entry into force of the new Parliament and Commission, the enhanced roles entrusted to the Committee of the Regions and the European Economic and Social Committee by the Lisbon Treaty, and the launch of the EU 2020 Strategy (however perfectible it may be) all form a perfect constellation of factors that should not be missed.

All stakeholders are not merely observers and addressees of this agenda. Their responsibility is to provide data that is reliable and well-timed. They must promote a constructive debate on IA, risk, and regulatory reform with the institutions. This necessarily implies also maintaining an effective dialogue among other constituencies. At the same time, stakeholders should not abandon their role as partners to the public administrations, not afraid to challenge them if necessary, but always ready to help by monitoring and steadily promoting their advances.

V. Instead of a conclusion: the new EJRR Impact Assessment section

The above observations have set the background of the launch of the EJRR Impact Assessment section. The section will regularly address IA at EU level and in Europe. Academics, practitioners and experts from various backgrounds and affiliations will be invited to contribute to the debate by reporting on and critically assessing recent developments, developing strategic thinking, and making constructive recommendations for ever improving IA processes. Clearly, there is no simple answer. No "plug-and-play model" will ever work. The multidisciplinary nature of the journal will help address the heterogeneity of the challenges and the contexts to be tackled. This will be reflected in the various approaches to IA, from its interface with risk analysis and studies on methodological aspects to some aspects belonging more to the legal domain and political science.[24]

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24 Ideas and proposals for contributions may be forwarded to Alberto Alemanno (alemanno@hec.fr) and Lorenzo Allio (lorenzo.allio@gmail.com).

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.

The Institutional Growth of the European Medicines Agency*

On 26 January 2010 the European Medicines Agency celebrated its 15th anniversary. The inspiring "life cycle" theory of Bernstein[1] suggests that we should regard the growth of a regulatory body as somewhat similar to the development of a human being. This anniversary marks the Agency's well-deserved entry into maturity now that it has grown to have six scientific committees and numerous other working parties. The Secretariat of the Agency has been recently restructured, and the old EMEA acronym has been dropped. In recent years, the Agency's sphere of responsibilities has been gradually expanding in line with new European legislation, most recently in the field of medicinal products for paediatrics and advanced therapies. The Agency has become established as the competent body to provide EU institutions and Member States with scientific advice on the evaluation and supervision of medicinal products – with claims that it enjoys a *de facto* or *semi*-regulatory power. After the entry into force of Regulation 1901/2006, the Agency may now also take decisions with legally binding effect *vis-à-vis* third parties on medicinal products for paediatric use[2]. New legislation in the pipeline, part of the "pharmaceutical package" (in the fields of counterfeiting and pharmacovigilance) will further increase the coordinating role of the Agency. Moreover, the Agency's unique institutional architecture, together

* All views expressed in this paper are strictly personal and should not be understood or quoted as being made on behalf of the European Medicines Agency.

1 Bernstein, M., *Regulating Business by Independent Commissions* (Westport Conn.: Greenwood Press 1977).

2 This has resulted also in the first dispute, still pending before the General Court, directed only against an administrative act of the Agency, *Nycomed Danmark v. European Medicines Agency*, T-52/09.

with the European Regulatory Network that it has created, has attracted great attention in administrative law circles,and it has been portrayed as an example of experimentalist governance[3].

On the day of its 15th anniversary, the Agency released for public consultation a draft document, the *Agency's Road Map to 2015: The Agency contribution to Science, Medicines, Health*[4] that stresses the growing importance of international cooperation and interaction with stakeholders. It also identifies the drivers for progress and change (i.e. new and emerging sciences, the demand for greater transparency and openness, the reconsideration of beneft/risk assessment and communication etc.). These key topics will form part of the debate on the future model of regulation of medicines in Europe.

Hovering over the future of the Agency are two other important factors that should be taken into account: the entry into force of the Lisbon Treaty and the transfer of responsibilities for pharmaceuticals within the European Commission from DG Enterprise to DG Sanco.

It is difficult to predict precisely the size and kind of impact of these two factors on the European pharmaceutical framework. However, it is worth noting that, for the first time, the Treaty makes reference to the role of the Union in the adoption of *"measures setting high standards of quality and safety of medicinal products and devices for medical use"* and it confers this competence under public health policy (Article 168(4)c TFUE). Therefore the safety regulation of medicinal products is to be considered as part of competences shared between the Union and the Member States under Article 4(2)k TFUE such as measures implementing the internal market (Article 4(2)a TFUE), while Member States retain their powers to set prices and conditions for reimbursement of medicinal products. However, the formal recognition of medicinal products under the area of public health makes it possible for the Commission to *"take any useful initiative to promote cooperation"* among Member States in the field of pricing and reimbursement through *"the establishment of guidelines and indicators, the organisation of exchange of best practice, and the necessary elements for periodic monitoring and evaluation"* (Article 168(2) TFUE). With regard to the European Medicines Agency, it should be emphasised that the Lisbon Treaty has intervened in broadening generally the *locus standi* of agencies in actions for annulment (Article 263TFUE), in actions for failure to act (Article 265 TFUE) and finally for preliminary rulings (Article 267 TFUE)[5].

The relocation of the Unit F2 "Pharmaceuticals" and of the European Medicines Agency from DG Enterprise to DG SANCO could also potentially bring about changes in this regulatory field. During the hearing at the European Parliament on 14 January the Health Commissioner Designate, John Dalli, made it clear that he would put "patient rights first" without necessarily reducing the competitiveness of the pharmaceutical industry, and that the third part of the "pharmaceutical package" (information to patients)would be reassessed to "*bring more patient perspective into the proposal*"[6]. Another important point that could have an impact on the institutional framework of risk regulation is the existence of dedicated scientific committees[7], not to mention of other Agencies[8], within DG SANCO able to provide advice via risk assessment in the area of the Agency's institutional remit, such as antimicrobial resistance, tissue engineering, etc.. In our view this should not be feared as a further layer of technocratic complexity or as a source of possibly conflicting scientific opinions, but rather be seen as an opportunity to improve and further integrate regulatory science for the control of risks in the public health and environment domains.

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3 Sabel, C./Zeitlin, J., *Experimentalist Governance in the European Union – Towards a new architecture* (Oxford University Press 2010).

4 Available at the Internet on www.ema.europa.eu.

5 The possibility of legal review of acts of the Agency should be also put in the context of a doctrinal position that favours the possibility of directly challenging the scientific opinions of the European Medicines Agency, notwithstanding the fact that they are merely preparatory acts, arguing on the basis of the *Les Verts* principle, cf. Chiti, E., An important part of EU's institutional machinery: features, problems and perspectives of European agencies, in *Common Market Law Review* (2009), p. 1420.

6 A press release of Mr. Dalli's hearing is available at the web site of the Parliament http://www.europarl.europa.eu/news/expert/infopress_page/008-67215-013-01-03-901-20100113IPR67206-13-01-2010-2010-false/default_en.htm.

7 Reference is made here in particular to the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environment Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and the Pool of Scientific Advisors on Risk Assessment established by European Commission Decision 2008/721.

8 The European Food Safety Authority (EFSA) in Parma and the European Centre for Disease Prevention and Control (ECDC) in Stockholm.