

Pharmaceutical Regulation 1 – Interview held in December 2022

- Question about the relationship between the MCA/MHRA and CSM/CHM
 - The MCA is very professional, works in great detail; in those days [1990s, early 2000s] people would just phone people up to ask for more details.
 - CSM/CHM is completely independent from the regulator; the committee can be of any size and always represents the main disciplines with an increasing focus on paediatrics over the years.
 - To assemble all the right talent the committee is subdivided into sub-committees.
 - Interviewee had first engagement with CSM in 1993 through one of the subcommittees.
- Question about the nature of the work and influence of the pharmaceuticals industry on its work
 - It's quite a tough job, you are trying to get to a point where you can think of public harm and benefit, as well as individual harm and benefit; this is very different to the evaluation of NICE, it's not about cost or whether we already have a drug like.
 - To what extent can the drug developers influence these decisions? A huge amount of effort goes into preventing it through conflict of interest rules; you can't have any interest whatsoever in the pharmaceutical industry; so to be on the committee you can have no shares; any academic research paid for by drug companies, the companies would own the intellectual property, so there is a very high opportunity for your own research; all conflict of interest rules are strongly applied and policed, you need to declare all of your interests; this means it is actually quite difficult to persuade people to do the job.
- Question about the workload of committee members
 - Very significant workload, especially for people chairing the committee; took a lot of time to deal with the committee's work; people often don't realise it's not just about approval and supervision of drugs, it's also giving advice on changes to the legal status of drugs (e.g. changing a drug's legal status from prescription only to over-the-counter), there one needs to be careful because it benefits the NHS if a drug becomes over-the-counter, so there is a lot of different pressures on these sorts of decisions; in general, we always had to think about the benefits and the risks of a drug.
 - There are a lot of issues that fall in the remit of the committee that people don't know about; for example, it used to be only doctors who could prescribe things, now it is nurses and people with a prescribing certificate too, and the CSM had to give advice on all these things.
 - There are some things that I can't talk about but others I can talk about; the BSE crisis, for example, caused a huge amount of work for the committee because all drugs contain bovine products (e.g. gelatine or bovine serum) and all of the sudden we had to consider whether that

changed the risk-benefit of all drugs and vaccines, for example, should we still be giving vaccines to babies if these vaccines contain bovine products?; the Head of Licensing [of the MCA] at the time spent two years assessing these risks but nobody ever saw this work; it involved hugely complicated questions about, for example, where manufacturers got their serum from and where their records were to show that.

- The workload also includes a whole other host of issues, for example, questions such as whether mountain rescue teams should be allowed to administer morphine; all these types of questions would come straight to the CSM/CHM.
- Another issue we considered related to the cold medicine ephedrine for which it turned out turned out that it could be used to make crystal meth, so what do you do about that? The medicine is still better than alternatives, so do you ban it? If you can't buy it in Boots, people could still just buy it in other countries, so we had to wonder whether the risk could just pop up somewhere else; in the end we decided to ban it because it's just against colds and there are other medicines available to help with those; it's now prescription only; so the committee had a much broader workload than it appears.
- We also did a lot of work on dextropropoxyphene, an opioid; people loved the specific combination which led to a sort of dependency because it was such effective pain relief, but it was very effective for suicide too; so we had to ask the question whether it should be removed from the market but it caused such an outcry which could come from any direction, patients, GPs, patient groups etc, and you don't get a chance to explain, people would say "you're naive, people will find a different way to commit suicide"; but actually there was a significant reduction in adolescent suicide after we took it off the market; but you never hear about this kind of work of the committee and I could go on and on; it usually all takes place behind the scenes.
- We talked a lot to colleagues in the Netherlands, Scandinavia and Germany because they also have a science-based regime like us.
- Another issue we dealt with was hormone replacement therapy; we knew it led to a small increase in the risk of breast cancer but we thought this was offset by a decrease in cardiovascular risks; but then an exceptionally large study, The Million Women Study led by Valerie Beral, showed that while very effective at preventing post-menopausal symptoms, the cardioprotective effect actually wasn't there; so this meant that the benefit-risk changed, the study also showed that the breast cancer risk was higher than anticipated, especially in older women and after long-term use; hormone replacement therapy was hugely popular and nobody wanted to hear of these risks because the symptoms of the menopause are ghastly; these considerations are always a compromise; in the end, we changed the license of all hormone replacement therapy to be valid just for the treatment of the menopause and only for five year use; with all

of these sorts of issues you can be villified very quickly, the press picks it up, journalists spent a very short time trying to understand the issue and you never get to explain.

- Then there was also the H1N1 pandemic, you try to get into a proactive mode to try and make a better pathway but always end up back in reactive mode very quickly.
- Question about the licensing and supervision of Vioxx
 - Remember Vioxx very well; it was very popular with people with rheumatoid arthritis, it was very good for all of these kind of things, and muscle damage too.
 - We knew with this product that we need to keep a balance between healthy arteries and the pain relief; there was a theoretical basis for arguing that it could cause harm; Garret FitzGerald made a huge contribution on this, he knew the system and predicted that there could be an effect on arteries .
 - When it started to come out in pharmacovigilance, through Yellow Card systems, we knew we had to do something, we now knew that this was harmful to some populations.
 - There were contradictory views between the rheumatologists and the cardiologists; you always get in more experts on the specific issue to get honest opinions; but different medical disciplines can't necessarily agree depending on their job.
 - Essentially if you do your job properly you don't have to keep on reassessing the same drug again later.
- Question about the relationship between the industry and the regulator
 - People think that there is a particular culture, that you see the world differently depending on your role; when you're on the CSM/CHM you are appreciated by most of the profession and very well-respected; everyone knows what you are giving up to do that job, but people in the regulator are not liked by the people they regulate or the people they regulate for.
 - There is a perception that it is a 'them and us culture', but that's not true; the regulator has to act impartially, it can't be seen as friend of a developer but it shouldn't be seen as the enemy either; so in the early 2010s the regulator introduced an open policy to foster early discussions with the drug developers; anyone could have an appointment to speak to an expert, even the NHS, expert committees, NICE etc could be brought into the discussion; this system still seems to exist now.
 - Another issue is that vested interests work everywhere, not just from the developers, but also in the public sector; each discipline and sub-discipline, creates its own vested interests; look at toxicology, just as an example, every since it was established as a discipline we know need toxicologists for all sorts of questions even though we could perhaps do things differently these days; this is not related specifically to toxicology but happens with every discipline.

- Question about whether regulators and expert committee members favour evidence from randomised controlled trials over other types of evidence
 - The gold standard are still RCTs, but now these usually need to be of a huge scale; not too long ago, RCTs would have around 5000 to 10,000 participants and that was seen as acceptable; now they can have as many as 120,000 participants, they try to establish which subset of people the drug will work for, and a trial of this scale can cost a billion pounds.
 - But there is always discussion about what the gold standard really is because some people argue that RCTs take place in highly controlled circumstances; but in real life studies the gold standard is not some kind of statistical standard, but what works in practice; in the end, you have to do both, real world behaviours can't be seen in clinical trials; there are now also distributed clinical trials, which are essentially half real world study, half medical clinical trial.
 - Things will change quite a lot in the future, now we have molecular science and more powerful tools to assess drug targets; which allows a much larger number of drug targets to be considered, perhaps a thousand a year; RNA drugs will also dramatically alter the landscape.
 - A real appraisal of what evidence is needed to consider 'what is essential for us to know/'; if we are too stringent we stop people getting drugs that they really need, so it is unethical to overregulate.

[Interview ends]

Pharmaceutical Regulation 2 – Interview held in January 2023

- Question about the professional prestige of expert committee membership
 - o Prestige was considerable; for medics at the time it had the advantage of helping to achieve higher levels of distinction, which had a crucial effect on salary and pensions.
- Question about workload of committee members, what the work entailed and how committee meetings worked in practice
 - o The workload of a committee member was ‘ridiculous’ in that it was so high; in the end, committee members could put as much work into committee business as they saw fit.
 - o In preparation for committee meetings, the regulator put together information on drug safety supplied by the respective pharmaceutical company; the companies supplied this information to the regulator; the regulator then wrote a very detailed report (around 100 pages per product); several of these dossiers would be evaluated in each committee meeting and committee members would receive them a week in advance of the meeting.
 - o Products were evaluated for quality, safety and efficacy; determining a right balance between safety and efficacy may be very difficult for some drug categories, e.g., cancer drugs versus pain killers.
 - o The process relied on the drug companies providing honest data; sometimes committee members would say ‘this data isn’t good enough’, and the companies were usually good at coming back with improved data; the scientific parts of companies tended to be ethical, which was not always the case for the marketing departments of the same companies.
 - o Decisions of the regulator do not take into account the cost of a particular drug.
 - o The meetings would usually start with a presentation from an official from the regulator, and if a particular committee member had specific expertise on a particular drug/issue they would usually be invited to speak first after the presentation; in my particular case I would often speak about the consequences of overdoses of a particular drug, which the drug companies generally ignored in terms of their data collection of existing drugs.
 - o If you had done work on the drug in question you either had to recuse yourself or stay to provide your insights on the drug if asked but you could not take part in taking decisions on the drug; the people who had done work on a particular drug knew them better than anybody else and usually they were quite critical about the drug.
 - o Most research papers on a particular drug were written by the industry, and usually they were not published or public when we were evaluating drugs in the committee; in the ADR committees we sometimes had published case reports as well as Yellow Card data.
 - o There has been a lot of mission creep where the industry has been very good at steadily increasing the population group a drug is marketed for and increasing the authorised doses for particular drugs through applying for variations; quite often the regulator’s officials approved these types of applications, and they were not subject to expert committee advice.
 - o Usually committee members would be very clear in their views and in expressing these views.

- I can only think of one instance of a minister overturning a decision, which we did not think should have happened, but that was very rare.
- In terms of safety, the biggest problems are usually the oldest drugs as they were not authorised under the same strict rules as drugs today.
- I lobbied very hard to get rid of a particular combination drug (coproxamol, paracetamol dextropropoxyphene); if you took too many of them they were rapidly lethal and they were also very addictive.
- Paracetamol is another interesting case: now there is only 32 in a packet, that amount could kill you, but at which level of overdose do you admit a patient to hospital and treat them? To lower the instances of this occurring it should really have been 24 tablets in a packet but the pack size was influenced by both the industry and doctors. In 2008 there was a tragic case of a girl who was admitted to hospital; one of the involved medics knew one of the senior regulators and they influenced them; many meetings about the right course of action; so the whole process can be usurped if a particular agency official and perhaps one committee member take a particular stance.
- Committee members did not usually disagree much, but sometimes the regulator could bring in an external expert when the expertise of the committee didn't quite cover a particular area, and these external experts sometimes worried me as they could be very influential.
- There aren't that many experts in particular area and the money committee members received was peanuts; in the past it was still possible to travel by first class rail or to fly first class, so at least you could do some work while travelling, but that isn't possible anymore.
- There's increasing pressure on academics to research and publish, rather than to sit on expert committees, and committee work is very difficult to arrange for hospital doctors because of their shift work; in general, committee membership is much easier for people who are based in London.
- In short, there was no real incentive to be a committee member if you were not a medic, except for the prospect of an OBE or similar for some people.
- Question about conflict-of-interest rules
 - Conflict-of-interest was an issue, although its importance gradually altered, became more thought about over the periods I was involved; for most committee members these conflicts were not crucial in decision making as it was usually the people who had done work on a particular drug who were the most critical about it; there is now a regular rotation in the people sitting on a committee.
- Question about the use of different types of evidence
 - Over time the data on adverse drug reactions became more important, particularly with changes to analytical methods of the data that brought new insights into drug safety.
- Question about responsiveness of prescribing doctors to drug safety updates
 - A change to the license of a drug doesn't make any difference to the prescribing behaviour of doctors; the most acute example of that at the moment is Valproate, which causes neural tube defects. This still seems to be prescribed despite many regulatory warnings.
 - Another example is quinine which is a treatment for malaria but four million people in the UK are prescribed the drug for leg cramps even though it doesn't work for leg cramps, and is very toxic in overdose; the FDA has taken it off the

market in the US for that reason; the law in the UK does not mention deliberate overdose so the regulator has been unwilling to withdraw quinine from wide availability.

- Question about experiences on different expert committees and how they compared
 - o In the committee on veterinary medicines, officials were leaning more heavily on committee members to attest the effectiveness of drugs, but there was often little evidence for the effectiveness of these drugs.
 - o In the pesticides committee there were some attempts at ministerial interference; for example, in one instance, a minister was very keen to see garlic extract licensed, and the committee said 'we are not going to do it'.
 - o In another case involving sheep dips and the minister re-appointed a biased expert to the process, as pressure groups were getting to him, and this caused major problems.
- Question about whether there is anything else about the topic that the interviewer should have asked about
 - o The press can play an important role in this area; sometimes that's good, such as in the case of Thalidomide, but often it is unhelpful.
 - o I'm also concerned about the revolving door; people who come from the industry are fine but people who go to work for the industry after working for the regulator are more worrying; if people spent six months of their lives evaluating a particular drug, they get emotionally invested in it and don't want to change their view on it if subsequent data analysis by the committee is challenging.

[Interview ends]

Pharmaceutical Regulation 7 – Interview held in March 2023

- Question about the interviewee's experience of being a committee member
 - o In some ways, I was a slightly odd committee member because I was not a clinical trials person or a pharmacology expert. I do not really know how one gets put on the committee. I spent a lot of time trying to understand the pharmacology side of things, but I realised that it was better for people with that kind of expertise to focus on the pharmacology.
 - o It was really interesting to see developments in medicine while being on the committee, especially if new drugs in my area came in. One difficulty is that you need to know about psychopharmacology.
 - o Some people were very enthusiastic about products but others were much more cautious. People were all very knowledgeable.
- Question about how conflicts of interest were handled
 - o The Chairman was very fair and cautious in handling conflicts of interest.
 - o The drug companies also had some excellent scientists who were true experts in their field and who engaged in their own independent research.
 - o But there were also the 'marketeers', those academics who were closely involved with companies. Some people were involved in clinical trials of companies. You can understand why they were enthusiastic about new drugs that had potential to help people with conditions in their particular field.
 - o Some academics' careers are interdependent with drug companies, but you did not see that in the committee. You can see that more with US academics but not really with current academics in the UK.
- Question about the relationship between the advisory committees and the regulator
 - o I have no particular knowledge about this issue. My expectation was that if the committee approved something, it would be approved by the regulator.
 - o Now NICE also plays a very big role.
 - o The psychiatric drugs coming through in the 1990s were mainly me-too drugs with quite significant side-effects. A few came through with fewer side effects. The companies were also pushing at more benefits than the drugs actually had. It is often a consideration what the price of a drug is, but this was not a consideration for the CSM. It was usually quite a marginal benefit that got a drug through.
 - o Companies have essentially given up on psychiatric drugs. There has been no major developments in the field for the past 20 years. The drugs in the field do not have obvious targets, the targets are always a bit vague, so the drug companies did not quite know where to go. Another reason for this situation is that the existing drugs have been vastly oversubscribed and over-marketed. Many of us in the field were very critical of these drugs and the companies. I now think maybe we should not have been quite so critical.
- Question about whether it is problematic that the CSM is involved in licensing and post-licensing decisions
 - o Britain is quite a small place. So there is a relatively small number of people in every speciality. And these people are all in demand by the drug companies and the regulatory bodies alike. At least in the EU system there are more people overall to do these jobs.

- Question about whether FDA decisions played a role in CSM decision-making
 - Not formally. But we were conscious of whether a drug had sailed through at the FDA or whether problems had cropped up.
- Question about whether there is anything else the interviewee would like to raise
 - When thinking about regulation and medicine, surgical procedures are an interesting case. Surgical devices, for example, are not really discussed. And surgeons can essentially do what they like. A lot of appendices and tonsils are removed unnecessarily. This is an area where there is a gap in terms of regulation.

[Interview ends]

Pharmaceutical Regulation 8 – Interview held in March 2023

- Question about the differences and similarities between Lipobay, Vioxx and Avandia
 - o Cerivastatin led the MCA to review its pharmacovigilance practices. Vioxx resulted in new legislation at the EU level. Avandia did not result in any comparable changes.
 - o Scientifically speaking, there are some important commonalities between the three drugs. In general, drugs of the same class tend to be similar, but this paradigm was not true for these three drugs. They all had side effects that were qualitatively or quantitatively different to other drugs in the same class.
 - o Rhabdomyolysis happened around twenty times as frequently with cerivastatin compared to other statins, and it is a really devastating condition. So this was clearly unacceptable.
 - o For rofecoxib we still do not know how much worse it really was than other coxibs.
 - o In the case of rosiglitazone, the story was a bit different. Prior to it, we had had the case of troglitazone, which was withdrawn due to hepatic side effects. Then there is pioglitazone, which can cause bladder cancer. This raises question in its own right about why it is still on the market, but risks of associated bladder cancer are small and its cardiovascular benefits are considered to outweigh this. So these two and rosiglitazone are all in the same class but cause completely different side effects, which was totally unexpected.
- Question about the approval process for rosiglitazone
 - o We did not have a lot of good diabetes drugs back then and there was clearly a need for a new treatment. There was also pressure from the diabetes community that argued that there was an unmet medical need. At the same time, the increasing number of people with Type 2 diabetes expanded the scale of the problem. So in general there was some pressure to authorise new types of drug for diabetes.
 - o Rosiglitazone did not seem to have hepatic side effects. Cardiovascular effects were already worrying in the authorisation documents, particularly cardiac failure. The drug increased **LDL** cholesterol, but we did not understand what exactly that would mean for cardiovascular risk. That was the debate, and there was some discussion about this during the EMA approval process. There were 210 days for the EMA approval process and the clock was ticking. In October 1999, we had to make a decision and it was a very finely balanced decision. There was no consensus but a substantial minority of delegates wanted to authorise the drug. So there was a vote and divergent opinions were noted. Sweden and the Netherlands acted as rapporteurs and the Dutch in particular were concerned. The argument was to ask for long-term data, which would have been unusual. The amount of time the drug was tested in clinical trials (up to 2 years) was normal at the time, as was the number of participants (around 5000). The UK voted against approval. The company appealed the decision and the CSM were asked to discuss the issue at this stage and concluded that the balance of benefit and risk was positive and that the drug could be authorised.
 - o SKB and GSK were merging at the time, so it is possible that this created a particular dynamic, which resulted in some political pressure on the government for approval. This is likely to be the basis of a newspaper report shortly before the

appeal was heard suggesting that the UK would be lobbying for approval of rosiglitazone.

- This situation was a rare and isolated case in this respect. Even though the minister is the formal licensing authority, the process is normally apolitical (although an obvious exception was the political pressure to authorise vaccines during the pandemic).
- When it comes to decision-making by the CPMP, however, the number of members (30 at the time) all coming from different countries and a variety of scientific backgrounds creates a very significant barrier against regulatory capture. Generally speaking, there was probably more scope for regulatory capture in the mutual recognition procedure. Companies would choose to go to one of the bigger authorities as this was perceived as likely to minimise the potential for a referral to the CPMP after approval.
- Rosiglitazone was approved on appeal with only about five CPMP members voting against it. In hindsight, the CPMP should probably have been more concerned about the effect of the drug on lipids.
- Question about the FDA approval of rosiglitazone
 - The FDA did not seem to have such concerns about rosiglitazone. In general, the FDA has a greater reluctance to remove drugs from the market than the European authorities. If a few people could benefit from a drug, the FDA usually chose to keep it on the market (and rosiglitazone is still authorised there today although little used. (Note: Cervastatin and rofecoxib were withdrawn by the companies worldwide). When it comes to withdrawing drugs there is the problem of not wanting to admit to having made the wrong decision and the greater potential legal implications in the USA may be relevant in that respect.
- Question about avenues of industry influence
 - Public health considerations drove the decisions. Companies drive development processes which is not necessarily inappropriate. Some people argue that comparative efficacy should be taken into account, but companies argue against that on the basis that it would be a major deterrent to the development of new drugs. But companies do not drive individual decisions. I never saw anything that made me believe that individual scientists involved in the UK and EU regulatory processes had responded inappropriately to pressure by industry. There was pressure from patient groups at times and this was before the time when patient representatives were routinely involved in the process.
 - Clinicians can have an influence on decisions which can sometimes be concerning. For example, influential advisory committee members would sometimes indicate that they would really like to be able to prescribe a particular drug to their patients. A recent example of this is the continued use of sodium valproate in women of childbearing age in the face of known adverse effects of the fetus. There was some clinician pressure with doctors that arguing “we know the risks, we can manage them”.
 - Regulators could be savvier about this. For example, they could prevent new usage of a drug or only allow existing patients to continue taking particular drugs but rarely if ever do so. The role of doctors is difficult in this regard, and they face an overload of drug safety information already.

- Question about the withdrawal of rosiglitazone and rofecoxib
 - The MHRA role in the case of rosiglitazone was interesting as it could only put pressure on the EMA and did not have the power to remove the drug from market. The initial meta-analysis from Nissen was concerning, but it had a methodological problem in terms of what it was comparing the drug with (a mix of various other treatment and placebo). Graham's study was really the first that gave a real indication of the differential risk between rosiglitazone and pioglitazone, which was almost a 20% higher rate of cardiovascular events with the former. You then have to ask why you would use the drug in a patient group that already has a high baseline cardiovascular risk.
 - This was the same as in the case of Vioxx, where the patient group using the drug often had a high baseline cardiovascular risk. So, if you are in your mid-sixties, for example, and let's say you have around a 10-12% chance of a stroke or myocardial infarction over 10 years even if you have no known risk factors. If you doubled this risk by taking Vioxx, you end up with quite a high chance of a major, potentially fatal cardiovascular event. Then you compare this to the risk of gastric bleeding. At first, Vioxx seemed potentially very useful because it had much less GI risk, but that was before we identified the increase in cardiovascular risk. The baseline absolute risk of GI events in the same population are much lower (perhaps an order of magnitude). Overall, most NSAIDs increase cardiovascular risk to some extent but naproxen appear to being the exception. Regulators have not yet completely dealt with the cardiovascular risks of NSAIDs because we do not really know enough about them. This is particularly true for drugs such as ibuprofen that are widely used without prescription meaning that we have no way of knowing who is taking them and how much of them they are taking. The interesting thing about coxibs is that they should be useful for people with high risk of GI side effects. But in general, the target population has both high GI and cardiovascular risks. The APPROVe study killed Vioxx but there was a safety review before that. As a regulator, you are in a much better position if both real world data and clinical trials show the same thing.
 - There was an EU referral about Vioxx and it was an particularly long process. These referral processes would quite often take a while to get everybody to agree with a variety of views being expressed by delegates from different countries. Also sometimes a company would dig its heels in.
- Question about the use of different types of data by regulators
 - The numbers game is important. About 5000 people had been exposed to the drug in trials at the time when rosiglitazone was approved. This was rather more than normal for the period, but to identify problems you often need to have more people and different types of population groups taking the drug. Once the drug is on the market, you get the numbers from the drug being used in the real world.
 - Now EU regulators have the power to enforce post-marketing studies which came into force in 2012.
 - There used to be post-marketing surveillance studies, but these were often valueless as they were not well designed by companies who considered them as "seeding trials".
 - Since the 2010 legislation there is a better balance between licensing and post-licensing regulatory requirements. Previously, licensing was the main regulatory power. This is a bit different now that more post-marketing studies being

demanded. PRAC now sits alongside licensing Whereas as the Pharmacovigilance Working Party reported into the CPMP.

- Question about the 'revolving door'
 - o Some people who came from industry were good: they knew what they were doing and reformed processes for the better.
 - o Even if a particular individual was influenced by companies, a single individual could generally not have a great influence on decisions.
- Question about the relationship between licensing and post-licensing within the regulator, and whether there is an organisational conflict of interest
 - o When the MCA was set up it was the intention to give both sides equal power and influence. In general, individuals in post-marketing were influential and were supported by the executive. They did not simply get overruled by licensing.
 - o Sometimes there was tension between the two. For example, this happened with terfenadine which is not an active ingredient, it only becomes active when it is processed in the liver. The problem was that if for any reason the liver did not metabolise the drug properly the parent drug could cause cardiac arrhythmias. That is relatively rare but the drug was available over-the-counter and often used by young people. The initial approach was to change it to prescription only but this did not fully mitigate the problem. And so it seemed logical instead to use fexofenadine, which was the active ingredient and did not need to be converted in the liver. Post-licensing talked to colleagues in licensing who thought that ideally there would need to be further trials to be able to do this. But in practice we already knew fexofenadine worked and was safer. Post-licensing won that battle and companies were supportive of this, but licensing was initially reluctant to do things differently.
- Question about the relationship between different advisory committees
 - o Individuals can be very influential on the advisory committees. On SCOP/PEAG the balance of expertise changed over time. Over time pharmacoepidemiology became more prevalent. There has also been a shift to a greater focus on public health and patients have become more involved.
 - o There was and is a hierarchical relationship between and SCOP/PEAG and the CSM/CHM. The CSM/CHM ultimately decides in the end.

[Interview ends]

Financial Regulation 1 – Interview held in June 2023

- Question about role at the FSA
 - I think I was appointed because I was perceived to be neutral between the industry and consumer groups, which is useful from the public perspective.
 - Legislation at the time gave this role a specific function to report to the Treasury about whether the FSA was working efficiently. I did this in the first week and then it almost became the least important part of my job.
 - There were numerous non-executive committees, and we also established a risk committee. This focused on risks to the FSA, on the risks of it failing to do what it was supposed to do. I insisted that it would report directly to the Board.
 - The FSA was the successor to a large number of private regulatory organisations. We spent a lot of time putting these together, getting everyone to work together. We put in a lot of effort, which did work.
 - The main function of the Board was overseeing the FSA's work. The amount of byelaws passed by the FSA was very time-consuming. Other regulators also had their own byelaws, and they were not necessarily written to harmonise with each other. It was virtually impossible to read and understand all the byelaws the FSA created. So senior officials from the department it came from took responsibility for it; they signed it to say that it conformed to FSA objectives.
 - I persuaded the FSA to operate a system of civil penalties instead of criminal penalties, which made investigations easier and you did not get the stigma associated with criminal penalties.
 - I also recommended that byelaws should contain general principles because I had seen organisations claiming that they did things they should not have done because it did not say specifically in the byelaws that they should not.
 - Board meetings happened once a month. You got the papers in advance; there were a lot of them. Too many, in my opinion, but it was very difficult to cut them down. The papers were extremely well-written. In theory, there were 20-30 decisions to be taken at every meeting. You could not read and know enough about each of them, so different members of the Board took interest in different issues.
- Question about the dynamics of the Board
 - There were around 12 non-executive directors, as well as executive directors. There were two to three people from the industry, one from a Building Society, one from a major bank, one from BP, and some people in-between. Some people, like Deidre Hutton, would side with the consumer side of things. There was never any obvious conflict on broad issues. The executive of the major bank would only intervene when he felt that the industry had something to contribute and was well respected.
 - The Board did not focus on particular issues because there was just too much to get through.
- Question about whether the FSA was perceived to have enough resources
 - It had to focus on financial consumer and conduct regulation but also prudential regulation, and a lot of the work was about that. To a degree, that took away from other regulatory functions. It was understandable that it was split up. It was a workable set-up but it was difficult to get it all done.

- Managing directors and their staff had to deal with changing condition in the area that they were working one, which could be challenging. But financial resources were not really an issue, and the FSA was not short of staff. It had a good reputation. It could attract really good people, also from the Bank of England, and excellent young people too. The pay was not as good as in the private sector but after a few years at the FSA they were very attractive to people in the City.
- Things move fast at the fringes of the financial industry, just remember how mortgage debt was packaged, which contributed to the financial crisis. I doubt whether anyone at the FSA or Bank of England or even in the City knew what was going on. I often wonder why we failed to pick it up, but nobody did, only when it was too late. The industry is always ahead of the regulator. I think if people within the FSA had realised they would have brought it to the attention of the Board.
- The question whether it was regulatory capture never crossed my mind. The closest we came to that was probably in that there was a general belief that we had to deliver light touch regulation, although it was not clear what that actually meant. To me, it meant that you should not issue any unnecessary regulations, so for example, that you needed to conduct a cost-benefit-analysis for all byelaws. Although I never found cost-benefit-analysis that useful, I think information and instinct are important too.
- Question about the importance of the revolving door
 - I had not heard of this specific term for it before but am really interested in it. I looked at staff retention rates, people would usually stay for around three to four years. Older people tended to stay longer, there was a good retention rate for them. For people who came in from the industry I am not sure that they came in with an industry mindset and I am not sure that that had any kind of effect. There also was not too much of this dynamic going on.
- Question about the relationship between the regulator and the industry
 - I think the industry was often quite afraid of the regulator. I felt that there was a very high ethical standard, a shared feeling that everyone had to behave well, which is not easy to generate and maintain. The leadership set a good example in this respect and talked about it too. Regulators who would go into companies to go and audit and spend time within the company had to get on with people from the company. Otherwise, they would not be able to do their job. Sometimes it was said that they got too close, but I could not say anything about that, I doubt it, given the high ethical standards. Back then, everyone was in the same building, which really matters. There were some well-educated, impressive people there.
- Question about the role of the media
 - The Board did receive press clippings, but we paid less and less attention to them over time.
- Question about the role of parliament and the government
 - The only explicit pressure I remember was from the Treasury itself and we tried not to give in to that.
- Question about the role of non-executive committees, especially the risk committee
 - The committees got better at it, for example, at reporting to the Board. There was also an internal audit sub-committee (for example, about corruption within the organisation). The risk committee took a lot of effort to set up. A lot of people did not quite understand what it was supposed to do but we wanted it to focus on the risks to the FSA. We had a lot support from the leadership.

- Did you ever have concerns about the organisation?
 - o It would have been difficult to find out because people would not necessarily have told you about problems. But we did receive the press clippings, which could sometimes be helpful for finding out about certain issues. But we were selective and did not take up all issues the press focused on.
- Question about regulatory capture
 - o I had never heard of the term. I wondered whether it happened at the FSA and whether I would have known if it had happened. I think it is unlikely that it happened, but perhaps it is possible that it happened in individual cases. The question is how one would go about finding out whether it happened, one could only go by inference but never prove it. Although one can investigate it, there is a question about what one hopes to gain at the end of it. For example, if we think about endowment mortgages and whether capture happened in this case: the FSA may simply not have wanted to put all consumers off a product that was a good product for some people. So that may look like capture when it is not.
 - o If we are wondering how to reduce the chances of capture, a strong set of shared ethics seems to be the best way.
 - o The whole idea of light-touch regulation could be seen as capture, but it was a political priority. But that came because of the decision to move away from self-regulation by the industry, and you needed the cooperation of the industry to make it work.
- Question about the role of the Consumer Panel
 - o I do not remember the details, but it was very useful and very proactive in its work. It had the power to alert the Board to problems, but that was very rare. We paid attention to the Consumer Panel. I am not sure whether this was the same for the Practitioner Panel, I do not remember.

[Interview ends]

Financial Regulation 2 – Interview held in August 2023

- Question about background and involvement in financial consumer regulation processes
 - It is important to note that this is essentially historical research as the processes in question happened quite a long time ago. Inevitably, I am giving my own perspective, based on looking back in time.
 - I was involved in the transition from the PIA [Personal Investment Authority] to the FSA's [Financial Services Authority] consumer panel.
 - The financial crash of 1987 led to stronger financial services legislation, and a new regulatory structure including the PIA which developed an innovative consumer panel.
 - The PIA brought together a range of different regulators and the FSA consolidated this further.
 - The PIA was the first regulator to set up a consumer panel.
 - The PIA also took over responsibility for financial services complaints from the Insurance Ombudsman Bureau (IOB) of which I was the Chair from 1991. The IOB was a voluntary scheme funded by the insurance industry. After the financial crash there was a rapid increase in complaints. The PIA, therefore, established a separate Ombudsman Scheme to deal with complaints about investments sold by PIA regulated firms, as it wanted to bring all complaints resolution together in one place.
 - From the late 1970s and the 1980s, I said, voluntary arrangements had been established for consumer representatives to meet the regulators, and some very well qualified people from consumer groups took part. The PIA as a new regulator recognised the need to get consumer input to its regulations.
 - So the PIA established a consumer panel, which I was asked to chair on behalf of the Board because I had expertise in relevant consumer issues. I had always worked for consumer bodies, after graduating with a background in social sciences.
 - When the PIA established its consumer policy, it involved the National Consumer Council (NCC) and Which?. These bodies had people who were extremely knowledgeable about consumer issues. It is always really difficult to find people who understand consumer issues and who can authoritatively interrogate developments in the market.
 - At that point in time, there was very little consumer research in financial services. Essentially, Which? or NCC might do a study about a particular issue which would provide some evidence. We [the consumer panel of the PIA] wanted to underpin our work with evidence and research. So we needed a research budget and the PIA accepted that.
 - The PIA was definitely not in the consumers' pocket, but it recognised that it needed consumer intelligence. The executive wanted the Board to buy into the concept of a consumer panel. There were some examples in other areas of regulation where the Chair of the consumer panel had to be independent from the Board (which is what later happened with the FSA's consumer panel too).
 - We, as the consumer panel of the PIA, always had a good working relationship with the PIA and we were well-respected, which goes a long way. The credibility of our arguments depended on the individual issue, but if parliament and the industry were against a proposal, it was difficult to achieve change.

- Question about the move to the FSCP and differences between the two consumer panels?
 - The move to the FSA consumer panel was a very gradual one. When the FSA was established, we had to fight and argue our case strongly to get the panel written into the FSMA. We mostly succeeded through the influence of the Select Committee. I suspect that Which? played an important role behind the scenes. It was a game changer to get the new panel established as a statutory requirement. The FSA panel had more teeth, in theory. But the panel of the PIA certainly proved its worth even without formal authority.
 - The first budget of the FSCP was £500,000, which was another game changer. It had three full-time dedicated staff. The panel reported to a Director at the FSA who had a consumer brief. This compared to one person as secretariat at the PIA panel and a budget of £50,000. In the first year, we [the FSCP] were not able to spend the whole budget. Panel members of the FSCP were paid due to the statutory basis of the panel. And you cannot expect people to do the amount of technical work required without payment. The Chairman was appointed for two days a week, but in reality, it took closer to four days a week to do the work at first. But we believed in the panel and that it was important; we really wanted it to work.
 - There was no loss in continuity in work due to the change from PIA to FSA.
 - When the FSMA was published, mortgage and general insurance regulation, two of the biggest areas of concern for consumer protection, were not included. General insurance was still regulated by a self-regulatory body, which also had a consumer panel. The FSA had an ongoing problem initially in that it did not know what its scope was going to be. By the time the FSA was up and running, mortgages were added to its remit in 2001 and general insurance in 2005.
 - There was quite a lot of discussion whether regulation of retail should be separated out, the PIA never had comprehensive coverage of the retail market. Ultimately legislators decided to put regulation of all firms together under a new, very large regulator [the FSA].
 - In this period there was a small number of people with stature in consumer policy who all knew each other and worked together. In the consumer panel, involvement of trading standards was really important as they understood enforcement at the local level. There were also people in the independent voluntary sector and people at the regional level that were important to bring in.
 - The FSCP was appointed by the Board of the FSA, but that was just a formal procedure. It never questioned the names who were put forward following an independent selection process based on open recruitment against clear criteria. That was probably a more valuable model than government appointments to ensure a clear separation from politics and in order to focus on issues of consumer policy.
- Question about the influence of the consumer panels on the PIA and FSA?
 - The PIA strongly believed in the importance of the consumer panel. You're only ever going to be effective if you can persuade people who do the work of the validity of your arguments and the need for protection. Boards generally should not do the day to day work; they are the responsible for governance and are accountable. But the day-to-day regulatory work is done by the staff.
 - At the PIA we had a route through straight to the top. I knew everyone and they were very sympathetic to our perspective. There had been enough scandals and they knew that change was needed. But at the FSA there were quite a few new players. So we established a business-like relationship with Howard Davies and

had an opportunity occasionally to present reports to the Board. The management of the FSA knew that we would present our views candidly.

- The FSA had a very professional body of staff. There was a small group with direct responsibility for the consumer panel. By and large they did not have other jobs with the FSA. So we could get advance intelligence from them on what was coming up. They could tell us about problems that were being identified. I spoke directly and clearly to people I knew we could trust to get our view across. We did this when we knew we were on safe ground. In general, we had a clear sense of what was achievable.
- It is for others to say whether we achieved enough. But I actually thought that we achieved a lot. Small changes were happening all the time, and these are needed for significant change to happen. The FSA had a Director of Consumer Affairs and a Board member, Deirdre Hutton, who took our reports on board. But there were not many members of the Board who naturally aligned with a consumer perspective. Most of them had wider responsibilities across the industry.
- There was this notion that there needed to be a balance between consumers and small businesses. But it was unclear why this should be achieved through the same structure as the one created for consumer representation. We won that argument through the Treasury Select Committee. It was unclear why you would want to balance interests in this particular way. The argument for consumer issues was that you needed good research to ensure that regulators were in touch with consumer's experiences. I don't think that this argument was relevant for small businesses but provision was made in the legislation for them to have a panel too.
- Question about whether the regulator was more industry or more consumer-focused?
 - Regulators naturally spend most of their day job speaking to people in the industry that they regulate. They visit these firms, and attend regular conferences. Regulatory staff would be attending industry and trade association events. And they would be getting pressure from industry all the time. Consumer organisations had few resources by comparison. But consumer representation was put on a much more professional footing at the FSA. Still, the FSA had maybe about 400 staff members at the time, and maybe four or five of them were dedicated to consumer issues. So what we had to try and do was to coordinate and to get a view informed by research into consumer's experience of buying financial products and investments..
- Question about whether external consumer groups were important in coaxing the FSA into action over endowment mortgages and PPI?
 - Yes, these groups were more valuable outside than inside. Compared to the FSCP, they could focus on the big picture and do overarching work, and go to the media with it. As the panel, we had to focus on very technical work, on going through new regulations line-by-line. This eventually made it difficult to recruit people to the panel to do this type of work, even though they are usually paid for their time.
 - At the time the fallout from pensions mis-selling was so big, it took so long to get action on it. So this dominated the financial services industry and Ombudsman's office for a long time.
- Any questions I should have asked?
 - There is the question of where we are now. And that is perhaps a little unfair because I am not involved now. But there is now a distinct lack of government funding for consumer organisations and Which? remains the dominant player. The coherence and coordination between different groups has been lost.

Company based market research and web-based monitoring of individual purchasing behaviour has replaced trend data about consumer issues and experience.

- Regulators are now often more focused on issues internally, and the scale of things that they are dealing with has increased a lot.

[Interview ends]