JPHSR Journal of Pharmaceutical Health Services Research

Royal Pharmaceutical Society of Great Britain

Research Paper

JPHSR 2010, 1: 53–60

Received April 13, 2010
Accepted May 26, 2010
DOI
10.1111/j.1759-8893.2010.00015.x
ISSN 1759-8885

The future of pharmaceutical policy in the European Union until 2025: results of a Delphi survey

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Abstract

Objectives To examine expectations of and opinions on the development of European Union (EU) and national competencies in pharmaceutical policy until 2025.
Methods Key issues of pharmaceutical policy (authorisation, pharmacovigilance, classification, distribution, advertising, pricing, dispensing, prescribing, post-licensing evaluation and reimbursement) were selected from published literature. Next a two-round Delphi questionnaire was developed in which 41 selected European experts were asked to rate the level of competence on these issues using a five-point Likert scale (1 = fully national, 5 = fully European).
Key findings Experts expect that authorisation, pharmacovigilance, classification, distribution, advertising and post-licensing evaluation show a steady and gradual trend towards European regulation. Pricing, dispensing, prescribing and reimbursement remain predominantly national competencies.
Conclusions Convergence due to the Europeanisation of the pharmaceutical market reinforces opportunities for (and in some cases necessitates) more European collaboration or regulation. National governments are well advised to support such collaborations and to actively participate in the direction of future EU policy instead of resisting it.
Keywords Delphi technique; drug and narcotic control; European Union; pharmaceutical policy; pharmaceutical services

Introduction

The pharmaceutical market in the European Union (EU; see Figure 1[22,23]) has received continuous political attention for many years. On a national level, European Member States try to contain rising drug expenditures, which pose a threat to the financing and accessing of healthcare. On a supranational level, the EU is seeking to liberalise the market and to encourage innovation and competitiveness of the European pharmaceutical industry, a strategically important industry. These national policy objectives conflict with supranational policy objectives. The attempts of the European Commission to liberalise the European pharmaceutical market and to establish a single European market for pharmaceuticals came to a standstill after some considerable achievements from 1965 to 1995. Particular progress was made using directives and regulations, which resulted in greater harmonisation of national practices regarding authorisation, classification, packaging and wholesaling. This process culminated in the establishment of the European Medicines Agency (EMEA) and the introduction of legally binding European centralised and decentralised authorisation procedures in 1995. As of 2010, there is no single European market for medicines. Although the Commission has sought to make progress through the G10 medicines group[1,2] using the open method of coordination, pricing, reimbursement, prescribing and dispensing remain predominantly the competence of the Member States. Member States are unwilling to give up their regulatory authority, out of fear the outcomes will negatively impact domestic industry (i.e. job loss) and their respective healthcare systems (i.e. more reimbursable products and/or higher prices for pharmaceuticals), depending on state-specific goals. The persistency of this fear is exemplified by the use of the subsidiarity principle. Instead, the Commission has become increasingly concerned with the competitiveness of the European pharmaceutical industry especially in relation to the success of the USA (see [3,4]). The Commission holds that the European pharmaceutical industry plays a key role in Europe

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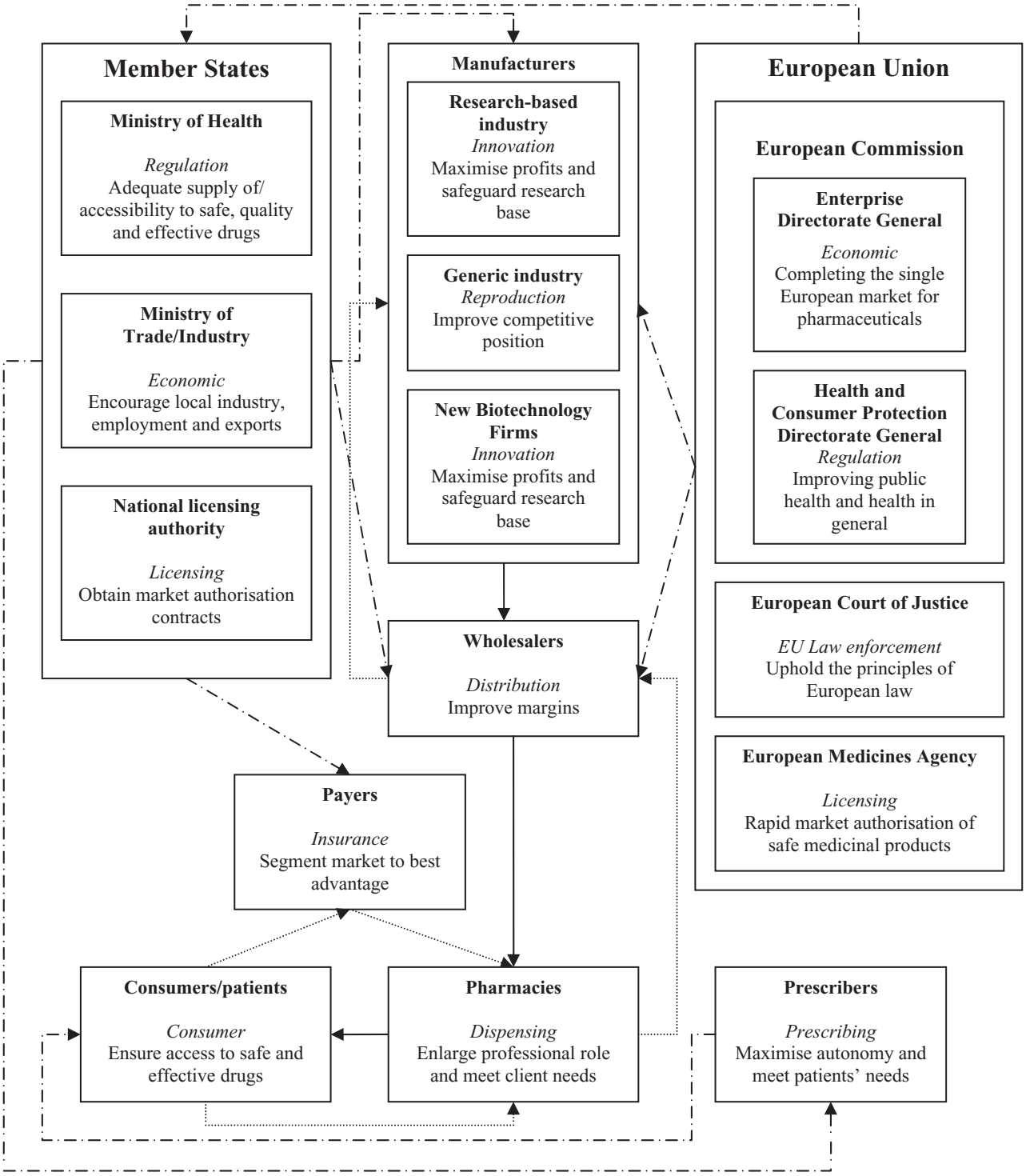

Figure 1 Stakeholders in the European pharmaceutical market: functions and policy objectives. Based on [22,23]. (⋯▸) Money; (⟶) Service/ medicine; (⋯▸) Influence.

becoming 'the most competitive and dynamic knowledge-driven economy by 2010', a major goal of the Lisbon Treaty. These goals have already proved to be too ambitious and were revised through the 2005 Partnership for Growth and Jobs.[5]

This paper examines the most likely directions for future pharmaceutical policy in the EU and whether this future will result in greater European influence or a strengthened national influence. Lastly, it discusses what this future may look like in more concrete terms.

Methods

Key issues of European pharmaceutical policy were selected using information from a literature review. These include authorisation, pharmacovigilance, classification, distribution, advertising, pricing, dispensing, prescribing, post-licensing evaluation and reimbursement. A Delphi questionnaire was then developed in which European experts were asked whether they expect these issues to be regulated and implemented at the national or European level in the future.

The Delphi technique

The Delphi technique is a procedure aimed at obtaining a reliable consensus of opinion from a group of experts through a series of questionnaires interspersed with controlled feedback.[6] Full anonymity is maintained in this process and the range of the answers converges towards a 'correct' and final answer provided by the median scores. The Delphi technique was developed by Helmer, Dalkey and Gordon at the Rand Corporation at the beginning of the Cold War to forecast the impact of technology on warfare. Over the years, new applications have been developed, such as the Policy Delphi in the 1970s, which does not aim at reaching consensus but seeks to generate the strongest opposing views on the resolution of a major policy issue.[7] The Argument Delphi focuses on ongoing discussion and finding relevant arguments, rather than focusing on the output.[8] The Disaggregative Policy Delphi seeks to cluster quantitative expert or interest group responses into similar groups[9] and the Wideband Delphi involves more interaction and communication between experts. The Delphi technique was chosen because information and opinions are drawn from multiple experts. The main alternative was to host expert meetings between European experts using the Nominal Group Technique (NGT), a method similar to the Delphi technique; however, although final judgements are made in isolation,[10] the group discussion that is entailed leaves room for influence and bias. In addition, there is evidence that traditional group meetings are an inefficient and ineffective method of forecasting and decision-making.[11] A systematic review by Rowe and Wright[12] looked at several empirical studies that analyse the Delphi technique as a forecasting tool. They found that Delphi groups outperform statistical groups (by 12 studies to two, with two ties) and standard interaction groups (by five studies to one, with two ties). Moreover, the Delphi technique is an established procedure that has been extensively reviewed in various studies (e.g. [12–16]). A clear methodological limitation of a Delphi study, however, is the difficulty to repeat and duplicate a study using the same experts and timeframe. Yet, research has shown that a degree of reliability is possible using this technique (e.g. [17–19]). Furthermore, the validity of a Delphi study depends on the quality of its design as much as the nature of its panellists.[12] These concerns have been taken into account when designing the questionnaire described below. Finally, the uncertainty and complexity surrounding the course of European health policy warrants a scenario study.

Table 1 Categories of respondents

Category	Round 1	Round 2
Pharmaceutical industry (R&D)	7	5
Pharmaceutical industry (generic)		
Wholesaler	1	1
Pharmacist		
Insurer/payer (NHS, sickness fund)	1	1
National government/regulator	3	2
European Union	1	
Academic	20	14
Consumer organisation		
Other	8	4

The European pharmaceutical policy questionnaire

In the questionnaire, experts were asked on key issues of pharmaceutical policy in Europe, how they estimate today's situation (2006) and what they expect the situation to be in 2010, 2015 and 2025. The key variable in these issues ranged from fully national (1) via predominantly national (2), even, or 50/50 (3) and predominantly European (4) to fully European (5). An extra category was added that asked the experts what they believe would be the optimal distribution of competencies. The questionnaire demanded a very broad expertise, ranging from authorisation to pricing, on national and European pharmaceutical policy. Recruiting appropriate respondents was achieved through various sources such as academics (based on their academic record) and the membership directory of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR; see Table 1). After selecting the addressees, around 200 experts were approached and academics comprised the largest group. To achieve a high response rate, a very simple and short design with closed answering categories was constructed. Some key features of the final first round design included a section with 'category of respondents', a section for the expert estimations of the current situation to assess whether there was unacceptable divergence in their estimations, and lastly a section with a list of expertise questions with three answering categories (1 = fully, 2 = average, 3 = not at all) to enable an ex-post selection of experts. Questions included 'Would you consider yourself an expert in the field of European pharmaceutical policy, both on the European and national level?' and 'Are you familiar with the current state of the European pharmaceutical market, including its actors and recent developments?' and two more specific questions: 'Are you familiar with European Law with regard to European healthcare, in particular the European Commission's public health competences (as laid down in e.g. article 152 of the Treaty establishing the European Community)?' and 'Are you familiar with European case law, especially Kohll/Decker, Smits-Geraets/Peerbooms and Vanbraekel and its possible consequences?'. The two latter questions were included as European (case) law was indicated in the literature review as having a potential effect which could alter the future course of the European pharmaceutical market.

Conduct of the Delphi questionnaire

The questionnaire was sent by e-mail and respondents were invited to forward the questionnaire to colleagues. As a result

the questionnaire even penetrated institutions the e-mail addresses of which are not available to the public. The questionnaire opened in the e-mail message window, which aimed to excite curiosity and a spontaneous reply. Other options were discarded. For example, filling out the questionnaire online may be an elegant way to conduct a questionnaire and while it has advantages regarding the processing of the evoked data, the immediate visibility of the questionnaire through e-mail preponderated. The conduct of the Delphi rounds included sending reminders and extending deadlines. In the second round, only the addressees whose results were received and included in the first round were approached. Full anonymity of the addressees was explicitly guaranteed in both rounds.

Results

The first round yielded 41 usable, filled-out Delphi questionnaires. Some answers were disregarded due to illegibility and/or insufficient expertise. Of the 41 respondents selected from round one, 27 (66%) replied in round two. The respondents come from various backgrounds (see Table 1), the largest groups being academics, 'other' (e.g. consultants, organisation) and the pharmaceutical industry.

Looking at the median scores (Table 2, bold numbers), the questionnaire shows what can be interpreted as an extrapolation of current trends. The answers to the question 'Will the following issues predominantly be regulated and implemented at a European level or at a national level?' (see Table 2) can be divided in two main groups. First, in those fields where a shared competence between the EU and Member States already exists, the experts expect a shift towards European regulation; that is, scoring at least 3 or more on the Likert scale in 2025 (see Figure 2). Authorisation, pharmacovigilance, classification, distribution and advertising show a steady and gradual trend towards European regulation. Second, in those fields of the pharmaceutical market where the sphere of competence (which mainly stipulates from Article 152 of the Treaty establishing the European Community, which states that 'Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care'.) of the Member States is strongest, only a one-point shift towards Europe is expected. This concerns those parts of the European pharmaceutical market that overlap with national health systems (i.e. the regulation and implementation of issues concerning publicly covered healthcare services, including reimbursed medicines). Therefore, experts expect that pricing, dispensing, prescribing and reimbursement remain predominantly a national competence and just a slight increase in European regulation and implementation is expected.

One exception is post-licensing evaluation, which shows a jump of two points in favour of European regulation. Post-licensing evaluation (i.e. the use of comparative benefit and cost effectiveness studies when making reimbursement decisions) takes place within national health systems and is currently a competence of the Member States. Nevertheless, the experts expect this to develop from a solely national competence into a field with evenly spread responsibility.

Although the answers show convergence in the second round and a trend is visible, a consensus is not achieved for all issues. Interestingly, some very different views exist on how the 'today' situation should be interpreted. Advertising in particular, and classification to a lesser extent, show widely diverging views. Although 41% in the first round seem to think that advertising is a fully national field, the remainder believe it is predominantly national (19%), evenly spread (14%), predominantly European (22%), and even fully European (3%; one respondent, a clear outlier). The second round still shows disagreement and even more people now view advertising (54%) and classification (58%) as a fully national field. These scores are less convincing than other issues, where close to 90% (pricing dispensing and post-licensing evaluation) and even 100% (prescribing and reimbursement) exists.

The expert opinion

A significant amount of experts refrained from giving their opinions, especially in the first round. This may indicate that a question was difficult to answer. One possible explanation was provided by a respondent who stated under his or her comments section, 'my opinion depends on the content of the policy, not where it is promulgated, and so that is why I have not expressed any opinion in that column.' Although justified, one can still state, irrespective of the contents of the policy, whether it is better to regulate and implement pharmaceuticals on a national or a European level. Furthermore, the experts' expectations seem to resemble the experts' opinions on the desired situation. This could mean two things: (1) the experts approve of the development of the European pharmaceutical market and agree on its course or (2) they filled out the questionnaire to serve their own interests. Or, as one respondent stated in the comment section, 'I have the strong feeling that the "consensus" will depend on the interests of the responders and the mix of responders.' Although a respondent may have been biased, the likelihood of the respondent using the questionnaire to impact the future of the European pharmaceutical market seems slim, considering the questionnaire was anonymous and this study serves no official policy-making purpose.

Discussion

The experts assumed that authorisation will gradually shift from a field of equally shared competence to a solely European matter. Therefore, we expect that it will no longer be possible to authorise a pharmaceutical for just one national market. A first step may be the removal of the exclusively national authorisation procedure by 2015. The various national licensing agencies will then serve solely as subcontractors for the EMEA. Secondly, the decentralised authorisation procedure could be phased out completely by 2025 after a gradual process of shifting certain therapeutic groups towards the centralised procedure, as done before with biotechnology products and orphan drugs.

The experts expect that pharmacovigilance will become a predominantly European field. The main European instrument for pharmacovigilance is the Eudravigilance data-processing network that came into effect in 2001 and was modernised in November 2005 as a result of the pharmaceutical review. This network, in combination with the Clinical Trials Directive, seeks to harmonise and streamline the exchange of data between national licensing agencies, the EMEA and pharma-

Table 2 Delphi questionnaire results

Issue		Today (2006)		Expectation						Opinion	
				2010		2015		2025			
		Round 1 (%)	Round 2 (%)	Round 1 (%)	Round 2 (%)	Round 1 (%)	Round 2 (%)	Round 1 (%)	Round 2 (%)	Round 1 (%)	Round 2 (%)
Market authorisation (licensing)	1	08									
	2	23	31	10							
	3	**45**	**58**	**45**	**73**	20	12	05	04	09	04
	4	25	12	38	20	**50**	**73**	45	30	25	**48**
	5			08	08	30	15	**50**	**67**	**66**	48
		$n = 40$	$n = 26$	$n = 40$	$n = 26$	$n = 40$	$n = 26$	$n = 40$	$n = 27$	$n = 32$	$n = 25$
Pharmacovigilance (post-marketing surveillance)	1	18	08	08		05		05			
	2	**49**	**65**	15	23	05	08	03	04	06	
	3	28	27	**51**	**58**	33	35	23	11	22	12
	4	05		23	15	**44**	**50**	**44**	**59**	**25**	**40**
	5			03	04	13	08	26	26	47	48
		$n = 39$	$n = 26$	$n = 39$	$n = 26$	$n = 39$	$n = 26$	$n = 39$	$n = 27$	$n = 32$	$n = 25$
Classification: Rx (prescription only), over the counter	1	38	**58**	18	20	08	08	03	04	10	08
	2	**38**	27	**38**	**58**	21	31	21	22	13	17
	3	15	12	23	15	**31**	**46**	23	**37**	10	13
	4	05	04	15	04	26	12	**28**	22	**32**	**38**
	5	03		05	04	15	04	26	15	34	25
		$n = 39$	$n = 26$	$n = 39$	$n = 26$	$n = 39$	$n = 26$	$n = 39$	$n = 27$	$n = 31$	$n = 24$
Distribution (wholesaling)	1	41	31	15	12	03	04	03		03	
	2	**46**	**62**	**38**	**58**	**36**	31	26	22	19	17
	3	08	08	33	23	33	**50**	**31**	**30**	**35**	33
	4	05		13	04	26	12	26	41	23	**38**
	5				04	03	04	15	07	19	13
		$n = 39$	$n = 26$	$n = 39$	$n = 26$	$n = 39$	$n = 26$	$n = 39$	$n = 27$	$n = 31$	$n = 24$
Advertising: e.g. direct-to-consumer advertising	1	41	**54**	16	20	05	08	03	08	13	13
	2	**19**	15	**34**	**36**	18	32	16	15	17	30
	3	14	12	18	12	**29**	**28**	24	**31**	**23**	**09**
	4	22	15	26	28	26	20	**29**	27	13	17
	5	03	04	05	04	21	12	29	19	33	30
		$n = 37$	$n = 26$	$n = 38$	$n = 25$	$n = 38$	$n = 25$	$n = 38$	$n = 26$	$n = 30$	$n = 23$
Pricing: e.g. pricing and profit controls, reference pricing	1	**80**	**88**	**59**	**62**	34	35	20	26	26	32
	2	15	12	24	23	**37**	**38**	**35**	**37**	16	**20**
	3	05		07	15	12	20	18	19	**23**	20
	4			07		12	08	15	15	13	12
	5			02		05		13	04	23	16
		$n = 40$	$n = 26$	$n = 41$	$n = 26$	$n = 41$	$n = 26$	$n = 40$	$n = 27$	$n = 31$	$n = 25$
Dispensing (pharmacy level): e.g. generic substitution, remuneration	1	**85**	**92**	**66**	**73**	44	42	38	26	42	29
	2	10	08	27	28	**34**	**46**	**30**	**52**	**26**	**42**
	3	05		05		17	12	20	19	13	08
	4			02		02		10	04	10	08
	5					02		03		10	13
		$n = 40$	$n = 26$	$n = 41$	$n = 26$	$n = 41$	$n = 26$	$n = 40$	$n = 27$	$n = 31$	$n = 24$
Prescribing: e.g. prescribing guidelines, budgets	1	**90**	**100**	**61**	**85**	41	31	26	19	29	17
	2	10		32	15	**34**	**62**	**35**	**56**	**23**	29
	3			07		20	08	20	19	23	**29**
	4					05		15	07	16	13
	5							03		10	13
		$n = 40$	$n = 26$	$n = 41$	$n = 26$	$n = 41$	$n = 26$	$n = 40$	$n = 27$	$n = 31$	$n = 24$
Post-licensing evaluation (comparative benefit/cost effectiveness)	1	**73**	**88**	34	35	17	08	10	04	16	08
	2	23	12	**41**	**65**	29	42	25	30	13	13
	3	05		22		**39**	**50**	**33**	**37**	13	21
	4			02		07		25	26	**35**	**42**
	5					07		08	04	23	17
		$n = 40$	$n = 26$	$n = 41$	$n = 26$	$n = 41$	$n = 26$	$n = 40$	$n = 27$	$n = 31$	$n = 24$
Reimbursement: by public payers, i.e. scope of benefit catalogue (including positive/negative list)	1	**90**	**96**	**70**	**81**	43	50	28	26	32	25
	2	10	04	20	15	**38**	**38**	**45**	**44**	**28**	**42**
	3			10		15	08	13	19	22	17
	4				04	05	04	15	11	10	13
	5									06	04
		$n = 40$	$n = 26$	$n = 40$	$n = 26$	$n = 40$	$n = 26$	$n = 40$	$n = 27$	$n = 31$	$n = 24$

Will the following issues predominantly be *regulated* and *implemented* at a European level or at a national level? 1 = fully national, 2 = predominantly national, 3 = even or 50/50, 4 = predominantly European, 5 = fully European. Bold numbers represent the median.

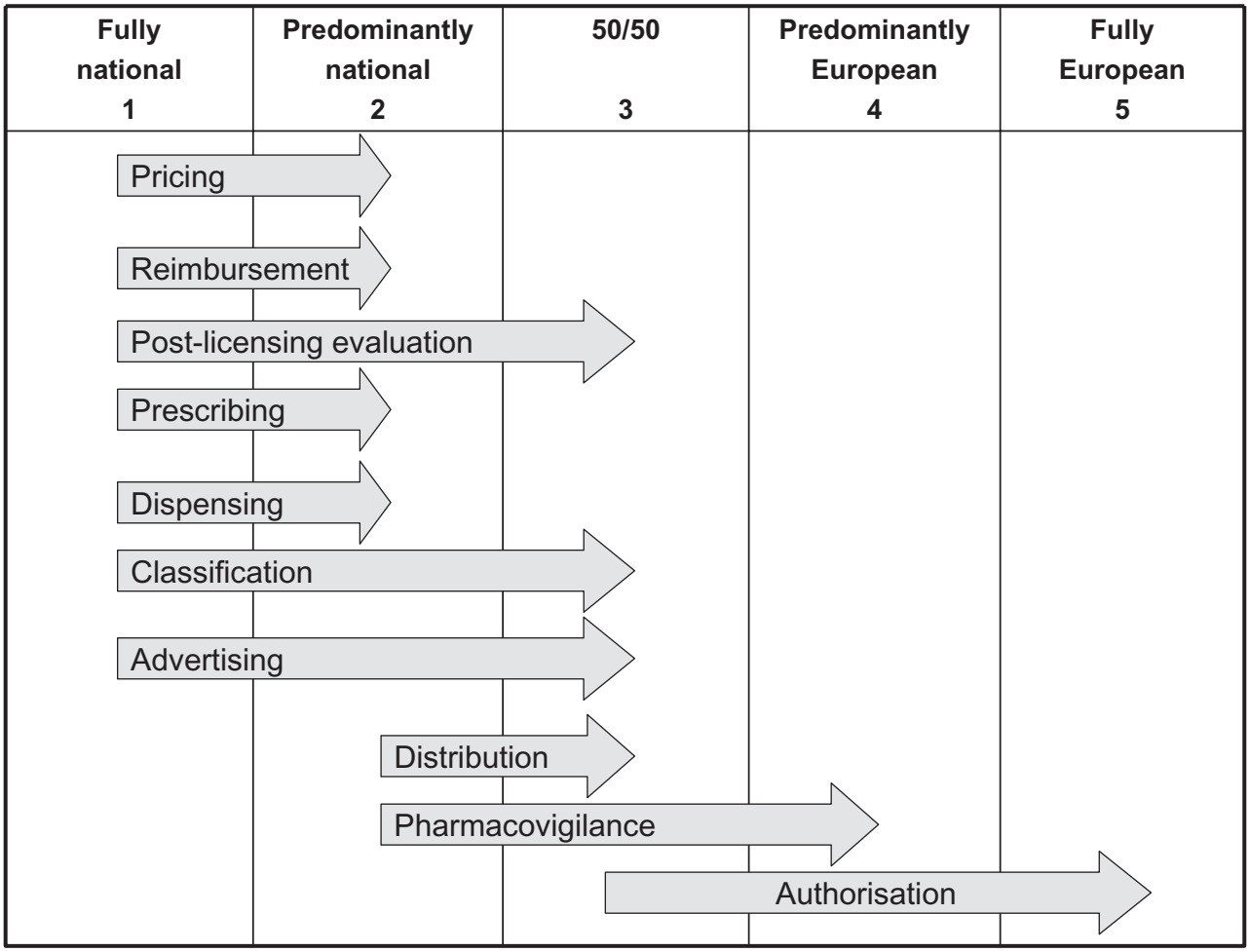

Figure 2 Expected shift in competence between 2006 and 2025 (rated 1–5).

ceutical companies. However, many different responsible authorities are involved and there are different procedures and responsibilities for products under the centralised and the decentralised authorisation procedures.[20] Therefore, the harmonising practice has so far been more successful for medicinal products licensed through the centralised procedure (CAPs), than for products licensed through the decentralised procedure. The European legal framework seeks to further harmonise regulation, pharmacovigilance practice, product information, and communication and cooperation between Member States. In short, we expect that the first development could be an equally shared competence between Member States and Europe in the next few years. The assumed abolishment of national authorisation and the decentralised procedure will also facilitate harmonisation and simplify the system. Therefore, all national pharmacovigilance systems may start working according to the same protocol and systems under the auspices of the EMEA, but national institutions will be left largely intact.

Title VI of the Community Code relating to medicinal products for human use[21] (hereafter referred to as the Community Code) outlines the criteria set to determine whether a pharmaceutical should be classified as a prescription-only medicine (POM) or an over-the-counter (OTC), non-prescription drug. However, these criteria have so far been applied nationally. National variations also exist as some countries split the OTC category into a pharmacy supervised list (P) and general sales list (GSL). Thus, one could say Member States have the upper hand in terms of regulation, which may have led respondents to view it as a solely national competence. Nevertheless, the European Commission regards a more flexible classification process, in particular where it concerns moving medicinal products from POM to OTC status, as essential for a competitive non-prescription market. These developments seem to support the experts' expectation that classification of medicines will develop into a field of shared competence between Member States and the EU. Therefore, we assume that the European Commission may try to use all its influence to implement the actions as proposed in the G10 recommendations. These recommendations include allowing the use of the same trademark for pharmaceuticals moved to non-prescription status and encouraging Member States to review their switching mechanisms. An amended classification directive could establish the categories POM, P and GSL on a European level. In other words, the directive follows the European trend by splitting up the OTC category.

It is, of course, hoped that this would make more drugs directly accessible to the public at lower level outlets, such as supermarkets. It also includes mechanisms for industry to apply for reclassification. This directive could further harmonise and thus Europeanise the European pharmaceutical market. However, the classification decision would still be applied nationally, but it can be expected that national differences in sale items will become less distinct.

The wholesaling sector will likely undergo further European harmonisation and liberalisation. The experts expect the sector to become predominantly European. Still very much nationally dominated, there is only one European directive that sets criteria that have to be met by wholesalers, such as adequate premises, qualified staff, and emergency plans for market withdrawal. These criteria, however, are enforced on a national level by very different national authorities, varying from federal states (Germany) to a national medicine agency (Finland) to a health inspectorate (The Netherlands). The first development could be more liberalisation across Europe through competition law. By enacting a regulation, the supervision of wholesaling a European matter will become the responsibility of the EMEA. The national competent authorities could then operate under the supervision of the EMEA.

Although there is a directive that prohibits public advertising of POMs, 54% of the experts rated it as a fully national field. This is a remarkable score bearing in mind that an advertising directive has existed since 1992 (now part of the Community Code) that prohibits direct-to-consumer advertising of prescription drugs. This can be explained by the fact that European countries had similar policies in place even prior to 1992. This may hamper the visibility and awareness of European involvement. Also, Member States decide on the methods they use for controlling pharmaceutical advertising and the penalties for violating the respective national framework. According to the survey, 31% of the experts expect that advertising will become an evenly shared competence and 27% expect it to become predominantly European. Therefore, we assume that due to an overall trend towards a more liberal European pharmaceutical market, more therapeutic groups could be open for direct consumer advertising, mainly as a result of the deregulated classification system. Greater harmonisation in the methods for controlling pharmaceutical advertising and penalty levels will then become more likely.

Regulation concerning dispensing pharmaceuticals to the public, pricing, prescribing and reimbursement mainly takes place within the national health system, where the competence largely lies at the national level. For this reason, it is consistent that the experts did not expect much European influence on the national regulatory frameworks even in the future. As Member States generally take more health policy-leaning perspectives, it can be expected that the emphasis remains on cost-containment, that more cost-containment measures will be adopted and that these cost-containment strategies will show more convergence. This would mean more stringent pricing regimes, increased use of generic substitution especially in immature generic markets, and rational prescribing, but also increased requirements for (and use of) economic evaluations (post-licensing evaluation). However, increased cooperation between countries will become apparent, which may be even supported or facilitated by the European Commission when it serves its public health goals or suits its market liberalisation agenda. Increasing the degree of generic penetration, for example, could contain pharmaceutical expenditure, but could also promote and facilitate a competitive European generic market.

The European Commission's limited competence in national systems does not mean that we assume Member States will keep full control over national pricing and reimbursement schemes. Some of the pricing and reimbursement schemes presently in force in Member States can have strong remit over the entire pharmaceutical market (i.e. outside the publicly funded national health systems). The European Commission can use its influence here to push through the G10 plan to pursue full competition for 'medicines neither purchased nor reimbursed by the state'. We assume that this will result in a competitive single European market for OTCs and other non-reimbursed medicines. The definition of what belongs to the national system (i.e. where national competence ends and where European competence begins) needs to be redefined over the next 20 years. Although Member States maintain full control of regulation concerning their healthcare budgets, restrictive pricing and dispensing can only apply to reimbursed pharmaceuticals.

Although post-licensing evaluation (clinical effectiveness and cost effectiveness studies) is growing in use and importance across Europe when making reimbursement decisions, the experts expect an even larger European role. However, it is unlikely that this would be instigated by the European Commission. The more industrial-policy leaning European Commission is more interested in opening up the markets and facilitating liberalisation than establishing more restrictive controls, let alone putting restrictions in place that could eventually block certain pharmaceutical products from being reimbursed in a certain Member Sate. Moreover, it is primarily a matter of national competence according to Article 152 of the Treaty establishing the European Community. Maybe the outcomes are not as contradictory as they first appeared, particularly if we assume that not all European initiatives have to come from the European Commission. Or, as one respondent rightly commented in the first round of the Delphi questionnaire, 'where you say "European" it does not necessarily mean European Commission, but it can be collaboration between the EU Member States.' Therefore, we expect Europe-wide economic evaluations to be initiated by national competent authorities (such as NICE in the UK and IQWIG in Germany) and even structural cooperation between such authorities. This cooperation will be increasingly possible since we assume that national cost-containment regulations and practices will show more convergence. In addition, many Member States, mainly Eastern European states, lack the technological and financial means to establish such agencies on their own and may be keen to collaborate. Furthermore, in their adoption of the G10 recommendations, the European Commission pleads for more exchange of national experience and more speed and transparency in the use of post-licensing evaluation. Their reasoning is that a patchwork of different national systems places a huge burden on industry and can delay access to the market. Hence, we expect that the European Commission will try to exert influence where it can, keeping in mind its limited competence, but with a different

policy perspective (faster and easier market access and reimbursement) than the Member States (cost-containment through rational use of efficient pharmaceuticals).

Conclusions

The results of the Delphi survey suggest that, after a relatively long standstill in the Europeanisation process, changes will become likely over the next decades. Although the European pharmaceutical framework with regard to, for example, authorisation, classification (although nationally implemented) and wholesaling will turn increasingly European, the Member States retain the regulatory overhand on vital decisions in their respective health systems. However, all national legislation that interferes with non-reimbursed medicines is likely to come under intensified European scrutiny. Furthermore, the regulatory framework for the pharmacy and wholesaling sector is expected to be liberalised over the next 20 years. Therefore, Member States should assess these frameworks to bring them more in line with European law. The expectation that apart from the non-reimbursed medicines markets also the generic market will increasingly be liberated should encourage Member States to assess their pricing policies in this regard to facilitate a competitive generic market. The expectation that post-licensing evaluation will be increasingly regulated and implemented on a European level does not necessarily take away the national competence to make own decisions. It makes sense for Member States to support collaboration in this field as it will help them carrying out this task more efficiently.

In brief, convergence as the result of Europeanisation of the pharmaceutical market reinforces the opportunities for (and in some cases necessitates) more European collaboration or regulation. National governments are well advised to support such collaborations and actively participate in the direction of future EU policy instead of resisting it.

Declarations

Acknowledgements

We would like to thank Katie Renaud for editing assistance.

Conflict of interest

The Author(s) declare(s) that they have no conflicts of interest to disclose.

Funding

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

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Note: all EU law, including treaties, legislation, case law and legislative proposals, referred to in this paper can be accessed at http://eur-lex.europa.eu/

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