THE EYES HAVE IT.
Taking on the role of European Commissioner for Health and Consumer Policy in November 2012, Tonio Borg brings with him 20 years’ experience as a parliamentarian, as well as the mantra that health “is an investment, not only a cost”. For the remaining years of the current mandate (ending in 2014), his priorities include revising existing regulations on tobacco products, protecting the food chain and improving quality of life for patients in the EU.1

Protecting the food chain
The recent horsemeat scandal brings with it a timely reminder that Europe’s food chain must be protected from fraud. According to Borg, none of the events of early 2013 indicate that there is a risk to safety or public health. However, there is no room for complacency, and it is the job of the European Commission (EC) to guarantee, in Borg’s words, that “the food on offer in the internal market is safe and that consumers have reliable information that is useful and necessary in making their choice. We can never exclude the possibility of fraud but we can discourage it effectively by maintaining our traceability and monitoring systems.”2

The unlabelled presence of horsemeat discovered in processed food products, including beef lasagne and burgers, does not in itself suggest a health crisis. EU legislation dictates that horsemeat can be used in mincemeat and meat preparations, provided it is declared on the label, where the consumer can see it. The overwhelming issue is fraudulent labelling – the primary responsibility of the food business operator is to comply with the relevant EU legislation.3 It might be possible to update animal labelling legislation to incorporate the place of origin, although, as Borg acknowledged in February at an extraordinary meeting on horsemeat in the EU food chain, issues regarding costs and the internal market mean this “will not be an easy ride”. Nevertheless, he contends, “this does not mean we cannot arrive there”.4

The EC has identified the culprits in a complex, long chain of production and distribution, thanks to its back-to-back food traceability system, which permits the immediate recall of any food found in any member state that does not meet the required standard.

“Our reaction in coordinating action across Europe has been swift,” Borg revealed on his official website. “We launched a plan in cooperation with member states to carry out controls of the foods destined for the final consumer and marketed as containing beef. The purpose is to check whether they contain traces of horsemeat. The plan also includes detecting possible residues of phenylbutazone, an anti-inflammatory drug which should not be in the food chain.”5

Smoking
In December 2012, the EC adopted a proposal to

CHANGE IS HEALTHY

Tonio Borg has already made his mark since replacing John Dalli as European Commissioner for Health and Consumer Policy, reports Public Service Review…

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revise its Tobacco Products Directive, which aims to strengthen the rules on how tobacco can be manufactured, presented and sold. It specifically bans certain tobacco products with strong flavours designed to appeal to young people by masking the harsh taste of tobacco, and makes the addition of large pictorial health warnings on cigarettes and RYO tobacco mandatory.

Tobacco kills almost 700,000 citizens each year – the equivalent of a city the size of Palermo or Frankfurt being wiped out, Borg remarked in a speech on the Tobacco Products Directive. On average, smokers die 14 years earlier than non-smokers, and the cost of treating smoking diseases is estimated at €25bn each year, with productivity losses at €8bn for the same duration.6

“The figures speak for themselves,” said Borg. “Tobacco kills half of its users and is highly addictive.” With 70% of smokers starting before they reach 18, the ambition of Borg’s proposal is “to make tobacco products and smoking less attractive and thus discourage tobacco initiation among young people”, adding that: “Consumers must not be cheated: tobacco products should look and taste like tobacco products and this proposal ensures that attractive packaging and flavourings are not used as a marketing strategy.”7

Further measures are also proposed for e-cigarettes and herbal products for smoking, which are not specifically regulated. There will be health warnings on e-cigarettes and a notification system for internet retailers, plus an age verification mechanism to ensure that tobacco products cannot be sold to children. Additionally, a tracing and tracking system will ensure that only products complying with the directive are sold in the EU.
An EC report published in February 2012 revealed that exposure to second-hand smoke in EU countries has diminished. 28% of Europeans were exposed to second-hand smoke in bars during 2012, compared to 46% in 2009. However, the figure is still too high. The report explains that the economic impact of smoking bans on revenues for bars and restaurants has been limited, but warns that some member states are lagging behind when it comes to comprehensive laws protecting public health. “Member States have made steady progress in protecting their citizens from second-hand smoke,” Borg said on the report’s publication in February. “Citizens’ exposure to smoking, however, still varies widely across the EU and there is a long way to go to make ‘Smoke Free Europe’ a reality. I urge all member states to step up their efforts to enforce legislation, commend those who have adopted ambitious smoke-free laws and urge the others to follow suit.”

e-Health
In December 2012, the EC launched an action plan to address obstacles to the use of digital solutions in Europe’s healthcare systems. Digital healthcare has yet to realise its extraordinary potential to improve health and social care, while also generating efficiency savings. However, there are already many patients and health professionals utilising telehealth solutions and smartphones to monitor their health and wellbeing.

Developing and promoting e-health and telemedicine forms a significant part of the EU’s Digital Agenda for Europe. “e-Health solutions can deliver high-quality, patient-centric, healthcare to our citizens. e-Health brings healthcare closer to people and improves health systems’ efficiency,” declared Borg in December 2012, suggesting that realising
a digital future for healthcare “will help turn the e-health potential into better care for our citizens.”

On a daily basis, healthcare professionals work hard to develop better medicine and treatments that will result in improved outcomes for patients, Borg highlighted in January 2013 in a speech to the European Parliament. Encouraging the innovation of products, services and processes is something policymakers should give structural support to even during times of austerity, he argued, outlining the need for “interoperable systems to fulfil the potential of e-health across the whole of Europe”.

Enhancing the way information is relayed and exchanged, he believes, is pivotal. “If we can successfully improve the ways IT health systems exchange information – both within and between member states – this will act as a launch pad for the wider and more efficient uptake of e-health within the European Union.”

Conclusion
Borg’s first few months in office as European Commissioner for Health and Consumer Policy have been challenging. His bold proposals for the reform of the Tobacco Products Directive was followed by the horsemeat scandal, which underlined the issue of fraudulent meat labelling. Meanwhile, the search for cost-efficiencies in European healthcare systems continues.

e-Health and research can contribute towards delivering patient benefits in the future, even in the current climate of austerity. €9bn of the overall €80bn budget of the Horizon 2020 will be solely dedicated to health research, covering a wide array of areas from understanding health and wellbeing, to healthcare provision and integrated care.

4 http://audiovisual.europarl.europa.eu/AssetDetail.aspx?g=2e85b292-9634-4d6b-b1d5-68b345270cd9
5 http://ec.europa.eu/commission_2010-2014/borg/personally_speaking/index_en.htm (no date given)

“Tobacco kills almost 700,000 citizens each year – the equivalent of a city the size of Palermo or Frankfurt being wiped out…”
Eye pathology is a medical specialty in which tissue from the eye and the ocular region, i.e. eyelids, tear system and orbit, are analysed by applying light and electron microscopy and genetic in situ techniques. Eye pathology is essential in ocular cancer treatment, providing diagnosis and prognosis.

History
In 1910, an eye pathology laboratory was established in the Department of Ophthalmology, State University Hospital, Copenhagen (Rigshospitalet). In 1972, the laboratory became an institute at the University of Copenhagen. In 1979, the first professor was appointed.

At present, the Eye Pathology Institute has a full chair professor and a part-time professor, the latter is also clinical professor at the Department of Ophthalmology, Glostrup Hospital, Copenhagen. Both are trained in ophthalmology and in general pathology (Fig. 1). The institute includes six PhD students and a few candidate/Bachelor’s students. The histopathological specimens are produced by two technicians, and the pathological reports are communicated by two secretaries.

Eye pathology service in Denmark
The service comprises 3,300 specimens a year. The service is national, meaning that all Danish eye departments and all ophthalmologists in private practices refer eyes and tissues from the ocular region to the institute. The service is free. Pathology reports are, in general, produced within four working days. Biopsies are received from tumours of the orbit and the eye, and acute biopsies are replied to within 30 minutes.

Part of the service is devoted to animal eyes, from experimental animals, veterinary ophthalmologists, zoos, and other university institutes. Animal eyes are a valuable source of models of human eye diseases.

In addition to the histopathological service, a clinical service is offered. Clinical pictures, scans and clinical histories of patients are mailed to the institute’s mail service. Suggestions of diagnosis and plans for treatment/biopsy are returned within a few days. Each month teleconferences are held with the main eye departments in Denmark.

Danish Ophthalmo-Oncological Group (DOOG)
Malignant tumours inside the eye and orbit are rare. In Denmark, with 5.5 million inhabitants, there are 60 malignant intraocular tumours a year. Most are melanomas of adults (55 per year). Among children, five retinoblastomas are found. Metastases make up another 60 tumours a year; however, only a few of these are biopsied because the primary tumour is already known. Malignant tumours of the orbit (60 per year) are mostly tear gland carcinomas and lymphomas.

All malignant tumours of the eye region are considered orphan diseases; consequently, centralisation of the diagnosis and treatment began in Denmark in the late 1970s. Today, all cancers of the eye region are dealt with in DOOG (http://doog.dk). This is a multidisciplinary team consisting of an oncologist from the Danish Cancer Society, two ophthalmologists from the Department of Ophthalmology Århus, serving West Denmark, and two ophthalmologists in Rigshospitalet, serving East Denmark. In addition, a radiologist and one of the professors from the Eye Pathology Institute are members of DOOG.
DOOG has produced diagnostic and treatment protocols for malignant tumours of the eye region in Denmark (www.dansk-oftalmologisk-selskab.dk). A national database keeps track of treatment quality and outcome. For example: the latest analysis showed it took nine days on average from the referral of a patient with an intraocular tumour until the patient had finished treatment, i.e. clinical investigations + diagnosis + treatment. The single longest period was five weeks.

30 years ago, biopsy of intraocular tumours was new and controversial. At that time, we launched the first prospective study of the benefits of transvitreal retino-choroidal (TVRC) biopsy (Fig. 2A and B). All Danish intraocular tumours were biopsied over a period of 10 years. We found that TVRC-biopsy is safe and reliable and does not increase the risk of tumour seeding or the risk of tumour related death. TVRC-biopsy is now performed in most of the world, and allows genetic analysis of the tumour tissue (Fig. 2C).

Eyes with malignant tumours are usually not enucleated today, but treated with eye saving techniques. The use of tumour genetic analyses has enabled the ophthalmologist to divide the tumour patients into two groups: one with limited risk of tumour death and one with very high risk. This is important because the total risk of tumour related death is 50% within 10 years after diagnosis, independent of type of treatment. Today, the malignant tumour is completely cured by the treatments. However, despite the fact that the tumours are found when they are small (most <15mm in diameter), many have already metastasised at diagnosis. At present there is no effective treatment against ocular melanoma metastases. The rapid development in tumour genetics may give such treatment options.

Eye pathology science

We are involved in the identification of specific genetic deviations of tear gland tumours. We have analysed why only a few choroid melanomas that invade the retina and optic nerve, and rarely metastasise to the brain in contrast to metastases from skin melanoma. Our findings indicate that the melanoma tumour stem cell of the eye is different from that of the skin. This may explain why ocular melanomas have different gene deviations compared to skin melanomas. We have conducted a study on conjunctival melanomas to explain why they develop, how they spread, their genetic deviations and which to fear. Throughout the last 10 years the institute has investigated ocular and eye region lymphomas, and at present we are leading a multinational study of eye region lymphomas that already has collected the largest sample of these tumours in the world.

The institute has added to the understanding of the pathogenesis of age related macular degeneration (AMD). AMD is the main cause of reduced vision among elderly people. The disease is characterised by an accumulation of inflammatory active substances (drusen) between the retinal pigment epithelium (RPE) and the vascular structures outside the retina. The RPE is slowly destroyed in AMD; however, in our pig model of AMD, we have
identified the stem cells of the retinal pigment epithelium, indicating that the cells might, in the future, be medically stimulated to regenerate.

Glaucoma is a family of neurodegenerative diseases that cause progressive loss of vision. Most of the glaucoma types share the clinical signs of increased intraocular pressure. The intraocular pressure is dependent on a controlled production of aqueous solutions from the ciliary body. The production is dependent on transport molecules in the ciliary epithelia. In recent years, a new group of transport molecules, the aquaporins, has been identified in many parts of the eye. We have concentrated on their anatomical distribution within the eye and their role in glaucoma. We have identified several aquaporin types in the various epithelia of the eye (Fig. 3A). Regulation of these aquaporins may be a new therapeutic approach to the treatment of glaucoma, especially since we have also found these molecules within the retinal cells. In addition, we have shown that in AMD drusen, the RPE cells are up-regulating their aquaporin expression (Fig. 3B).

“Only the tissue, examined under the microscope, can tell whether a tumour has spread or has been completely removed.”
The future
Eye pathology adapts to the rapid progress of clinical ophthalmology. Flow cytometry is now tested on minute biopsies from the internal eye. Genetic analyses are performed on the very limited number of tumour cells obtained through TVRC-biopsy; however, these techniques only give basis for diagnoses and prognosis. Only the tissue, examined under the microscope, can tell whether a tumour has spread or has been completely removed. Eye Pathology is also needed in the future. With a national service like the Danish with its centralised databases, and with more than 100 years of archived material, epidemiology of ocular diseases has been highly useful. Therefore, dedicated ophthalmic pathology ensures the highest quality of clinical ophthalmology and facilitates so that patients are rightly diagnosed and treated within the shortest time and at the best price.


Fig. 3: A: Aquaporin 6 is strongly expressed in the cytoplasm membranes of the non-pigmented ciliary epithelium (brown stained cell layer, bar = 50μm). B: Drusen (*) under the RPE (arrows) in a patient with early AMD. The RPE cells covering the drusen express aquaporins (red stain, bar = 50μm)

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In spite of significant progress in the treatment of many eye diseases, visual loss unfortunately remains a reality in 2013. The Certificate of Vision Impairment (CVI) formally certifies a person as sight impaired (partially sighted) or severely sight impaired (blind). The purpose of the CVI is to provide a reliable route for individuals with sight loss to be brought to the attention of social care. Registration, which is a voluntary choice, is provided by Social Service Departments (SSDs).

Certification and registration are widely perceived by patients as being of great value in conferring a range of benefits – for instance, those who are registered as blind and receiving supplementary security income (SSI) are entitled to personal income tax allowance; those who are registered as blind or partially sighted may also be entitled to discounted travel and various welfare benefits such as Attendance Allowance, Disability Living Allowance, or Personal Independence Payment and Employment and Support Allowance, as well as assistance in coping with sight loss, which can make a substantial difference to the person’s quality of life.

In addition, analysis of CVI data provides information on the prevalence of sight loss. In England, a new preventable sight loss indicator has been included in the Public Health Outcomes Framework. The aim of this is to target resources to improve early detection and better outcomes of the three major causes of sight loss (glaucoma, age related macular degeneration (AMD) and diabetic retinopathy). From April 2013, the indicator will be measured annually, based on CVI data. The Royal National Institute of Blind People (RNIB) has also introduced a sight loss data tool that provides factual information about sight loss and CVI and registration data for each region and local authority in England. Again, this is very helpful in directing resources appropriately. 

The numbers of CVIs issued to adults has significantly fallen since 2003, in spite of evidence of an increase in the population of people with visual impairment and bodies such as the RNIB and the Royal College of Ophthalmologists (RCOphth) having continuously promoted the importance of certification and registration. The reasons for this are likely to be multifactorial, but in recent research the RNIB has identified a number of stages in the process where barriers and delay can potentially occur.

Certification of vision impairment is completed by a senior eye specialist (ophthalmologist) – usually a consultant. Deciding when to certify a person with visual impairment may be self-evident in some patients, but in others, particularly those with long-term conditions who may be undergoing treatment, (e.g. wet AMD), vision can fluctuate, leading to uncertainty in deciding whether a patient is eligible. Further guidance in this area is likely to be necessary, but there is widespread support amongst consultants as well as strong evidence of the value of Eye Clinic Liaison Officers (ECLOs) in supporting the process. Although provision of ECLOs throughout the UK is variable, these individuals, where available, can significantly help to ensure that patients are certified at the appropriate time rather than at the end of the clinical process, which has traditionally been the case.

NHS consultants are under increasing pressure and ECLOs can greatly assist in explaining the certification and registration processes to eligible patients and ensuring that patients diagnosed with significant sight loss receive appropriate and timely support.

One possible reason cited as a cause for the decline in certification has been the withdrawal, albeit inconsistently across the UK, of a payment to ophthalmologists for completion of the CVI. However, following a recent survey of consultants by the RCOphth, only a minority of respondents considered this an issue, with many indicating that their preference – where a fee is payable – is for it be donated to help fund ECLOs in...
their departments. There has been a request for greater clarity about this, as well as appropriate time made available for ophthalmologists to complete CVI forms.

There are separate, but similar, CVI forms for use in England, Scotland, Wales and Northern Ireland. There is also a special form for children with visual impairment. All require the consultant to have assessed how much vision is present (visual acuity) and the extent of vision present (visual field). The cause(s) of visual loss is also recorded, as well as details about other relevant medical conditions/disabilities and social information.

For example, to be registered as severely sight impaired both eyes would have:
• Visual acuity of less than 3/60 Snellen with a full visual field;
• Visual acuity between 3/60 and 6/60 with severe reduction of visual field;
• Visual acuity of 6/60 or above but with very restricted field of vision.

For sight impaired, the criteria for both eyes would be:
• Visual acuity of 3/60 to 6/60 with full visual field;
• Visual acuity of up to 6/24 with moderate reduction of visual field;
• Visual acuity of up to 6/18 if there is extensive loss of visual field (e.g. half of field missing).

Following certification, the form should be sent to the local SSD within five working days, so that registration can be initiated, subject to the patient’s consent. Evidence from the RCOphth suggests, however, that this requirement is not widely known and ophthalmologists are therefore reminded of the importance of this in avoiding delay. They should also be aware of the referral of the visual impairment form, which can be issued by eye clinics and used to alert SSDs to the needs of people with visual impairment in advance of certification. As well as being sent to the patient and their general practitioner, the CVI should be submitted to the Certification Office at Moorfields Eye Hospital for anonymised data collection. It has been suggested this be mandatory to ensure that epidemiological information about the prevalence of causes of visual loss is as accurate as possible. Improvements to the form and process have been suggested to facilitate both this process and also speedy communication with SSDs, with strong qualified support for the concept of an electronic system (eCVI).

The RCOphth is already working closely with members and stakeholders to promote best practice regarding the CVI process, in raising awareness of the importance of CVIs – both for patients in need of support services and in building as comprehensive a picture as possible to plan for improved future eye services.

2 www.rnib.org.uk/aboutus/Research/reports/otherresearch/Pages/certification-registration-processes.aspx

For further information, please visit www.rcophth.ac.uk or www.nhs/conditions/Visual-impairment/Pages/Introduction.aspx

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