thorisation status, as the latter requires higher criteria than those envisaged for THMP. However the remaining question is to what extent other products currently outside pharmaceutical *regime* yet at the same time fulfilling criteria for THMP definition will be voluntarily switched to the THMP category. Therefore policing the proper application of Article 2(2) of Directive 2004/24/EC by national pharmaceutical inspection authorities and/or by the European Commission may become an issue that determines the achievement of the intended harmonisation.

Given all the above, the Management Board of the European Medicines Agency has endorsed a number of actions aimed at improving the availability of herbal medicines in Europe, and emphasised the importance of coordinated actions within the European medicines regulatory network. This is in view of the April 2011 deadline, which marks the end of the transition period for Member States to apply provisions of Directive 2004/24/EC to traditional herbal medicinal products on the national markets[20].

However, it has to be underlined that the obligation set out in Article 2(2) of the Directive 2004/24/EC is addressed to Member States, therefore the European Medicines Agency and its Committee on Herbal Medicinal Products (HMPC) could only serve as platform for discussion and exchange of views and experiences associated with this exercise.

Risk Communication

This section discusses issues related to risk communication across a range of publicly perceived high-risk industries (such as pharmaceuticals, nuclear, oil, etc.). It reports critically and provides analysis on risk communication as an outcome of risk research within these industries. Contributions are intended to include methods working towards the advancement of risk perception research and describe any lessons learned for successfully communicating to the public about risk.

Regulatory Transparency: Forthcoming Lessons from the FDA

*Sweta Chakraborty and Ragnar E. Lofstedt**

Over the past ten years or so there has been a move from consensual style regulation to a new more participatory-transparent model in many parts of Europe and North America[1]. This move may be primarily attributed to an erosion of public trust[2] brought forth mainly through the sheer number of regulatory scandals ranging from MMR in the UK and Cox-2s in the US[3]; the risks of which have been further amplified by the media[4]. This has led to a new model of regulation that is more deliberative and transparent than its predecessor[5].

Arguably, the key component to this model is ensuring that the policy-making process is as transparent as possible[6]. This includes: placing policy deliberations on the internet; making public correspondence between policy makers, the public, and lobbyists; having industry share information on pollution, clinical trials and other safety related data on the internet; and encouraging scientists to debate scientific uncertainties in public[7]. It is difficult to disagree with this. Many of the past regulatory scandals came to fruition primarily because the regulatory policy-making process was non transparent, with decisions made behind closed doors, and

20 Please see <http://www.ema.europa.eu/pdfs/general/manage/mbpr/16937110en.pdf> (press release from EMA Management Board meeting, 17–18 March 2010).

* King's College London.

1 R. E. Lofstedt, "Risk communication and management in the twenty-first century", *International Public Management Journal* (2004), Vol. 7, pp. 335–346.

2 J. S. Nye Jr., P. D. Zelikow and D. C. King (eds), *Why People Don't Trust Government* (Cambridge, MA: Harvard University Press, 1997).

3 R. E. Lofstedt and D. Vogel, "The changing character of regulation: A comparison of Europe and the United States", *Risk Analysis* (2001), Vol. 21, pp. 399–406; R. E. Lofstedt, "The impact of the Cox-2 inhibitor issue on perceptions of the pharmaceutical industry: Content analysis and communication implications", *Journal of Health Communication* (2007), Vol. 12, pp. 471–491.

4 R. E. Kasperson, O. Renn, P. Slovic et al., "The social amplification of risk: A conceptual framework", *Risk Analysis* (1988), Vol. 8, pp. 177–187.

5 European Commission (2001), "European Governance: A white paper", COM 2001, 428 Final (Brussels: European Commission); R. E. Lofstedt, "Risk communication and management in the twenty-first century", *International Public Management Journal* (2004), Vol. 7, pp. 335–346; UK Strategy Unit (2002), "Risk: Improving Government's Capability to Handle Risk and Uncertainty –summary report" (London: Strategy Unit, Cabinet Office).

6 European Commission (2001), "European Governance: A white paper", COM 2001, 428 Final (Brussels: European Commission); UK Strategy Unit (2002), "Risk: Improving Government's Capability to Handle Risk and Uncertainty –summary report" (London: Strategy Unit, Cabinet Office).

7 A. Fung, M. Graham and D. Weil, *Full Disclosure: The perils and promise of transparency* (Cambridge: Cambridge University Press, 2007); M. Graham, *Democracy by Disclosure: The rise of technopopulism* (Washington DC: Brookings Press, 2002).

where the principal actors did not take into account a wide array of social and environmental values. Indeed, greater transparency in the policy-making process is seen by many policy makers as necessary for rebuilding public trust (e.g., European Commission 2001).

Specifically in the pharmaceuticals sector, calls for transparency increased following the Cox-2 inhibitor scandal. Merck's $2.5 billion blockbuster painkiller, Vioxx, was approved by the FDA on 20 May 1999 and had since been widely prescribed to patients with arthritis and other conditions causing chronic or acute pain. Merck immediately began an intense $450 million plus direct-to-consumer advertising campaign that marketed the drug as cardiovascular-event free. The campaign was a success. However, evidence of increased adverse events linked to Vioxx began to surface[8] and the drug was eventually voluntarily withdrawn from the market on 30 September 2004. On 18 November 2004, FDA whistleblower Dr. John Graham testified to the Senate Finance Committee his estimation that in the five years Vioxx had been on the market, the drug caused between 88,000 and 139,000 heart attacks, 30 to 40 % of which were likely to be fatal[9].

Media reporting resonated the scandal, spreading a general distrust of the pharmaceutical industry. The results were that of a "low-trust environment" posing a new challenge to communicating potential drug risks to consumers[10]. Merck was publicly perceived as a greedy, profit-driven company, willing to sacrifice lives for sales, ignoring and perhaps being untruthful about the blatant, existing evidence that connected Vioxx to increased instances of cardiovascular disease[11]. Industry was generalised as capable of deceit and perceived as prioritising financial targets ahead of public health. On 5 November 2005 the reputable medical journal, *The Lancet,* criticized Merck and the FDA for allowing the drug to be available to millions of consumers until it was recalled[12]. The FDA faced accusations of purposefully withholding recall of the blockbuster drug as a favour to Merck, alleging a conflict of interest as taking priority over the protection of public health[13]. The integrity and effectiveness of regulators across the globe also came under serious scrutiny[14]. For example, the MHRA (Medicines and Healthcare products Regulatory Agency) in the UK was viewed as lagging behind the FDA in sponsored studies of the drug that would have provided the independent evidence necessary for an earlier recall. Thus, the MHRA appeared to be following suit rather than taking proactive measures to ensure protection of its public[15].

The recall and consequent litigation of Vioxx prompted widespread debate on the safety of prescription drugs in America, causing the FDA to voluntarily commission an Institute of Medicine Report on drug safety for the purpose of an independent audit that would address the regulatory shortcomings of the FDA and offer recommendations to improve risk assessment, surveillance, and the safe use of drugs[16]. At the time of the Vioxx controversy there were also moves for greater transparency both within and outside the FDA. For example, on 5 November 2004, just over a month after Merck's withdrawal of Vioxx (30 September), the FDA announced that the CDER (Centre for Drug Evaluation and Research) would formalise a programme to help ensure that the opinions of dissenting scientific reviewers would be formally addressed and made transparent in the Agency's decision-making process (FDA 2004).

Outside the US, there were also moves toward greater transparency by the MHRA, the UK pharmaceutical regulatory agency. For example, in May 2003, the Agency published all the evidence, both published and hitherto unpublished, on which the

8 C. Bombardier, L. Laine *et al.* (2000), *Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis*, 343: 1520–1528.

9 J. Graham, "FDA, Merck and Vioxx: Putting Patient Safety First?", Senate Finance Committee Hearing, 20 November 2004.

10 R. E. Lofstedt, "The impact of the Cox-2 inhibitor issue on perceptions of the pharmaceutical industry: Content analysis and communication implications" (2007), *Journal of Health Communication*, Vol. 12, pp. 471–491.

11 K. Abbasi, "Is drug regulation failing?" (2004), *BMJ*, 329: 865; J. Lenzer, "FDA is incapable of protecting US 'against another Vioxx'" (2004), *BMJ*, 329: 1253; M. Herper, "Face Of The Year: David Graham" (2006), Forbes.com, 2007, available on the Internet at <http://www.forbes.com/2004/12/13/cx_mh_1213faceoftheyear.html>.

12 R. Horton, "Vioxx, the implosion of Merck, and aftershocks at the FDA" (2005), *The Lancet*, 364(9450): 1995–1996.

13 J. Avorn, *Powerful Medicines: The benefits, risks and costs of prescription drugs* (New York, NY: Knopf, 2004).

14 K. Abbasi, "Is drug regulation failing?" (2004), *BMJ*, 329: 865; A.S.D. Spiers, "Save the FDA" (2005), *BMJ*, 330: 308; R. E. Lofstedt, "The impact of the Cox-2 inhibitor issue on perceptions of the pharmaceutical industry: Content analysis and communication implications", *Journal of Health Communication* (2007), Vol. 12, pp. 471–491.

15 K. Abbasi, "Is drug regulation failing?" (2004), *BMJ*, 329: 865.

16 Institute of Medicine, "The Future of Drug Safety: Promoting and protecting the health of the public" (Washington DC: National Academy of Sciences, 2006).

Agency had based its decision with regard to SSRIs (Selective Serotonin Reuptake Inhibitor). Similarly in June 2005, the MHRA began releasing data on all the clinical trials on which the Agency had based a decision, allowing the public to see again the evidence on which a drug is licensed[17]. Likewise there have also been moves for greater transparency within the Canadian medical sector[18].

Back in the United States, the FDA responded largely in agreement to the recommendations offered in the IOM report, acknowledging and responding to each particular point raised. The 2006 report specifically cited the lack of clear regulatory authority, chronic under-funding, organisational problems, and a scarcity of post-approval data about drug risks and benefits as the reasons behind the FDA's weakening capability to evaluate and address the safety of prescription drugs after they have reached the market[19]. Such a measure was a clear reaction to the transitive scrutiny from the pharmaceutical industry as an effort to quell the ensuing public distrust directed towards regulatory bodies[20].

Calls for regulatory reform did not end there. Testimonies from interested members of the US Congress resulted in the passing of a more transparent communication strategy in the September 2007 Food and Drug Administration's Amendments Act (FDAAA) that took into account many of the recommendations that had first been made in the IOM report[21]. One of the key requirements in this legislation (Title IX, Section 921) included "Regular biweekly screening of the Adverse Event Reporting System (AERS) database and post a quarterly report on the Web site of any new safety information or potentials of risk" (FDAAA 2007). Accordingly, the FDA has since 5 September 2008 been posting on its public website potential "signals" of adverse events related to prescription drugs currently on the market. The FDA's official stance with regard to the quarterly postings is that "patients should not stop taking a medication" if they see it on the list; and rather, they should continue taking their medication unless their doctor advises differently (FDA 2009).

Forthcoming research by the authors will show that such measures towards increased transparency do not necessarily constitute the best risk communication strategy for reaching the lay public. The outcomes of making information available at an early stage in a drug's ex-post pharmacovigilance lifecycle may prove counterintuitive[22]. While it is hypothesised that the lay public would prefer more information than not, it is also hypothesised that they will not know what to do with the information and might prefer to err on the side of caution by stopping taking a prescription drug. Already, 38% of respondents in a recent survey said that they would stop taking a prescription drug due to distrust for a source of information (i.e. pharmaceutical companies, national news, the FDA, etc.) about medicines and/or health alerts[23]. Keeping in mind the environment of distrust following the Vioxx controversy, it is imperative to consider how the public will perceive and react to drug safety communications, particularly once a drug has already been approved for the market[24].

Forthcoming research by the authors further gauging public perceptions are likely to lead to the conclusion that the FDA should explore ways to disclose these mandatory quarterly reports in a less alarming and conspicuous way, giving more background on the limitations of these reports[25]. Regardless, FDA communications must be optimised through application of good risk communication practices, performing research with target audiences, and seeking advice from its Risk Communications Advisory Committee. Implementing alternative best practice advice on how to communicate reports on the ongoing internal AERS signal investigations to Congress, informed critics and patients will prevent unneces-

17 A. Breckenridge, Evidence given to the House of Commons Health Committee hearing. The Influence of the Pharmaceutical Industry, 20 January. In House of Commons, Health Committee. The Influence of the Pharmaceutical Industry. Evidence (London: Stationary Office, 2005), pp. Ev347–348.

18 J. Lexchin and B. Mintzes, "Transparency in drug regulation: Mirage or oasis?", *Canadian Medical Association Journal* (2004), Vol. 171, pp. 1363–1365.

19 Institute of Medicine, "The Future of Drug Safety: Promoting and protecting the health of the public" (Washington DC: National Academy of Sciences, 2006).

20 R. E. Lofstedt, "The impact of the Cox-2 inhibitor issue on perceptions of the pharmaceutical industry: Content analysis and communication implications", *Journal of Health Communication* (2007), Vol. 12, pp. 471–491.

21 B. M. Psaty and D. Korn, "Congress responds to the IOM drug safety report-in full", *Journal of the American Medical Association* (2007), Vol. 298, n. 18, pp. 2185–2187.

22 S. Chakraborty and R. Lofstedt, "Transparency and the FDA: Two Pilot Studies", Working Paper.

23 MSRI (2010), "FDA Risk Communication Program Research", Final Report, King's College London.

24 S. Chakraborty, "Ex-Post Pharmacovigilance and Trust: A Perspective", 1(1) *European Journal of Risk Regulation* (2010), pp. 83–85.

25 S. Chakraborty and R. Lofstedt, "Transparency and the FDA: Two Pilot Studies", Working Paper.

sary alarm and any early or inappropriate termination of essential prescription drugs. Whenever the FDA does issue health communications to the public, it should solicit input from the target audience and ensure that such communications include appropriate context and explicit statements on the level of scientific evidence underlying each safety alert.

These recommendations should also be considered by global agencies prior to the implementation of similar communication strategies. As it stands, in the wake of the Vioxx controversy, the integrity and effectiveness of regulators across the globe (such as the UKs MHRA) also came under serious scrutiny[26]. Hitherto untested communication initiatives, such as AERS-signals postings to the public, have the potential to be similarly criticised. However, the EMEA's current efforts to create a new database, the EudraVigilance database, as a single point for receiving and sharing reports reveal the beginning of an appropriate drive towards transparency[27]. Further efforts towards making networks of European and national safety web portals and safety information available on the public web as a matter of routine (for publications of recommendations, opinions, and urgent safety announcements) should first take into consideration the implications of the public reception to the FDA's AERS-signals initiative.

Food

This section aims at updating readers on the latest developments of risk-related aspects of food law at EU level, giving information on legislation and case law on various matters, such as food safety, new diseases, animal health and welfare and food labelling.

Providing Food Information to Consumers – Proposed Legislation under the Screening of the European Parliament

*Giuseppe Luca Capodieci and Zeev Noga**

On 16 March 2010, the Members of the European Parliament (MEP) voted on the Commission's Proposal for a Regulation on provision of food information to consumers. Some amendments to this proposal had been proposed in a report by the EP committee on environment, public health and food safety (COMENVI).

The committee report, presented by the German conservative Renate Sommer[1], was approved after the MEPs had voted on almost 800 amendments. Many changes in the existing legislation were being requested, especially for new inclusions in the list of mandatory information requirements. This report aims to inform readers of the main outcomes, following the recent adoption of a report due for a first reading in the Parliament's plenary session at the end of June[2].

I. Brief background

The draft EU regulation intends to modernise, simplify, and clarify food labelling within the European Union by making it more relevant to the needs of EU consumers. It is widely accepted that clear labelling, including easy-to-use nutritional information, is essential for helping people to make informed decisions about what they choose to buy and eat. The current horizontal food labelling legislation, being a Directive[3], allowed a certain degree of discretion at Member State level on how the non-mandatory information must be displayed on food labels (e.g. nutrition labelling, see afterwards). Therefore different "modi operandi" were developed during the last 10 years in different EU countries concerning information such as nutrition and origin. This is one of the main reasons why this proposal has, until today, undergone an extensive consultation process which involved not only the two institutions elected to participate in the codecision procedure, but also a con-

26 K. Abbasi, "Is drug regulation failing?" (2004), *BMJ*, 329: 865; A.S.D. Spiers, "Save the FDA" (2005), *BMJ*, 330: 308.

27 Vincenzo Salvatore, "Towards a new role for the European Medicines Agency in Pharmacovigilance?", presented at the 1st Conference on European Risk Regulation "Latest Developments in EU Risk Regulation: REACH, Nanotech, and Pharmaceuticals", 22 March 2010, Brussels, Belgium.

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1 Renate Sommer is a member of the conservative Christian Democratic Union, part of the European People's Party.

2 The Council will then have to adopt its position before the proposal is again debated in the Environment Committee.

3 Currently, EU general labelling requirements for all foodstuffs are set out in Directive 2000/13/EC. This Directive sets the compulsory information that has to be included on all labels, such as the name of the product, the list of ingredients, the use-by date and any special conditions of use.