



The Economics of Competition: A European Perspective

Lecturer: K. Hinde

Room: 403 Northumberland Building

Tel: +44 191 2273936

Email: kevin.hinde@unn.ac.uk

Personal Web Page: <http://www.kevinhinde.com/>

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Theme 2.

Regulatory Strategies and the Impact of the State

Chapter 3

An Introduction to theories of regulation by the state

3.1. Introduction

In this chapter the emphasis is on a critical appraisal of economic theories of regulation by the State. The chapter is brief because the issues emerge in subsequent case studies. In particular the issue of regulatory capture is raised in the chapter on the National Lottery. The debate about the geographical scope of regulation is illustrated in the case study on pharmaceutical product licensing (Chapter 5) and the issue of public choice and property rights (at the heart of the privatisation debate) is similarly dealt with in Chapter 7. It is also possible to get a good overview in Baldwin and Cave (1999, Chapter 3) and Baldwin et al (1999, Chapter 1)).

In this chapter you will be introduced to the following theories:

- Public Interest Theory
- Public choice and Private Interest Theories and
- A simple game theory explanation of why we need regulation.

3.2. What are the principle Economic explanations of Regulation?

□ Public Interest Theory

In this approach the regulator is seen as acting in pursuit of the public rather than private interests, e.g. where markets fail. The regulator was also seen to be trustworthy and a disinterested expert.

There are clearly difficulties in defining what the public interest is. Indeed, there is a concern that public interest outcomes fail to materialise. Some argue that institutions that begin life as political instruments continue as such, serving interests other than that of the public. This implies scepticism concerning the disinterested nature of regulators. Regulators are usually politicians or civil servants and critics argue that they have their own agendas.

There is also a regulatory capture problem that results in the regulator approving unwittingly of the regulatee's actions that are not perceived to be in the public interest.

Some authors see regulation as the product of relationships between different interest groups in society and that it is competition for power between these groups that provides the various forms of regulation.

□ Private Interest Theory and Public Choice

The main proponents of private interest theory are the Chicago school of economics, notably Stigler (1971) and Peltzman (1976). They stress the role of private economic interests in driving regulation. So where there is a failure of competition or there is a monopoly, then monopoly profit would result which the legislature has the power to redistribute. The regulated firm would then have the incentive to influence the regulator so that they could benefit from a 'regulatory rent'. A market for regulation would come into existence. The commodity of regulation would go to those who most valued it. Industry has the most to lose

and so lobbies the regulator intensely. Lawyers win at the expense of consumers as this process captures the regulator.

The assumption is that all actors are income maximisers (even politicians are seen to maximise their incomes from the electoral promises associated with regulation).

Public choice models, associated with the 'Virginian School', entail these wealth maximising assumptions but also other motives, including ideological, bureaucratic or social objectives. Thus, Niskanen (1971) emphasises the propensity of bureaucrats to maximise agency budgets. This type of argument has been at the heart of the debate as to why the government should run nationalised industries. This was supplemented by what has been called the 'Property Rights' school of thinking (see Wiseman, 1978) which suggested that state owned industries have a number of inherent faults. First, there is no direct interest in the yield from state assets because there are no shareholders (i.e. owners with property rights). Second, Ministers cannot exert sanctions (as in the private sector) by selling assets because of the political process. Third, there is difficulty in obtaining the appropriate capital requirements because expected future profitability information is regarded with some scepticism by capital markets. Fourth, management is less constrained in state owned industries in that poor management will not depress the capitalised value of the enterprise and tend not to be visible. Thus, state owned industries have inflated costs. In contrast, the argument goes, private sector managers are accountable to the capital market. Poor profits translate into poor share values and thus managers face the prospect of losing their job if takeover results.

Dunleavy (1991) notes how agents of regulation engage in 'bureau-shaping' to create job satisfaction. A good example of this is given in the paper by Shaw et al (1996) and referred to in Chapter 7. This paper showed how local government finance officers in the North East of England were quite prepared to re-shape their core business to suit key professional finance functions as the government desired more outsourcing of their departments. Though the policy was never carried through, Chief Finance Officers were quite willing to privatise 'ancillary functions' such as payroll and the Council tax (a local tax).

And Majone (1996) points out how regulators seek to maximise the scope of their political influence across activities and space

These approaches are assuming that

- There is no informational incompleteness in respect of the maximisation of utility or wealth.
- That civil servants and politicians and civil servants are altruistic and public spirited.
- That civil servants and politicians are accountable to parliamentary bodies and independent scrutinisers (e.g. the National Audit Office and the media).
- That civil servants can act in the public interest if appropriate incentive schemes are in place. This includes the existence of a competitive managerial labour market as well as remuneration packages.

What this suggests is that there is scope for state run activities and that regulation by the State may be necessary to achieve certain social and economic outcomes as we noted in chapter 1. To end this brief chapter we describe how the Prisoner's Dilemma game might be adopted to explain regulation. This will have relevance in later chapters.

3.3. Using Game Theory to explain regulation

A Classic Game: The Prisoner's Dilemma (Due to A.W. Tucker)

In this game 2 prisoners have been brought in for questioning by the police about a serious crime. The police have some information and so can make certain charges hold but they need to question the suspects if they are to get the whole picture. The police interview the suspects in separate rooms. The prisoners now find themselves in a dilemma. The game is shown in the matrix below. Both have two choices, to confess or not confess. The pay offs for prisoner 1 are shown in the right of the bracket and those for prisoner 2 on the left. They are negative to reflect years in prison.

The game assumes that both players maximise their payoffs. The game involves complete but imperfect information. Each player knows the payoffs but is unsure (in this 'one-shot' game) as to the choice the other will make. This is the dilemma. Prisoner 1 and 2 both know that the optimal outcome is not to confess but can either be assured that the other will cooperate with this strategy. Take prisoner 1. They know that if they cooperate prisoner 2 might defect. They would then get 10 years in prison whilst their co-accused would get a very lenient sentence (6 months). Similar rationality will prevail for Prisoner 2. Given this they both end up confessing.

		PRISONER 2	
		Confession	No Confession
PRISONER 1	Confession	(-5, -5)	(-0.5, -10)
	No Confession	(-10, -0.5)	(-1, -1)

The outcome is known as a Nash equilibrium: each player does their best given what they assume the other(s) is (are) doing. Named after the mathematician, John Nash, who discovered the concept in the late 1940s, this is a stable, self-enforcing and generalised equilibrium concept in Game theory.

There are implications here for the process of regulation. Substitute 'Prisoner 1' and 'Prisoner 2' for 'Firm 1' and 'Firm 2' and change the strategies to 'Low Price' 'High Price' and change the payoffs (this time measured in millions of £s profit) as shown in the figure below. Again, the outcome would be the Nash Equilibrium Low Price, Low Price. This would be good for society as it means competition prevails.

		FIRM 2	
		Low Price	High Price
FIRM 1	Low Price	(2, 2)	(4, 0)
	High Price	(0, 4)	(3, 3)

Alter the payoff to (1, 1) by imposing fines of £2m each on the cartel

However, one of the outcomes of this general game is that when the game is played over many time periods' cartels can develop. Both players optimise their payoffs in the bottom right hand quadrant.

The presence of a regulator with the power to alter the payoff from forming a cartel, say by imposing a fine in excess of £1 million for cartel formation would ensure that competition always prevailed. Society would then be better off and so would the firms. But remember the cost of regulation should not exceed its benefits.

Reading

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Chapter 4

Competition Issues and the Regulation of the National Lottery

This is a paper by me published in the Review of Policy Issues, Winter 1997. There is a brief update that includes recent developments at the end of the chapter.

Aims

- ❑ To utilise and develop existing theoretical work by examining the case of the UK National Lottery.
- ❑ To draw parallels with the privatisation and regulation of public utilities

Objectives

You will

- ❑ be able to provide information on the institutional characteristics of the National Lottery.
- ❑ identify and explain the actual and potential bidding schemes associated with the establishment of the National Lottery.
- ❑ explain the competition issues associated with the regulatory process.

Further Activities

- ❑ Test whether you can fulfil the objectives set out above.
- ❑ Go to the eLearning platform and consider the web activity associated with this case study.

Abstract

This paper examines the supply of the National Lottery with a specific focus on the role of the regulator, OFLOT. The question addressed is how can the current regulatory process be improved to allow greater distance between the regulator and the operator, Camelot? This question arises because the regulator was a prime mover in determining how the operator was chosen as well as regulating its activities. Moreover, subsequent events have shown that anti-competitive tensions prevail. Parallels are drawn with public utility regulation because Camelot owns and controls a large network. The solution lies in providing the regulator with greater competition powers as in the public utility case. Further, when the licence comes up for renewal serious re-consideration must be given to the strongly vertically integrated structure.

4.1. Introduction

The revenue raising potential of the UK's National Lottery (NL) has surpassed expectations. Since its launch on 14th November 1994 the opportunity to win a fortune and help a worthwhile venture has struck at the very heart of the British psyche. Nearly 30 million people regularly play the NL each week, spending about £68 million on the weekly on-line draw and £20 million on scratch cards making it the "largest lottery in the world" (1). In 1995 around £5 billion was realised from ticket sales: 50% of this is returned in prize money; 28% goes to the

National Lottery Distribution Fund which is then allocated to "Good Causes"; 12% goes to the Treasury in tax; and the remaining 10% is split equally by the retailer and Camelot plc, the operator.

Much that has emerged so far about the NL has concerned the demand side. Expenditure on the lottery exceeds that of spending on consumer items such as newspapers, magazines and confectionery. It has also displaced expenditure from traditional sources. For example, some charities have noted problems with fund raising; pools operators have faced direct competition in the long-odds gambling market and jobs have been subsequently lost; betting on greyhound racing has fallen dramatically because the NL taps deeply into its customer base; small retailers who do not sell NL tickets have found falling sales whilst those who do state that customers become more aware of the other products sold in the outlet (2). However, little has been written about supply side issues. This paper redresses the imbalance by showing that whilst the NL has been successful in selling tickets there are still public policy concerns about the institutional arrangements that need to be examined. One particular question is addressed: How can the regulatory process be reformed to ensure greater distance between the regulator and operator? This issue arises partly because of the 'two hats' worn by the regulator, that involved in choosing the operator and then regulating them. It also arises because of the monopolistic position achieved by the successful bidder and subsequent developments. The solution, it is argued, lies in stronger regulation, particularly in respect of competition powers, as well as a re-consideration of the future industrial structure of the NL. Some might argue that the regulation of the NL is more rigorous than that generally applied in the gaming market. However, the creation of the NL offers the monopoly right of supply across a national network, drawing more parallels with the privatisation of public utilities in the UK. It is in this context that the regulation of the NL must be compared. Thus, the NL is a case study of monopoly and regulation set against the background of the privatisation debate.

4.2. Institutional Framework

The explicit aims of the new NL, as set out in the 1992 White paper and enshrined in the 1993 National Lottery Act, are the protection of player's interests and maximisation of revenues going to the National Lottery Distribution Fund (NLDF) so that 'Good Causes'- sport, art, national heritage, charity and millennium projects - can be supported. In establishing a NL the government created a new institutional framework. Mechanisms had to be instigated so that money could be re-directed from ticket sales toward worthy capital projects. Arrangements had to be made so that a private operator could supply the lottery. Finally, a body was required to regulate the operator and protect the consumer.

4.2.1. Quangos

To re-direct funds new 'quangos' have been created - The National Lotteries Charities Board, The National Heritage Memorial Fund and The Millennium Commission. These each receive 20% of the NLDF. Existing non-departmental public bodies such as the various national Sports and Arts Councils receive the remaining 40%. The most positive aspect of the 'quango' is that appointees usually bring with them qualified expertise. However, questions about accountability and independence are often to the fore (3). Whilst in theory such bodies answer to Ministers, and thus to Parliament, in practice the strategic and operational decisions of such bodies are made privately so that the link to democratic accountability is tenuous. It is also suggested that many appointments to boards occur through ministerial patronage and that a web of appointees has developed with similar political and cultural views. A specific issue in relation to the NL quangos is whether they have acted equitably in distributing funds. Large sums have been spent on projects deemed of 'national importance' but which many argue only serve a small portion of the population. There is a clear spatial maldistribution across the regions that may partly reflect this (4). Citizens of London spend, on average, £1.10 per week on the lottery and get back almost £0.70 for every pound spent which when added to the £0.50 handed back in prize money makes London the largest net gainer from the NL. At the other end of the scale, the East Midlands spends £1.38 per head each week on the lottery but only receives about £0.09 for every pound spent on NL tickets.

4.2.2. *Private Ownership and Regulation*

The White Paper and Act emphasised the importance of a national lottery being supplied by a private concern; a unique characteristic when compared alongside similar European lotteries. The emphasis on the private sector controlling the NL is very much at the heart of the Conservative Party's position on public expenditure and state ownership. The Government has recognised the need for large-scale capital projects in hitherto neglected areas but has de-emphasised the State's role in providing them. Raising revenues for capital projects via traditional taxation mechanisms is considered inappropriate given the possible 'crowding out' effects created by the burgeoning state sector. A privately owned and controlled NL in which individuals are free to choose whether they want to buy a lottery ticket is considered philosophically sound and fiscally prudent. The Treasury have, to date, assumed the NL to be 'revenue neutral', i.e. the fiscal revenues raised from ticket sales offsets the loss of indirect tax from expenditure displaced, but predicted that the Public Sector Borrowing Requirement will be reduced by several hundred million pounds in each year to 2001 (5). This is due initially to the lag between income and expenditure on the NLDF: money realised has not been spent yet. Over the medium term the exchequer forecasts gains mostly because the tax inflows from employment in 'worthy causes' will exceed the tax foregone from jobs lost in sectors affected by expenditure displacement.

The more specific argument for a privately operated NL embraces Public Choice and Property Rights theory (6). Thus, any state run enterprise will be subjected to productive inefficiencies because those who manage or control them act to fulfil their own rather than the public interest; only private ownership brings effective accountability so the argument goes. The underlying assumption is that the capital market is perfect and that the transfer of shares can eradicate inefficiencies. The privatisation programme has emphasised the need for wider share ownership to encourage this end. Sales of public sector assets to private bidders, via management buy-outs and direct sales, were limited to small-scale entities or single companies who traded on the stock market. However, the NL is large-scale project, as the opening paragraph shows, and all the bidders were consortia. No one could buy shares directly in any of the bidding organisations and so efficiency could, at best, only be weakly guaranteed by shareholders from one of the contributing firms.

As the provider of the NL would obtain a monopolistic position in supplying the NL, regulation was required. Like other public utility privatisations the government created a regulator - the Office of the National Lottery (OFLOT) - headed by a Director General (DG). However, unlike previous privatisations, which involved a transfer of an existing business from the private to the public sector, this was a new venture. The Government therefore placed an additional responsibility on OFLOT, that of choosing the operator as well as regulating its activities. This 'twin-hatted' role of the regulator raises questions about the current regulatory framework, particularly the prevention of possible anti-competitive practices. To understand regulation of the operational phase of the NL it is necessary to examine the bidding scheme. As well as providing important background information about the bidders and the bidding method adopted it has a direct bearing on the resulting structure of the industry.

4.3. **Bidding for the Lottery**

The DG of the NL invited bids in late 1993 for a Section 5 licence from private commercial organisations deemed 'fit and proper'. The winner would have sole control over the technical, retailing and marketing infrastructure of the lottery. Infrastructure bidders were also required to submit details of the 'on-line' and scratch card games that would be played and for these a Section 6 licences would be granted. There were 10 initial bids though only 7 met the initial application requirements and so subjected to the complex evaluation procedure undertaken within the DG's office. Applicants were asked to submit bids showing the present value of expected total revenue and revenue retention at alternative revenue scenarios. Adjustments, based upon independent econometric forecasts and surveys, were made to account for variations in voluntary contributions to the NLDF, launch dates, the number of proposed retail outlets involved, prize payouts, jackpot size and rollover frequency as well as intended marketing and advertising expenditures.

Table 4.1, taken from the National Audit Office enquiry into the bidding process (7), shows how the various bidders fared. Camelot plc offered the highest contribution to the NLDF by a significant margin; it planned to use some 27,000 outlets compared with its nearest rival, LotCo plc, who proposed 19,000 outlets; and it offered the lowest operator retention over most revenue scenarios. Even where alternative assumptions were made about *this* bidding method, the National Audit Office concluded, that "the differences fall within the normal range of variation in professional judgement and, more important, would not influence the outcome of the process, i.e. the choice of the successful applicant" (8). Camelot plc, a consortium made up of Cadbury Schweppes, De La Rue, GTech, ICL and Racal, was awarded a section 5 Licence to develop and manage the infrastructure of the NL in July 1994. This licence terminates on 30 September 2001. Camelot was also awarded a Section 6 licence until 31 December 1997 to run an on-line game. Further Section 6 licences have been subsequently granted to Camelot to run Instant scratch card games, the first launched in March 1995.

The application process for the NL was unusual in that it did not involve a bid indicating a price applicants would be willing to pay for the monopoly rights of supply. The theory of Chadwick-Demsetz auctions explains that such bidding schemes should leave the winner only earning a normal rate of return and similarly maximise the gain for the contract seller (9). The granting of independent television and radio franchises, for example, have involved 'sealed' bids with the winner offering the highest price to provide the service. This method was subject to criticism at the time as the number of bidders for some licences was small; there was only one bidder for Central TV network, for example. When the number of likely bidders is small an 'open-bidding' scheme is preferable. McMillan, for example, shows that since the Moscow Olympics in 1980 the Olympic organisers have maximised their return from the sale of exclusive television rights of Olympic coverage by informing the 3 major U.S. television networks of each others bid (10).

However, the regulator argued that a fee-based approach was inappropriate. In the invitation to bid phase there was great uncertainty as to the UK's propensity to purchase lottery tickets. It was argued that the additional burden of a fee would reduce the number of bidders and not necessarily maximise the returns for the NLDF. The DG instead preferred a "risk sharing" approach. If ticket sales were below expectation then a fixed licence fee would not create any further pressures on the operator. If ticket sales were greater than expected then economies of scale would allow applicants to offer higher proportions to the NLDF when submitting their bids. The evaluation of the NL by the National Audit Office considered the application procedure for the method used as "a sound approach" (11). However, it did not consider whether other bidding schemes would have offered greater returns to the NLDF in the longer term. Subsequent events have shown that Camelot has made profits in excess of what theory would constitute as 'normal'. Whilst an increase in ticket sales produces increases in amounts to 'Good Causes', a fee based approach with an appropriate sliding scale to accommodate the vagaries of sales, may have committed more to the NLDF rather than Camelot. This type of scheme is used, for example, to award television contracts for coverage of the Olympics, with fees increasing as advertising revenue rises.

The legacy of the bidding scheme has raised some controversy because the operator has made some unanticipated gains. The National Audit Office recently showed that interest accrued to Camelot in ways that were not specified in its initial bid (12). The sum involved totalled around £7 million in the year ended 31 March 1996. Around £6 million reflects the degree to which Camelot has fallen short of its Section 5 licence target to pay a specified level of prizes. This undistributed prize money is calculated on an annual basis and then paid in to the NLDF, in the interim Camelot can make financial gain from the shortfall. The rest of the 'unspecified' interest earned by Camelot resulted largely from the timing of its payments of advanced ticket sales into The Player's Trust, an intermediate institution which handles prize money payouts and payments to the NLDF, and established in the event of Camelot's financial collapse.

The National Heritage Committee (NHC) recommended that Camelot should pay interest earned on the prize shortfall into the NLDF (13). However, a retrospective re-negotiation of the Section 5 licence to incorporate changes in payments to the NLDF is unlikely at present. First, any changes to the Section 5 licence would require Camelot's consent, which seems

unlikely, and this may lead to the possibility of other parts of the licence being re-negotiated. Second, the DG and the Government argue there is no guarantee that 'Good Causes' would benefit from any change (14). This may be so but, if the process of regulation is to work properly, players should be the recipients of unanticipated benefits not Camelot. The lessons from this and other bidding schemes must be incorporated into the Section 5 licence renewal.

4.4. Competition and the regulatory framework

An important issue is whether the regulatory framework is sufficiently effective to protect players interests and maximise revenues for the NLDF. The NHC considered that these twin duties may be compromised because of OFLOT's unique position of choosing the operator and then regulating it. Thus, having chosen the operator they might act so as to justify their choice at the regulation phase. The NHC recommended that the Government separate these two functions before the licence comes up for renewal and in reply the Government stated that it would be considering this (15). However, this is not likely to occur until the next millennium. So the issue of 'regulatory capture' remains.

One way of addressing this in the interim would be to allow independent assessment of the whole regulatory process. The National Audit Office went to great lengths to explain that its powers under the National Audit Act of 1983 did not permit it to examine Camelot's financial records, quoting the Public Accounts Committee recommendation that it do so and the Treasury's rejection of such a proposal (16). The tone of the National Audit Office report in this respect was one of frustration in that they could only verify the efficiency and security of payments to the NLDF via OFLOT and that Camelot's role in this process could only be assessed indirectly, i.e. via information they gave to the regulator. Thus, independent evaluation of the regulatory process was based, to some degree, on the trust between Camelot and OFLOT rather than hard facts.

Another (possibly complimentary) method would be to increase the regulator's powers, particularly with respect to competition. OFLOT's current powers are rather limited in scope. Under Section 9 and Section 10 of the Act OFLOT can take out a high court injunction to prevent a breach or revoke a licence. To date though only warnings have been issued for technical breaches and sales to under 16s.

OFLOT has no specific authority to promote competition, unlike the regulators of public utilities. However, OFLOT was a prime-mover in the design of the bidding scheme and so shaped the resulting industry structure. Crucially, the 1993 Act does not pre-suppose that a Section 5 and Section 6 licensee are one and the same organisation (17). So, by combining the licence to run games with ownership of the network at the bidding stage OFLOT has facilitated a strict vertically integrated structure for the on-line game and vertical integration with the possibility of network access on scratch card games.

Competition in the networked scratch card market has not yet occurred though substantial spare capacity via such a computerised system would not seem unrealistic. The Director General of OFLOT states that he has made numerous approaches to potential Section 6 licensees but that the margins available are probably insufficient to attract entry into the scratch card market (18). Further, he argues that Camelot complies with all information requests and that the very existence of the NL has stimulated the scratch card market in general (19). However, it is also the case that any Section 6 licensee has to be in accordance with a Section 5 licensee. "The Act does not empower the Director General to impose a Section 6 licensee on an unwilling Section 5 licence holder" (20). Thus, the power to deter entry exists and the current regulatory framework would offer only weak resistance should it be tested.

The opportunity to currently exercise monopoly power in a weakly regulated, vertically integrated, market is further underlined by Camelot's control over retail outlets in the running of both games. Shop owners have complained that Camelot's selection procedures have been arbitrary and unfair. OFLOT, however, has no statutory responsibility in respect of retailer choice. In response, the National Heritage Committee recommended "that, since Camelot has a monopoly in the choice of outlets, OFLOT should be given the responsibility to

ensure that decisions on granting and refusing lottery terminals are made in a fair and open manner" (21). Such a proposal would put it in line with the Irish Republic's lottery regulator but it was a recommendation the Government does not wish to implement (22).

Camelot won the monopoly rights to supply the on-line game and have become a dominant firm in the scratch card market because of their exclusive use of a national network. For the year ended March 1996 they declared after-tax profit of £51.1 million (23). Camelot presents this by stating that after-tax profit is slightly less than 1.5 % of every ticket sold. An alternative view, based on the statutory distribution of the proceeds realised, is that this represents almost 30% of Camelot's retention from every ticket sold. The NHC recommended that Camelot "giv[e] a suitable proportion of their additional, unanticipated, profits to charity" (24) as one way of alleviating public concern about the monopolistic position acquired by Camelot. The government though will not change the regulatory framework; profits will not be regulated and Camelot can make its own decisions about charitable donations (25).

Competition regulations have no place in the current regulatory regime. The belief is that by allowing Camelot to maximise its profits returns for 'Good Causes' will be similarly maximised. But, competition and maximisation of the NLDF are not mutually exclusive. Competition does not mean zero profits, rather a 'normal' rate of return. Presently, Camelot's profits are excessive, hence the NHC's call for an increase in charitable donations. Addressing these sorts of competition issues before the licence is renewed, perhaps by allowing each side to refer issues to the Monopolies and Mergers Commission as is the case with some public utility regulation, would protect players and the NLDF as well as providing further distance between the regulator and operator.

To address the regulatory capture issue over the longer term the Government will have to consider the case for vertically separating the NL in the licence renewal phase. Not to do so would leave Camelot with unassailable monopolistic advantages. When the Section 5 licence is due for renewal in 2001 Camelot will have had 7 years experience in running the lottery and will still have a substantial and viable, mainly sunk, infrastructure. These two factors are likely to deter rivals from bidding. If a rival were to make a higher bid than Camelot then it may face the 'Winner's Curse', i.e. paying a price that makes the running of the lottery unprofitable. Camelot's experience may provide it with the opportunity to exploit this fear. In addition, it makes sense from society's viewpoint not to duplicate scarce resources but there is a valuation dilemma. If any rival were to win they would have to satisfy themselves they were obtaining a fair price for any assets transferred. A bilateral monopoly problem exists and there is no equilibrium point in respect of price. If Camelot had no alternative use for the assets it would accept their scrap value whilst if a rival had no alternative source it would pay as much as their replacement value. This difference in possible asset valuation requires hard bargaining that may not be possible before the bids have to be submitted. The existence of these potential bargaining costs may therefore act as a deterrent to any rival bid (26). Thus, OFLOT must consider methods to encourage rival bids for the Section 5 Licence. This may require some drastic action. The State or an independent private firm (perhaps Camelot) could control the sunk cost element and there could then be competition for network use. Any transfer of assets would naturally require an arbitration framework to overcome valuation differences. Further, in separating both functions the Government would also have to ensure independent regulation of both sectors.

That there is no divorce between network ownership and network use is very much against the trend in respect of public utility privatisation. For example, in the recent privatisation of the railways the Government created a company called Railtrack that manages the national network of lines, signals, stations and earthworks (tunnels and bridges). It then allowed competition for the railway market by franchising routes and timetables. By vertically separating the industry and providing independent regulation over both aspects of railway provision the Government hopes to avoid monopoly pricing and strategic entry deterrence. The principle of policy consistency suggests there would seem a case for vertically disintegrating the NL when the licence is renewed. On the other hand, an assessment of the costs and benefits of alternative industry structures may suggest that the present strongly vertically integrated framework should remain. If this is so then the Government should ensure that sunk cost elements are excluded from bids at the licence renewal stage. An

arbitration process will have to remain for the possibility of asset transfer and stronger competition regulations put in place. Whether such arrangements would create 'a level playing field' and foster competitive bidding at the licence renewal phase is a moot point. However, at the very least, it would signal to the general public that the regulator was distancing themselves even further from the operator.

4.5. Update

The UK National Lottery is an interesting case of a real monopoly established by Statute in 1993. Over the course of the running of the lottery events have changed the regulatory process. Today we have a National Lottery Commission. Prior to this, circa 1994 to 1998, we had a Director General. The prevailing argument was that by allowing a panel to oversee the lottery rather than one individual 'regulatory capture' would be avoided. Of course the lottery license came up for renewal in 2001 and The People's Lottery' lost out to Camelot in rather awkward circumstances.

The second change that has occurred since the inception of the lottery is that of the expansion of the funding to include health and education projects in the list of 'worthy causes'. This change occurred in 1997 when the Labour government came into office, and was implemented in the 1998 National Lottery Act. There was considerable debate as to whether the lottery should displace government expenditure in 1993 but the conservative government noted that the lottery was for additional funding – 'good causes' that would not be financed otherwise through taxation. Unsurprisingly, this policy change has given rise to the charge that lottery funding is replacing general public expenditure in health and education.

The final important change arose at the end of the first lottery license. Camelot won the right to run the lottery from 1994 and put in place an infrastructure of machines in retail outlets, telecommunication linkages and massive computer databases. With such a sunk cost theory predicts that there is unlikely to be any new bidders for the second round unless there was some mechanism for transferring the assets from Camelot to any potentially successful bid. A bilateral monopoly problem results in determining the price of assets to be transferred. The alternative is that all bidders for the new license require new games and infrastructure. This is, in fact, what the National Lottery Commission chose to do. However, it is interesting to note that there were only 2 firms (consortiums) bidding for the second lottery license, Camelot and The People's Lottery. Why so few? Again, theory predicts that potential bidders may be deterred by the possibility of the 'Winners Curse'. That is, the inexperienced winner of a bid believes that it has paid too much for the license.

4.6. Conclusions

The lottery has been successful in generating sales but there are still policy concerns on the supply-side that need addressing. The particular focus of this paper has been whether the regulatory process is sufficiently rigorous to avoid the possible charge of regulatory capture. Concern has emerged over the twin-hatted role of the regulator, OFLOT, who chose and regulates the operator. This has been exacerbated by the monopolistic position of the operator, Camelot, and by some of its practices. One way of providing greater distance between the regulator and operator is by allowing the former to have powers to prevent anti-competitive behaviour. Competitive outcomes from the NL currently require altruistic behaviour on the part of the operator. There are few incentives to abstain from anti-competitive practices. The capital market cannot guarantee productive efficiency from a consortium in which shares can only be purchased indirectly. Allocative efficiency is unlikely if the regulatory framework is impotent to deal with abuses on a network or satisfactorily transfer substantial sunk costs at the end of the licence. And both forms of inefficiency are probable if regulatory capture is present.

This paper has further argued that, when the Section 5 licence is due for renewal, there will have to be an arbitration process available to overcome asset valuation problems in the event of the transfer of the substantial sunk costs. This will permit greater competition in future bids for the Section 5 licence and signal to the general public that there is substantial distance

between the regulator and operator. By not addressing competition from the outset the NL has developed a strongly vertically integrated industrial structure, a structure spurned in recent privatisations. Thus, there may well need to be vertical separation of network ownership and use at the licence renewal stage.

The powers of the regulator have to be much more like that provided for in public utility regulation. Although gambling and public utility products are very different, the scale of this national, largely addictive, game is such that it can be treated as a necessity good. The regulators of the public utilities have relatively strong powers and there is clear distance between them and the operators. There is also clear recognition that the regulation framework should act as a safety net, to be there if things go wrong. The NL net needs to be stronger and wider than is currently the case.

Notes and Reading

1. The information contained in this paragraph comes from 2 sources: H.M. Treasury (1996) *Economic Briefing*, no. 9, HMSO, London, and from the internet address <http://www.connect.org.uk/lottery>. The quotation is from the Treasury.
2. National Heritage Committee (1996) *Second Report. National Lottery, minutes of evidence*, Volume 2, House of Commons Paper 240 ii-ix, Session 1995-96, HMSO, London.
3. Mulgan G (1994) Democratic Dismissal, Competition, and Contestability among the Quangos, *Oxford Review of Economic Policy*, vol. 10 no.3, pp 51 -60.
4. The information taken for the statistics that follow comes from The Observer, *London never a Lottery loser*, 28 July 1996, p 5.
5. National Heritage Committee (1996) *ibid* volume 2 vi, pp 195-205.
6. There are innumerable references on this issue but as a useful overview in the context of the privatisation debate see Parker D (1991) Privatisation ten years on: a critical analysis of its rationale and results. *Economics*. Vol xxvii, 4, no, 116, pp 154-163.
7. National Audit Office (1995) *Evaluating the Applications to Run the National Lottery*, House of Commons Paper 569, Session 1994-95, 7 July, HMSO, London.
8. *ibid* p 31.
9. See for example Schotter A (1994) *Microeconomics: A Modern Approach*, Harper Collins, New York, Chapter 7.
10. McMillan J (1992) *Games, Strategies and Managers. How managers can use game theory to make better business decisions*, Oxford University Press, Oxford, chapter 11.
11. National Audit Office (1995) *ibid* p 21.
12. National Audit Office (1996) *Payments to the National Lottery Distribution Fund*, Report by the Comptroller and Auditor General, House of Commons Paper 678, Session 1995-1996, HMSO, London, pp 48-50.
13. National Heritage Committee (1996a) *First Special Report. The National Lottery. Government Response to the Second Report from the National Heritage Committee*, House of Commons Papers 58, Session 1995-96. p iii.
14. See footnotes 12 and 13.

15. National Heritage Committee (1996) *ibid* Vol 1 p x. and National Heritage Committee (1996a) *ibid* p iv.
16. National Audit Office (1996) *ibid* pp 8 - 12.
17. National Audit Office (1995) *ibid* p. 4. The technical reason for this agreement is that Section 5 of the 1993 Act requires the licence holder to recover sums due to good causes from the Section 6 licence holder. See National Heritage Committee (1996) *ibid* Vol 2iii, pp 69-70.
18. National Heritage Committee (1996) *ibid* p 70.
19. Director General of the National Lottery (1996) *Annual Report 1995/96*, House of Commons Paper 540. Session 1995/96. HMSO. London.
20. National Audit Office (1995) *ibid* p 4.
21. National Heritage Committee (1996) *ibid* Vol. 1 p xi.
22. National Heritage Committee (1996a) *ibid* p iv.
23. See Financial Times 9th June 1996, p 28.
24. National Heritage Committee (1996) *ibid* Vol 1 p x.
25. National Heritage Committee (1996a) *ibid* p iv.
26. See Armstrong M, Cowan S & Vickers J (1994) *Regulatory Reform. Economic Analysis and British Experience*. MIT Press, London

Table 4.1**National Audit Office Calculation of contribution to Distribution Fund over the life of the licence**

	Lot Co plc	Camelot plc	The Lottery (RT) Ltd	UK Lotteries Ltd	The Enterprise Lottery Co Ltd	GBLC plc	Games for Good Causes plc
Raw Contribution	6,305	6,229	6,132	5,997	5,979	5,714	4,959
Profit Donation			61		118		
Escrow Account		55					
Launch Date	(38)		(117)	(30)	30	34	50
Retail Density	252	747	(1349 to 675)	180	60	(171)	(149)
Prize Payout	(315)	436	(491)	(480)	60	(229)	843
Lotto Game Structure	(63)	(125)	123 to 1594	60 to 480	-	(457)	(248)
Marketing Spend	(63)	(498)	123	(480)	(478)	628	545
Adjustments	(227)	615	(1650) to 495	(330 to 750)	(210)	(195)	1041
Adjusted Contribution	<u>6,078</u>	<u>6,844</u>	<u>4,482 to 6,627</u>	<u>5,247 to 5,667</u>	<u>5,769</u>	<u>5,519</u>	<u>6,000</u>

Figures are present values in £ millions based on the average revenue case.

Source:

National Audit Office (1995)

Chapter 5

The Geographical Scope of Regulation. The Case of European Pharmaceutical Product Licensing.

5.1. Introduction

In this particular case study we examine how the system for regulating the granting of product licenses in the pharmaceutical industry has changed over time. In particular we will note that product licenses are now granted at the European level where they were once determined by national government. The case study is largely based on Kaufer (1990) and Earl Slater (1996) with updates from elsewhere (e.g. Earl Slater, 1998; OECD, 2001; and www.emea.org).

5.2. Why should we regulate the pharmaceutical industry?

Regulation is in the interest of most companies as well as the consumer. The rationale is fairly straightforward. There are high research and development costs involved in bringing pharmaceutical products to the market and a considerable amount of testing to satisfy regulators. Such an environment may conflict with the profit motive required by powerful shareholding groups and so lead to inappropriate reductions in the gestation time between product inception and launch, possibly with deadly consequences.

An article by Alan Earl-Slater (1996) cites the example of the thalidomide disaster of the late 1950s and early 1960s as an occasion when the cost of not regulating the Pharmaceutical Industry was borne by the consumer. Those who took the drug thalidomide to prevent morning sickness and whose babies were born disabled with arms and/or legs deformed paid the price of the drug not having been approved for human consumption.

It was as a result of the thalidomide tragedy that governments decided to set up policies to regulate market entry. Some countries however, such as Norway, had regulation in place dating as far back as 1934. Earl-Slater notes though that: '**All nations in the EU now require that a pharmaceutical product intended for human consumption must have an official market license before it is allowed onto their market**'.

5.3. How has the regulation process for new pharmaceutical product licenses granted within the EU changed in recent times?

Until 1994 the market licenses were provided on a **national level**. The authorities of each individual state provided the national license. Since 1995 there has been a pan-EU market license. However, this approach has taken time to develop.

From around **1975 to 1995** the **multi-state procedure** was the required approach. Under this scheme when a product was allowed onto one member state's market (In the European Community) the company could apply through the European Committee for Proprietary Medicinal Products (CPMP) for market license in initially five, but subsequently to two other member states. The other countries' licensing authorities would then have 120 days in which to consider the application and come to a decision. Member states though were not ruled by the CPMP. They only took the CPMP's opinions into consideration as member states had **sovereign power** over what drugs came onto their market.

A more centralised approach to market licensing came into effect from **1 July 1987**. This was called the '**concertation procedure**', so called because it was based on the concerted efforts of the member states to lower industry compliance costs. The procedure was activated when a company submitted an application to any member state's competent licensing authority for drugs derived from biotechnology or human plasma. Indeed, the concertation procedure was compulsory for these types of drugs. The concertation procedure provided a centralised opinion - via the CPMP - on the product license application. Again though the CPMP's opinion was not binding on member states.

So up until 1994 there were three procedures

1. The national procedure
2. The multi-state procedure
3. The concertation procedure.

However, in reality the power of veto meant that there really only one route: national licenses. In effect, national sovereignty was retained by each State in the European Union.

From **January 1995**, however, a new product licensing system came into play in the EU: This approach is consistent with many of the new regulations that have been developed to create a single EU market.

It comprises of two main parts.

- 1) A European Medicines Evaluation Agency (EMA) and
- 2) A decision by the European Commission's.

The EMA is a revamped CPMP with a bigger budget and supported by improved scientific, administrative and technical staff. The EMA will operate two routes: mutual recognition and centralised. These routes are very similar to the pre-1995 procedure of multi-state and concertation procedures. The EMA gives opinions on market applications to the European Commission.

This new system differs from the pre-1995 system in three ways.

First, the routes become compulsory in 1998. The pre-1995 route will be phased out (though there have been some slight modifications – see www.ema.org).

Second, the European Commission will decide on whether or not an application through the routes gets a product license.

Third, the product license if granted by the Commission, will cover all member states; i.e. it will be a pan-EU product license. Thus from January 1995 to 1998, three routes to product licenses existed in the EU; single national procedures for products that only want to be licensed in that single member state market; the route of mutual recognition; and the centralised route. However, this new system is clearly usurping national sovereignty. This raises two questions. Why has this new system come into being and should we be concerned? The latter question is more emotive than the first because it involves political and somewhat subjective judgements about the nature of the democratic process within the European Commission and Parliament. In the following section the latter question is submerged within an answer to the former.

5.4. Why has a new system emerged?

The EMA system involves two core aspects of regulation: the transfer of member states' regulatory powers to the EU and the co-ordination of regulatory policies on drug licensing. The EMA takes away member state autonomy. There is no guarantee that centralising the final powers and building yet more bureaucracy will be successful.

The growth of regulatory policy making in the European Commission and associated political institutions has arisen, according to Majone (1999) for three interdependent reasons. First, national governments tend to be mostly interested in those activities that involve fiscal transfers to the European Supranational Authority (mostly agricultural support and redistributive policies such as regional aid) whereas much of the cost of the regulatory programme is borne by organisations and individuals who have to comply with the growing plethora of directives from Europe. In addition the rigidity in the budget forces the European Commission to look for new avenues in to which to expand its competencies. Third, there is a preference for firms trading across Europe to have a uniform set of rules rather than deal with individual member states. These reduced regulatory costs for firms are complemented by the opportunity to reap economies of production and marketing in a larger European market.

There are at least several sets of motivations behind the construction of the EMEA system. First, as a result of an **EU prisoners' dilemma (or Bilateral Regulatory Failure)**; second, extensions of **politico-bureaucratic business, including the inability of the pharmaceutical industry to nurture effectively any feasible alternative to the EMEA system**; and third, as a result of certain **market failures**.

5.4.1. EU prisoners' dilemma or Regulatory Failure

Some explanation of the growth of European regulation was offered above but we need to understand why national governments surrender sovereignty. In the Prisoner's Dilemma game two European countries that embark on reaching individual bilateral agreements could cooperate with each other and share the regulatory burdens (indeed, there may be economies of scale in regulation) and provide an attractive location for pharmaceutical companies vis-à-vis other EU nations who had not made similar agreements. However, as with any agreement parties have to find suitable partners, determine the nature and scope of the agreement, allocate appropriate resources to it and police the agreement. Given information asymmetries and the high costs associated with such activities there are powerful incentives for either party to defect on the agreement. Indeed, in the 1970s the Benelux countries (Belgium, Netherlands and Luxembourg) formed such a bilateral agreement on pharmaceutical product licenses but it was short-lived because of disputes relating to the share of resources devoted by each.

The logic of this game therefore is that it will drive parties (individual countries) to disagree and fail to keep any agreement or bargain struck over pharmaceutical product licensing policy and practice, unless the parties involved have as much concern for each other as they do for themselves. In order to reach the best outcome for the parties involved (the individual countries making up the EU) there is need for an enforceable, mutually acceptable and credible strategy over pharmaceutical market licensing policy and practice.

The EU prisoners' dilemma suggests that it is the collective entity (EU as a whole) that provides the framework in which member states can reap the benefits of a pan-European pharmaceutical market licensing policy. Individual member states will relinquish sovereignty to an EU forum and a political decision-making body if there are opportunities for conciliation and arbitration of disputes and a sharing of responsibilities.

5.4.2. The politico-bureaucratic dynamic

It was noted above that the growth in regulation was partly a response to a need to extend bureaucratic competencies given the structure of the budget. However, a point raised by Majone (1999) suggests that supranational decision-making bodies may be more willing to listen to pressure groups and technical expertise than national governments. This is partly due to the highly technical nature of regulatory policymaking, including those associated with pharmaceutical products. Engaging in such debates at a national level may be considered to costly for individual governments. However, Europe's supranational authority is a source of innovative regulation. In addition, Earl Slater (1996) points out how the industry have not been able to organise an alternative system of regulation. Competing interests have not led to a unified approach among the companies themselves (on which see section 5.5).

5.4.3. Market failures:

A. Market power:

The argument of the need for the EMEA system owing to market failure includes market power. This can exist at various levels. First, by engaging in harmonisation of product licensing across member states the opportunity for large pharmaceutical companies to engage in an abuse of market power becomes more limited. Consumers and competition regulators should gain as pricing and marketing behaviour becomes more transparent. Moreover, with a larger market to sell in firms should be able to reduce prices. Second, the State can be seen as a monopoly. Up until 1994 the individual member states of the EU had been playing the role of territorial monopolies in the provision of market licenses and it could be argued that the EMEA supranational authority system replaces the nation state as a monopoly. However, the EU could then raise 'prices' (or the cost of the system via increased bureaucratisation) and thus lead to lower levels of new pharmaceutical products being brought on to the market.

Moreover, states, through health service providers such as the UK National Health Service, act as territorial monopolies because of the volume of pharmaceutical purchases. This could have major consequences for the provision of new drugs if nation states decide to cut the costs of expensive new drugs.

Thus, the monopsony power of nation states could override the harmonisation and efficiency benefits associated with a large market.

B. Information economies

One of the problems with pharmaceuticals is that scientists have incomplete information about their use, safety or efficacy, in spite of the considerable testing that is carried out. Thus, there are new therapeutic uses for aspirin being found as a secondary prevention myocardial infarction and prevention of pre-eclampsia in pregnancy. The anti-viral drug, Amantidine has been found to have uses in Parkinson's Disease. Chloroquine, mostly used to prevent malaria, is being used to help rheumatoid arthritis sufferers. There are numerous other examples too (Earl Slater 1996).

The EMEA may encourage more complete information than would be possible under an uncoordinated system. It will also lead to more coordinated behaviour where drugs have been found to have inappropriate profiles or side effects, as was the case with Halcion 250mg dosage. In this instance the UK licensing authority withdrew the license because it was concerned about clinical data that was ten years old. Other nation states though did not follow suit. The EMEA system then has been implemented to improve imperfections in information and to facilitate a coordinated and credible response to information issues.

C. Externalities and Information

Information problems prevail in all products and services but particularly in pharmaceuticals as noted above. However, information problems may be due to information asymmetries between the players in the regulatory game. The firms know more about market conditions than the licensing authorities. Licensing authorities know more about their own regulatory conditions, rules and procedures than the firms do. Firms know more about their products than the physicians and the patient is probably the least informed of them all in the market place.

Clearly too there are some enormous positive externalities associated with health care. With a harmonised system opportunities of equal access to the latest pharmaceutical products should realise higher levels of social welfare for all (in theory at least). Prior to the implementation of the EMEA system disputes, resulting from information asymmetries between member states would lead to blockages in the granting of licenses. A harmonised system with greater flows of information should lead to positive externalities.

5.5. Why should firms accept a European solution?

Understanding why a new system of regulation comes into being requires an analysis of the receptiveness of the industry to such a regulatory regime. In other words, is it really the uniqueness of the product that has led to this form of European regulation? Weber and Hallerberg (2001) note there are different acceptances of European regulation according to the nature of the transaction costs associated in the industry and the nature of the competitive threat. Thus, the aerospace and motor vehicle industries have different regulatory arrangements. The former faces severe external competition from American aerospace manufacturers. Aerospace products also involve very high transaction costs, large sunk costs and a low volume of sales. As a result European firms backed by substantial state aid formed the pan-European firm, Airbus Industries. In motor vehicles the long term transaction costs are quite low and competition is largely intra-European. For this reason there are low levels of intervention in the Motor vehicle industry. However, occasionally, transaction costs can become rather high as assets are being redeployed to alternate uses. Where foreign competition exacerbates the adjustment process the firms have successfully managed to lobby for import controls, in the 1980s this took the form of voluntary export restraints by Japanese car manufacturers.

In the pharmaceutical industry the level of transaction costs are high given the secrecy associated with drug manufacture and the possibility of high-risk failures with the substantial research and development costs. The levels of asset specificity are high because of the intrinsic knowledge held by scientists. However, the competitive threat from outside Europe is not high. Most pharmaceutical companies stick to their own patch because of the need to service market needs and by 1990 EU drugs firms held almost one-third of the global market sales. National product license regulation though did considerable damage to the development of intra-European competition. There was enormous duplication of drug trials and the Cecchini Report (1988) estimated that multiple submissions cost firms between \$40-55 million in extra staff each year. There were also enormous variations in the time it took national bodies to approve new drugs. While France was seen to take on average four months to consider new drugs, Italy, Belgium, Spain and the Netherlands often took up to three years (Vogel, 1998). The European Federation of Pharmaceutical Industries Association, the industry lobby group, noted the damage with some alarm. By the mid-1990s Europe was falling behind American firms in new product development, notably biotechnology. American firms had access to a faster track system, the Food and Drug Administration, which was quickly becoming a world leader in the regulation of new drug development, review and post-market surveillance (Katz, 1993). The time for a new regulatory regime in Europe was ripe and the firms gladly accepted it.

5.6. Conclusion

In this brief chapter the changing nature of the regulatory system toward new pharmaceutical product licenses was examined. The new system has involved a transfer of power from nation states toward a supranational licensing authority with the backing of the European Commission. There are a number of reasons why this has developed. Partly it is due to the general forces associated with the move towards a single market and the politico-bureaucratic dynamic associated with the nature of the European budget system. However, there are some particular reasons: the positive externalities associated with a widening of opportunity to access new drugs, the gathering of more information and the reduction in market power. It also required acceptance by the firms. The new system is still emerging and for the moment is succeeding. It will continue to do so as long as the cost of regulation is not prohibitively high for firms and nation states continue to see the benefits of health care exceeding their budgetary costs.

Activity 5.1

Get hold of the following source

OECD (2001) *Competition and Regulation Issues in the Pharmaceutical Industry*, Roundtable, DAFFE/CLP(2000)29, available at <http://www.oecd.org>.

This document provides some useful insights as to the development of competition and regulatory processes within the global pharmaceutical industry. Look at the evidence provided by one country in this roundtable forum and compare it with another.

What differences and similarities do you see in the regulatory processes? Can you offer an explanation as to why these differences and similarities exist?

Is the regulatory process hampering or helping the development of the pharmaceutical industry in the countries concerned? Explain your answer.

Reading

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