

controls. The package also foresees new entities and documents: Border Control Posts (hereinafter, BCPs) will replace the different entities currently tasked with border control duties. It is proposed to establish common requirements for BCPs with the possibility for the Commission to further refine such requirements to take account of specific features related to the different categories of animals and goods being controlled. Harmonised rules for the designation, listing, withdrawal and suspension of BCPs will also be laid down. A new Common Health Entry Document (hereinafter, CHED) has been proposed to be used by operators for the mandatory prior notification of arrival of consignments of animals and goods and by competent authorities to record controls on such consignments and any decisions taken. Under the proposed regime, the Commission will be empowered to establish the format of the CHED, the modalities for its use, and the minimum time requirements for the prior notification of consignments to BCPs.

Finally, the Commission proposes to upgrade the system dedicated to recording and tracing official control results, the Trade Control and Expert System (TRACES), established by *Commission Decision 2003/24/EC of 30 December 2002 concerning the development of an integrated computerised veterinary system*⁷ and currently used for the management of data and information on animals and products of animal origin and official controls thereon, so as to allow its use for all goods for which EU agri-food chain legislation establishes specific requirements or official control modalities.

V. Conclusions

With the adoption of the package of measures on animal and plant health, seeds and official controls in these sectors, the Commission has initiated the legislative procedure. The package of measures still needs to be adopted by the Council and the European Parliament. The Commission estimates that the package will enter into force in 2016. The reform will have

a great impact on the import of food, commodities, seeds and plants into the EU. Issues like the use of veterinary medicines and plant protection products and their residues are also concerned by the reform. It is early to predict whether certain elements of the reform, such as, for example, the proposed BCPs and the CHED in relation to imports from third countries and the upgrading of the TRACES system, will contribute to a system of controls that works smoothly and does not result in new requirements, formalities and controls which, in the worst case, establish sanitary and phytosanitary barriers or technical barriers to trade into the EU.

Lifestyle Risks

This section discusses the regulation of “lifestyle risks”, a term that can apply to both substances and behaviours. Lifestyle risks take place along the line of “abstinence – consumption – abuse – addiction”. This can concern substances such as food, alcohol or drugs, as well as behaviours such as gambling or sports. The section also addresses the question of the appropriate point of equilibrium between free choice and state intervention (regulation), as well as the question of when risks can be considered to be acceptable or tolerable.

In line with the interdisciplinary scope of the journal, the section aims at updating readers on both the regulatory and the scientific developments in the field. It analyses legislative initiatives and judicial decisions and at the same time it provides insight into recent empirical studies on lifestyle risks.

Under the influence? The Alcohol Industry’s Involvement in the Implementation of Advertising Bans

*Oliver Bartlett**

On 1 March 2013 an independent report called “Health First” was published calling for, amongst other things, a total ban on alcohol advertising in the UK. This article seeks to evaluate the major hurdles that would stand in the way of the UK, and indeed the EU itself, pursuing such a prohibition. It argues that the involvement of the alcohol industry is the main roadblock preventing the enactment of a radical but much needed policy. It advocates disassociation with the alcohol industry and a willingness on the part of EU policy makers to fight any challenges

⁷ OJ 2003 L 8/44.

* Durham Law School. The author would like to thank the anonymous reviewers for their helpful comments. He would like to also offer grateful thanks to Prof. Amandine Garde (Liverpool Law School) for her support and valuable comments on drafts of this report. All mistakes remain the author’s own.

that the industry raise in opposition to strong alcohol advertising regulation.

I. Introduction

On 1 March 2013 an independent group of experts, supported by over 70 public health organisations, released a report entitled *Health First: An evidence-based alcohol strategy for the UK*,¹ which detailed recommendations for a more stringent set of alcohol control policies for the UK.

One of the key recommendations put forward by the report was a complete ban on all alcohol advertising and sponsorship,² a policy that would be a radical development in terms of the UK's current approach to controlling alcohol advertising. Some states in Europe already have a total ban on alcohol advertising, and further afield more are steadily being enacted, such as the prohibition in Russia, in force from January 2013. It is against this background that this contribution reflects on what might stand in the way of implementing such a ban in countries such as the UK that currently have less stringent alcohol advertising rules, and also at EU level where alcohol advertising is given a similarly soft treatment.

Such a step is certainly desirable – according to WHO figures, alcohol-related causes accounted for 11.8 per cent of all deaths for the age group 15 to 64 years in the EU in 2004.³ Excessive alcohol consumption is also the primary cause for many non-communicable diseases, for example causing between 75 and 80 per cent of liver cirrhosis in the EU.⁴ Although it is not necessarily the case that an increase in the general level of alcohol consumption will relate to an increase in the level of alcohol related harm experienced by a population, studies exist which conclude that 'both average volume of alcohol consumption and patterns of drinking have been shown to influence alcohol-related burden of disease'.⁵ Thus, any increase in consumption must at least be seen as likely to contribute to an increased level of excessive consumption.

The evidence base suggests strong links between alcohol advertising and higher consumption rates. Numerous reviews and studies have reported findings that show exposure to alcohol advertising to be related to increased consumption,⁶ with the Science Group of the European Alcohol and Health Forum

concluding in an Opinion in 2009 in relation to young people as a particularly vulnerable group that there was "consistent evidence to demonstrate an impact of alcohol advertising on the uptake of drinking among non-drinking young people, and increased consumption among their drinking peers".⁷

A total ban could therefore contribute significantly to lowering drinking rates in Europe, and would certainly be progress on the largely inadequate Articles 9(1)(e) and 22 of the Audiovisual Media Services Directive,⁸ which remain the EU's only attempt to directly regulate alcohol advertising.⁹ This report seeks to highlight however that the regulatory process for alcohol control cedes much influence to the producers of alcoholic beverages themselves, and that unfortunately this constitutes a major problem for making such improvements a reality.

The report will advance this argument in two parts: the reasons why industry involvement in alcohol control policy leads to difficulties will first be analysed, followed by a discussion of what policy makers need to take into consideration if they are to overcome these obstacles. It will conclude that if ei-

1 *Health First: an evidence based alcohol strategy for the UK* (The University of Stirling 2013) www.stir.ac.uk/management/about/social-marketing (last accessed on 18 March 2012).

2 *Ibid.*, at p. 26.

3 Peter Anderson, Lars Møller and Gauden Galea (eds), *Alcohol in the European Union: consumption, harm and policy approaches* (Copenhagen: World Health organisation Regional Office for Europe, 2012), at p. 17.

4 *Ibid.*, at p. 20.

5 Jürgen Rehm, Robin Room, Kathryn Graham et al., "The relationship of average volume of alcohol consumption and patterns of drinking to burden of disease: an overview", 98 *Addiction* (2003), pp. 1209 *et seq.*, at p. 1222.

6 Lesley Smith and David Foxcroft, "The effect of alcohol advertising, marketing and portrayal on drinking behaviour in young people: systematic review of prospective cohort studies", 9 *B.M.C. Public Health* (2009), pp. 51 *et seq.*; Petra Meier, "Independent review of the effects of Alcohol pricing and promotion: Part A: Systematic Reviews" (2008) available online at <http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_091383.pdf> (last accessed on 6 August 2013); Matthis Morgenstern et al., "Exposure to alcohol advertising and teen drinking", 52 *Preventative Medicine* (2011), pp. 146 *et seq.*

7 Science Group of the European Alcohol and Health Forum, "Does marketing communication impact on the volume and patterns of consumption of alcoholic beverages, especially by young people? – a review of longitudinal studies" (2009) available on the internet at <http://ec.europa.eu/health/ph_determinants/life_style/alcohol/Forum/docs/science_o01_en.pdf> (last accessed 6 August 2013).

8 Council and Parliament Directive 2010/13/EU on Audiovisual Media Services, OJ 2010 L 95/1

9 For more detail on the criticisms of Articles 9(1)(e) and 22, see the analysis in: Oliver Bartlett and Amandine Garde, "Time to seize the (red) bull by the horns: the EU's failure to protect children from alcohol and unhealthy food marketing", *EL Rev* (2013), forthcoming.

ther the UK or the EU does wish to seriously consider a total ban on alcohol advertising, EU and national alcohol policy makers must stop affording the industry the level of influence on policy making that it is currently allowed to exert.

II. Why implementing a total ban is made extremely difficult by industry's undue influence in policy making

This section argues that at both national and EU level the industry is too close to the policy making process and that therefore, considering their active opposition to restrictive policies such as total bans, the more influence policy makers allow them the more problematic pushing through a total ban will be. The *Health First* report does acknowledge that “to be effective, regulation must be independent of the alcohol industry”,¹⁰ however this is not currently reflected in policy making.

Unlike the tobacco industry, who have been ostracised from international tobacco policy making through Article 5(3) of the Framework Convention on Tobacco Control (FCTC),¹¹ the alcohol industry is freely allowed to mix with policy makers and is even actively invited to contribute in regulatory terms to the control of its own promotional activities.

At EU level this mainly occurs through the EU Alcohol and Health Forum, which was set up following

the adoption of the EU Alcohol Strategy¹² and aims to “support, provide input for and monitor the implementation of the strategy”.¹³ Industry operators and associations alone comprise over 25 per cent of the current membership of the Forum, which at the time of the Forum’s inception led to concerns of “appearing to sanction industry involvement in EU Health policy”.¹⁴ Six years later, it is evident that fears that “ineffective approaches favoured by industry will become de facto EU policy”¹⁵ have now been realised. The publication released¹⁶ detailing the highlights of the 4th Open Forum on Alcohol and Health contains no commitments promoting strategies that are known to be effective – instead the lead commitment from The Brewers of Europe has “set about ensuring that fully integrated, consumer-friendly national self-regulatory systems for beer advertising exist[ed] across Europe”,¹⁷ the result of which has been that self-regulation, an approach shown to be ineffective at preventing alcohol advertising from reaching or appealing to children,¹⁸ is being pushed to the vanguard of alcohol advertising control policy. The fact that the integration of an ineffective strategy championed by the industry is done under the auspices of the European Union will make it considerably more difficult to initiate a counter-drive for effective legislative standards.

In the UK as well, the industry is actively relied upon to play a key role in shaping alcohol policy. The UK Government’s Public Health Responsibility Deal, launched in July 2010, encourages a new approach to dealing with alcohol related harm centred around partnership with the industry, and this forms an integral part of the Government’s approach to tackling advertising in its new Alcohol Strategy, published in March 2012, to which the *Health First* report cited above has been a response. It seems that the UK Government refuses to acknowledge that bans can be a proportionate response,¹⁹ and instead of initiating a much needed overhaul of the current self-regulatory scheme favours ‘work[ing] with industry and other relevant bodies to help raise public awareness of the controls’.²⁰ Involving the industry in this way permits them to not only repudiate criticisms that the industry facilitates alcohol related harm, but at the same time to weave low-impact interventions into the fabric of the UK’s alcohol control policy. Thus, the platform given to industry at the heart of the UK’s regulatory approach constitutes a substantial blocking factor on attempts to convince the Government that

10 *Health First*, *supra* note 1, at p. 27

11 Framework Convention on Tobacco Control, 16 June 2003, in force 27 February 2005, Geneva, available at <<http://whqlibdoc.who.int/publications/2003/9241591013.pdf>> (last accessed on 6 August 2013)

12 Commission Communication on An EU strategy to support Member States in reducing alcohol related harm, COM(2006)625 final, at p. 16.

13 *Ibid.*

14 Nick Sheron, “Alcohol in Europe: the EU Alcohol Forum”, 7 *Clin Med* (2007), pp. 323 *et seq.*, at p. 323.

15 *Ibid.*, at p. 324.

16 European Union, “European Alcohol and Health Forum Highlights: Open Alcohol and Health Forum 23 November 2012 –Brussels” (2012) available on the Internet at <http://ec.europa.eu/health/alcohol/docs/alcohol_health_forum_highlights_en.pdf> (last accessed on 6 August 2013).

17 *Ibid.*, at p. 21.

18 For an independent evaluation of the effectiveness of self-regulation, see Avalon de Bruijn, Esther van den Wildenberg and Anouk van den Broeck, *Commercial promotion of drinking in Europe: Key findings of independent monitoring of alcohol marketing in five European countries* (Utrecht: STAP, 2012), available on the internet at <www.eucam.info/content/bestanden/ammie-eu-rapport_final.pdf> (last accessed on 6 August 2013).

19 See Home Office, *The Government’s Alcohol Strategy* (London: Home Office 2012), at p. 7.

20 *Ibid.*, at p. 8.

radical measures such as bans should be pursued instead.

Aside from their direct involvement in the regulatory process, the industry have also exploited the many pressure points that have been established through the development of a close relationship with policy makers. A specific example of this unprecedented access occurred prior to the adoption of the EU Alcohol Strategy, when the industry managed to secure an input into the report *Alcohol in Europe*²¹ which formed the evidence base for the future Strategy. In a later article, the report's authors note that due to formidable industry lobbying before the publication of the report, "the Commission agreed to 'peer-review' [the] report, unlike for any of their previous public health reports",²² and that "astonishingly, the industry was allowed to nominate half of the scientists invited to the review".²³ This indicated that the Commission are not only sensitive to the pressure exerted by the alcohol industry, but were moreover willing to accommodate their demands, raising the question of what else the industry could achieve.

III. What policy makers must consider in order to overcome these obstacles

Given that much of the industry's access to policy making is attributable to governmental invitation, a total ban as mooted by the *Health First* report is only as far out of reach as policy makers would like it to be. This section will therefore seek to suggest what policy makers must start considering if they wish to reduce industry influence and place themselves in a stronger position from which a total ban on alcohol advertising could realistically be enacted.

An effort must primarily be made to reverse the practice of viewing the industry as a partner in the fight against alcohol-related harm. So far this outlook has led at EU level to the fact that the "industry's self-regulatory regime is endorsed by the Commission"²⁴ resulting in an Alcohol Strategy that "bears the hallmark of a massive compromise between the health argument and the commercial interests".²⁵ At national level, particularly in the UK, it has led to a blindness to evidence based regulation whereby the Health Secretary has defended the Responsibility Deal by declaring that "we will not treat the food and drink industry [and by implication the other indus-

tries in the deal including alcohol] as if it was comparable to the tobacco industry";²⁶ completely failing to recognise that "there is now evidence to show that the food, drink and alcohol industries use similar tactics and strategies to the tobacco companies to undermine public health interventions".²⁷ This trust in the alcohol industry must be tempered, or else we risk allowing the industry to "establish itself as a partner to an extent that may be difficult to reverse".²⁸

There has been recent discussion on whether to move towards the adoption of a Framework Convention on Alcohol Control, taking a lead from the FCTC.²⁹ One benefit that might arise from such a development could be the enactment of a provision similar to Article 5(3) of the FCTC. This would bar all policy collaboration with the industry, securing a reduction in the substantive input of industry operators into alcohol policy making. Taylor and Dhillon note that "achieving multilateral agreement is especially challenging in the context of alcohol due to industry influence".³⁰ However, as others rightly point out, "experience with other industries, especially through tobacco control efforts, can also teach us a lot about how to critically examine and resist the alcohol industry's behavior and practices".³¹ Consequently, an international commitment

21 Peter Anderson and Ben Baumberg, *Alcohol in Europe: A public health perspective* (London: Institute of Alcohol Studies 2006), available on the internet at http://ec.europa.eu/health-eu/news_alcoholineurope_en.htm (last accessed on 6 August 2013)

22 Ben Baumberg and Peter Anderson, "The European strategy on alcohol: A landmark and a lesson", 42(1) *Alcohol and Alcoholism* (2007), pp. 1 *et seq.*, at p. 1.

23 *Ibid.*, at p. 1.

24 *Ibid.*, at p. 503.

25 Anders Ulstein, "No ordinary partner", 23(6) *Nordic Studies on Alcohol and Drugs* (2006), pp 499 *et seq.*, at p. 502.

26 See Ian Quinn, "Lansley: 'Responsibility Deal is achieving big results'", *The Grocer*, 20 April 2012, available on the internet at <<http://www.thegrocer.co.uk/topics/health/lansley-responsibility-deal-is-achieving-big-results/228388.article>> (last accessed on 6 August 2013).

27 Rob Moodie, David Stuckler, Carlos Monteiro et al., "Profits and pandemics: prevention of harmful effects of tobacco, alcohol, and ultra-processed food and drink industries", 381 *Lancet* (2013), pp. 670 *et seq.*, at p. 672

28 Anders Ulstein, "No ordinary partner", *supra* note 24, at p. 503.

29 See for instance: A Taylor and Ibadat Dhillon, "An international legal strategy for alcohol control: not a framework convention – at least not yet", 108 *Addiction* (2012), pp. 450 *et seq.*; Robin Room, "Healthy is as healthy does: where will a voluntary code get us on international alcohol control?", 108 *Addiction* (2013), pp. 456 *et seq.*

30 Allyn Taylor and Ibadat Dhillon, "An international legal strategy for alcohol control", *supra* note 28, at p. 451.

31 Virginia Barbour et al., "Let's be straight up about the alcohol industry", 8(5) *PLoS Med* (2011), pp. e1001041 *et seq.*, at p. e1001041.

to move alcohol policy forward without the input of the alcohol industry, inspired by the provisions of the FCTC, is not something that should be shielded away from.

Of course thought must be given to the inevitable counter argument to an analogy with tobacco policy, which correctly points out that tobacco and alcohol as substances differ fundamentally since tobacco is always harmful whatever the dose whereas it is only excessive consumption of alcohol that is harmful, with research even suggesting that low levels of alcohol consumption may have beneficial health effects.³² However, excessive consumption of alcohol is a greater problem than is generally acknowledged. In the European Union the average adult consumption of alcohol according to WHO figures was 12.5 litres of pure alcohol, or 27g (nearly three drinks) per day, which is more than double the world average.³³ In many Member States such as the UK excessive consumption of alcohol is common,³⁴ to the extent that the UK Prime Minister acknowledged in the Government's new Alcohol Strategy that binge drinking accounts for half of all alcohol consumed in the UK.³⁵ The levels of excessive alcohol consumption that exist lead alcohol to be the third leading risk factor for disease and mortality in Europe directly after tobacco and high blood pres-

sure, which therefore indicates that to apply principles developed in relation to the regulation of tobacco to the regulation of alcohol is not disproportionate.

Policy makers must also be careful to prepare for the inevitable legal challenge to any strong alcohol policy. Several national alcohol advertising bans have been disputed directly by the industry in domestic courts, including the French Loi Evin in *Bacardi France*,³⁶ the Swedish total ban in *Gourmet*,³⁷ and the Norwegian total ban in *PediceL*.³⁸ Furthermore, the challenge to the EU's total ban on cigarette advertising³⁹ tells us that EU measures on alcohol might come under fire as well. The proportionality assessments made by the Court of Justice of the European Union of these bans, which determine whether or not the legislator has gone too far in promoting public health at the expense of other interests, have been somewhat erratic. In *Tobacco Advertising 2*,⁴⁰ although the Directive was eventually struck down for the reason that some of its prohibitions on static forms of advertising (i.e. non cross-border) advertising 'in no way help to facilitate trade in the products concerned'⁴¹ and thus did not meet the conditions of recourse to the chosen legal basis of Article 114 TFEU because they did not 'genuinely have as [their] object the improvement of the conditions for the establishment and functioning of the internal market',⁴² the engagement with proportionality in the case was weak, did not sufficiently engage with the evidence and 'may cut both ways'⁴³ when relied on in later judgements. Although this was the first and only time the Court had struck down a piece of EU legislation, the refusal to discuss proportionality in any depth may have set the tone for future assessments of public health legislation. The Court in *Gourmet* did not engage with proportionality at all, instead regrettably leaving it to the national court, which then declared the Swedish ban disproportionate. However the Court did do so in *Bacardi France*, although again not with any level of detail – it 'merely observed'⁴⁴ that the French prohibition was appropriate, which led to the French ban surviving. Given this inconsistent treatment of the proportionality of bans adopted in the name of public health, policy makers must ensure that the evidence supporting such measures is engaged with early on, in order to leave no doubt that advertising bans are a proportionate response to protect public health. The more that is learnt from legal precedent, the bet-

32 See for example: Francois Booyse and Dale Parks, "Moderate wine and alcohol consumption: Beneficial effects on cardiovascular disease", 86(2) *Thrombosis and Haemostasis* (2001), pp. 509 et seqq.

33 World Health Organisation, *Alcohol in the European Union: Consumption, harm and policy approaches*, (Copenhagen: WHO Regional Office for Europe 2012), at p. 1.

34 D Craig, M Dakkak, I Gilmore et al., "A drunk and disorderly country: a nationwide cross-sectional survey of alcohol use and misuse in Great Britain", 3 *Frontline Gastroenterology* (2012), pp. 57 et seqq.

35 *The Government's Alcohol Strategy*, supra note 18, at p. 2.

36 Case C-429/02 *Bacardi France* [2004] ECR I-06613.

37 Case C-405/98 *Konsumentombudsmannen (KO) v Gourmet International Products AB (GIP)* [2001] ECR I-01795.

38 Case E-4/04 *PediceL AS v Sosial-og helsedirektoratet* (Directorate for Health and Social Affairs) [2005].

39 See Case C376/98 *Germany v Parliament and Council* [2000] ECR I-08419.

40 Case 380/03 *Germany v Parliament and Council* [2006] ECR I-11573.

41 Case C-376/98 *Commission v Parliament and Council (Tobacco Advertising 1)* [2000] ECR I-08419, para 99.

42 Case C-376/98 *Commission v Parliament and Council (Tobacco Advertising 1)* [2000] ECR I-08419, para 84.

43 See Amandine Garde, "Freedom of commercial expression and public health protection: the principle of proportionality as a tool to strike the balance" in Laurence Gormley and Niamh Nic Shuibhne (eds), *From Single Market to Economic Union – Essays in Honour of John Usher* (Oxford: Oxford University Press, 2012), at p. 122.

44 *Ibid.*, at p. 129.

ter the chance policy makers will have of defending strong policies.

IV. Conclusion

The current EU Alcohol Strategy was due to expire in 2012, and we are now awaiting a new Strategy from the Commission. In the meantime, initiatives such as the *Health First* report are very welcome, both at national and EU level. However if we want to see the Commission and national governments make the strong commitment to legislation that is called for by this report, much effort is needed to persuade them to first cut loose the alcohol industry who for years have managed to exert considerable influence at all levels in order to block effective regulation.

One American judge has summed up the nature of all dangerous consumption industries in the context of tobacco bluntly but, it is submitted here, truthfully: “Who are these persons who knowingly and secretly decide to put the buying public at risk solely for the purpose of making profits and who believe that illness and death of consumers is an appropriate cost of their own prosperity”.⁴⁵ It is not until policy makers realise that there is no reconciling this identity with effective public health regulation, and start managing this conflict of interest in the alcohol field appropriately, that policies as bold as a total ban on alcohol advertising can be put into action.

Pharmaceuticals

This section updates readers on the latest developments in pharmaceutical law, giving information on legislation and case law on various matters (such as clinical and pre-clinical trials, drug approval and marketing authorisation, the role of regulatory agencies) and providing analysis on how and to what extent they might affect health and security of the individual as well as in industry.

EU Initiative to Tackle Medication Errors – Proposals and Challenges

Els Janssens*

Medication errors represent a serious public health concern. They are reported to be an important cause

of adverse drug reactions adding billions of euros to healthcare bills around the world.¹ Considering that a large proportion of medication errors can be prevented efforts should be made to bring down their incidence. The European Medicines Agency (EMA) organised a workshop on 28 February and 1 March 2013 to raise awareness around the problem of medication errors and to formulate proposals to improve reporting and prevention of medication errors through collaboration between the European Commission, the EMA and the national authorities for drug and patient safety. A final report of this workshop is available on the Agency’s website².

Medication errors are generally understood as any mistakes in the prescribing, supplying, dispensing, preparing, administering or monitoring of medicinal products. A classic example of a medication error is a drug overdose but situations where a wrong medicine or a wrong formulation of a medicine is given to a patient also classify as medication errors. A legal definition does not exist. Instead, multiple definitions and terms have been commanded over the past years subject to individual researcher’s preference. This may explain the variation in prevalence of medication errors³ but at the same time underlines the need for agreement on a definition and classification of errors because the incidence of medication errors of different classes are different as are the potential remedies.⁴ In other words harmonisation of terminology is key for any improvement strategies aimed at tackling medication errors.

Supported by legislative initiatives medication errors are increasingly monitored through drug safety systems. The recent review of the European pharmacovigilance legislation has indeed broadened the de-

45 Opinion of Judge H Lee Sarokin, *Haynes v Liggett Group Inc.* 140 F.R.D. 681 (D.N.J. 1992), at p. 683.

* European Medicines Agency. Any views expressed in the report are the personal views of the author and do not represent a position of the European Medicines Agency.

1 EMA press release of 1 march 2013 (EMA/130601/2013).

2 EMA medication errors workshop report -<http://www.ema.europa.eu/docs/en_GB/document_library/Report/2013/05/WC500143163.pdf>.

3 M. Lisby, L.P. Nielsen, B. Brock and J. Mainz, “How are medication errors defined? A systematic literature review of definitions and characteristics”, 22(6) *International Journal for quality in healthcare* (2010), pp. 507–518 (Advance Access Publication: 17 October 2010), as quoted by Jeffrey Aronson and Robin Ferner in their presentation “Do we have a common understanding of medication errors?” during EMA workshop on medication errors on 28 February 2013.

4 R. Ferner and J. Aronson, “Clarification of terminology in medication errors – Definitions and classification”, 29(11) *Drug Safety* (2006), 1011–1022.