regulation in which relevant interests and approaches are properly balanced, with empirical evidence on benefits and costs (and for whom) as well as appropriate regulatory design.

Could the case for reshuffling have been strengthened either by the particularities of the legislative programme ahead or, alternatively, by the special virtues of DG SANCO? The first option is a possibility in the light of the controversies about the 'pharma package' of 2008, in particular, the draft Directive on information (on medicines) to patients. This draft Directive has been exposed to a sharp conflict between

the industrial pharma perspective and the health care view, with stakeholders outside industry maintaining that the latter view ought to prevail. The subsequent stalemate has led to accusations of what analysts would call 'capture' of DG Enterprise by the pharma sector. The debate has been complicated by the difficulty of drawing the line between what exactly advertising is and what constitutes 'pure' information for patients. If this would be seen as a compelling reason for the reshuffling, the question arises why DG SANCO would be regarded as capable of resolving the trench war. Would it really be as simple as arguing that the pharma sector would have nobody left to argue for their interests? In any event, the RIA stage of the package is now long behind us. Today, it is up to the Council and European Parliament to legislate, with DG SANCO (with its new tasks) in a supporting and explanatory role at best.

The second option is that DG SANCO might have special virtues. As the name tells us, public health and consumer protection certainly matter a lot for pharmaceutical issues. The most important question is undoubtedly the authorisation of medicines, after solid risk assessment and extensive testing. The autonomous EU medicinal Agency (EMEA) and the underlying EU regulation are, broadly speaking, a major improvement over the last few decades. This fact alone has largely neutralised any capture that might have existed in DG Enterprise, or, probably more important, of governments of some member states. Apparently, over time, DG Enterprise has not been an obstacle to these developments; indeed, it has been very active in propelling this process. DG SANCO currently deals with the economic evaluation of medicines (their effectiveness, in fact), an issue that is essentially in the hands of the member states. After all, it is the member states that retain (and are very keen to retain) the full competences of their own varieties of national health care systems and their financing. For pharma, the background of evaluation is that less effective medicines might no longer be reimbursed given tight health budgets. Member states work together in a health technology assessment network. A case can of course be made for harmonising the criteria and cut-off points at EU level for the (in)effectiveness of medicines so that the internal market for these drugs is not fragmented by inconsistent approvals between 27 member states. In actual practice, however, such a harmonisation is highly sensitive in the light of different national interests, traditions and existing price levels. It seems that even a joint data collection exercise on 'less' effective medicines is already problematic. The Council rejection of the cross-border health services Directive (where DG SANCO was in the lead) on the 1st of December 2009, meant to create greater certainty about the right of patients (including re-imbursement) when seeking health services abroad in the EU, shows once again that member states are very sensitive indeed in this area. Regarding DG SANCO as the 'guardian' of patients' rights quickly runs into the opposition of member states, even though the European Court of Justice (ECJ) has developed considerable case-law on the matter. Remember that the cross-border health services Directive was taken out of the Bolkenstein proposal for a horizontal services Directive (now, Dir. 2006/123), prepared by DG Markt; apparently, it was assumed that a special health perspective (assigned to DG SANCO inside the Commission) would be more appropriate. Perhaps it is, but nothing has been resolved since. It reminds us of another reshuffling, that of food safety from DG Agri to DG SANCO. The incident that prompted this was the BSE scandal, where vested interests in the UK but also in the EU Veterinary Committee and elsewhere, had too long belittled or purposefully ignored BSE and its drastic consequences. But this shift was part of a much larger reform. The crux of the vast improvement in EU food safety since the late 1990s is the combination of another autonomous EU Agency (EFSA, for risk assessment and advice) and much better food safety rules. This rearrangement of the substance and governance of EU food safety is thus a much larger exercise than a mere reshuffling of portfolios to DG SANCO, although there can be no doubt about the (late) wisdom to do so.

Can the question of 'who drafts EU regulatory proposals' still matter because of the role of the relevant DG to be entrepreneurial and assume initiatives where needed? A lead DG is expected to take the initiative for a proposal or a revision or, for that matter, for the removal of gaps, mistakes or inconsistencies in existing EU laws. DG SANCO should regard the reshuffling as an opportunity to further solidify its regulatory approach in the EU interest. It could do so by making a stronger case for regulation at the EU level, if appropriate, and by promptly correcting inconsistencies in the current *acquis*. On both accounts, one can find examples showing that DG SANCO is probably still on a learning curve towards better EU regulation. On the first issue – making the case for EU level regulation – one may refer to the regulatory and other activism springing from the broader EU public health agenda, long driven by DG SANCO (ever since Commissioner Byrne's tenure, if not before). It is almost unnatural to be against the substance of the agenda as it is all in the pursuit of making Europeans healthier, whether

via campaigns, regulation, behaviour or research. Once again, however, it swiftly runs against the clear assignment of (only very limited) EU competences on health in the treaty, even excluding harmonisation of certain national regulations at EU level. It must mean that DG SANCO has to work under severe constraints concerning health, depending on the issue. One can appreciate the sentiment of frustration that these constraints might give rise to. Still, also the health care 'mission' can only be pursued at the EU level, if the (subsidiarity) arguments for EU compulsory rules are solid, whilst the legal basis is correct. However, in reporting on draft RIAs, DG SANCO has repeatedly been told by the IA Board that its subsidiarity test (which should make the functional case for a shift to the EU level) on several proposals was not compelling.

The second example refers to a lack of initiative (the opposite of activism) in correcting a clear mistake and is a little special. As is known to specialists (and many Swedes), the status quo in EU tobacco regulation (dealt with by DG SANCO) is most peculiar. Whereas tobacco is not forbidden in the EU (with nearly 100 million smokers today), a product called "snus" (smokeless tobacco, held in the mouth and popular in Sweden for centuries) is outlawed except in Sweden (and this merely because Sweden could assume a negotiating position when acceding the EU). Some smokeless tobacco variants are harmful (yet still allowed in the EU), but snus is a complete outlier: it is not a cause of oral cancer (the original fear of the EU), and Sweden (where some 20% of males use snus regularly) has a far better record in lung cancer, heart diseases, pancreas, oesophagus and stomach cancers than any other EU country. Moreover, it goes without saying that smokeless tobacco has zero effects on by-standers, a key difference with cigarettes, for example. After a long period of inaction, DG SANCO decided to let the EU Scientific Committee on Emerging and New Health Risks (SCENIHR) study the health risks of snus and the outcome is at the very least throwing up considerable doubts (given the data problems) about the suspected harm caused by snus; moreover, the few drawbacks, when found, are significantly less than the similar ones for smoking. Realising this glaring inconsistency in EU tobacco policy, one begins to wonder why the prohibition was and is maintained. Worse, a series of remarkable ECJ cases has been prompted by the distortion in ferry services between Sweden and Finland (and the island of Åland) – where the ownership of the boats determines whether or not one can sell snus – and by a tobacco trader in Germany selling snus. The reason apparently is that snus is regarded by some as a stepping stone to smoking: thus, the first step – turning to snus – should remain forbidden, preventing the incipient smoker to ever reach the second step, smoking cigarettes, although that is not forbidden. The Swedes argue exactly the opposite: snus serves as a tobacco-harm reduction strategy and it has been shown to work. Recently, Norway has begun to allow snus in some cases and a very careful and prudent report by Karl Erik Lund of the Norwegian Institute for Alcohol and Drug Research argues forcefully that snus can serve as a complementary measure to other harm-reduction strategies.

It will be interesting to observe what DG SANCO will propose in the upcoming revision of the EU tobacco Directive. In this case, 'who drafts' matters because it is apparently heresy in circles of tobacco controllers to admit a glaring inconsistency, for fear of being accused of creating a loophole for new smokers, irrespective of (comparatively large) benefits of substitution of cigarettes by (relatively harmless) snus. This flies in the face of Better Regulation principles.