L@b Brief | February 2022

GIVEN THE terrible news from Ukraine I'm sure everyone's thoughts are with the people there. It's likely that many of you trade with either Ukraine or Russia and will now face difficulties. If you are affected, please get in touch.
At the other end of the scale, it's not long now until we will be enjoying our first major in-person conference for over two years. We have sold out of spaces at the main conference hotel and also at the overspill hotel, but we still have places for day attendees so it's not too late to book your place.
We have speakers explaining how you can take advantage of the Race to Zero to build your bottom line, and GAMBICA members sharing their insights on developments which will shape the lab industry for years to come. And as usual we will have plenty of time for debate, discussion and socialising. I do hope you can join us.

Jacqueline
PS... The frogs are about a story in the standards bulletin about the use of formaldehyde to test fume cabinets. If you have a view, please get in touch..

INSIDE *this* MONTH

UK News

New £7 million fund to help UK Health Tech SMEs with regulation

A NEW Health Technology Regulatory and Innovation Programme to help UK Health Tech SMEs cope with regulation for both UK and EU jurisdictions has been funded by Innovate UK.

Companies looking to sell into the EU market now must adhere to the new medical device regulations (MDR), and impending invitro diagnostic medical device regulations (IVDR). This may lead to some UK companies finding that their products no longer meet the regulatory requirements to be sold within the EU.

SMEs seeking to commercialise their products often lack internal expertise and capacity to ensure regulatory compliance. This funding and support programme will help Health Tech SMEs access regulatory assistance and knowledge for medical technology and invitro diagnostics.

The programme also offers guidance and education on regulatory systems and an opportunity to engage with industry regulatory experts.

Applications were opened on 14th February 2022 and close on 31 May 2022. Applications will be reviewed on a weekly basis and awards made on a first-come, first-served basis if the minimum threshold criteria are met. Companies are encouraged to apply as soon as possible.

To apply, visit the programme website, available here. The application form itself is here. For further information and support, email: health.techprogramme@uk-cpi.com

GAMBICA members press the case for customs reform in response to sudden government call for evidence

THE GOVERNMENT has released a sudden call for evidence on customs policy focussing on:

- Improvements to help traders access a quality customs intermediary sector
- How the benefits of the Simplified Customs Declarations Process (SCDP) can be expanded
- How transit facilitation can be improved.

The call has come in the wake of the setting up of GAMBICA's new Inward and Outward Processing Group, which is looking at customs and related issues experienced by members temporarily importing goods for servicing or calibration.

At the first meeting of the group the following issues were raised in relation to Fast Parcel Operators (FPOs):

- constant delays and errors and poor performance compared to freight forwarders;

- poor IT systems which do not provide appropriate options for designating parcels as 'temporary imports'
- need more to improve the training of FPO staff, including in the HMRC's CHIEF system;
- the need to adjust targets so that there is no incentive to put the more complex temporary import and exports to the back of the pile; and
- this is a David and Goliath situation in which FPO clients have little or no control.

The following HMRC and customs issues were also raised

- Customs in general is now taking 2-3 days longer, there appears to be a lack of resources and it is not clear that customs is adequately staffed.
- By contrast, customs brokers have tripled in size.
- HMRC guidance is poor.
- The overall IP/OP system is far too detailed for low-risk activities by low-risk companies with a low overall value.
- HMRC's focus on the high capital value of equipment being temporarily imported not on the low charges made for servicing and calibration.
- There are considerable difficulties for importers of used equipment, which is sometimes very old in finding and holding evidence of the cost of equipment.
- Training of HMRC staff is poor with inconsistencies and poor understanding of this area of operation and therefore poor advice to third parties.
- More transparency is needed in how to find customs processing codes, even accountants find the HMRC website is very difficult to navigate.
- A high level of detail is needed in HMRC commodity codes and there is a forthcoming change to the number of digits in the codes (although it was felt that the tariff checker was very useful).
- There are often lengthy delays in recovering VAT.

Licencing issues

- Because of the short validity of hazardous goods export licenses, and the current freight difficulties, licences often expire before shipping/courier in place

Overall, it was agreed that there is a fundamental lack of clarity as to the interpretation of the current HMRC guidance with advice from third parties varying widely. A priority is to gain a view from HMRC on the major areas of difficulty and to address the gold plating of HMRC's policy on temporary imports which is far too onerous for the value of the work being undertaken. Fast parcel operators must also be encouraged to address their poor systems and lack of training.

A programme of actions is being developed for GAMBICA to support members suffering the difficulties of temporary imports and we will keep you up-to-date with them as they occur.

HMRC and HM Treasury are hosting a webinar on Wednesday 2 March at 3.30pm to introduce the call for evidence, give guidance about how to reply, and answer any questions you may have. Sign up here

The call for evidence opened on Monday 7 February and will run until Monday 2 May. Those wishing to contribute can find out how to do so at GOV.UK or send me your views and I will incorporate them into GAMBICA's response.

Northern Ireland problems?

AS PART of our continuing engagement with the business department, BEIS, we have been asked to help in gathering evidence of how our sector is managing with regard to moving goods between Great Britain and Northern Ireland, and supporting customers.

The information we gather will help inform policy-making on implementing the Northern Ireland Protocol. The UK is currently in deadlock with the EU on this issue, which it is affecting the broader trading relationship with the EU.

We are therefore keen to hear from members, in confidence, as to your current experience. That includes service and maintenance activities, where relevant. Your feedback will be anonymised and will be hugely valuable and appreciated. Please indicate as to whether you would be willing to participate in a longer survey and interview, directly with BEIS.

We will aggregate your anonymised comments with those of other firms and feed back to participating members.

Reminder to register for dual use and technology export licencing

HMRC HAS recently reminded GAMBICA members that our EU-Exit resulted in changes to export control legislation, including the EU-Dual Use regulation. This regulation incorporated the list of 10 categories of controlled items which previously didn't need a licence for exporting to the EU. You can find the items here. If you are exporting these items to the EU, you need to register once for this licence here, and keep records of when you export against it.

Cyber risk alert

THE NATIONAL Cyber Security Centre (NCSC) is encouraging firms to take steps to reduce the risk of cyber-attacks. Risks are judged to have increased due to the crisis in Ukraine.

NCSC advises actions including:

- patching systems;
- improving access controls and enabling multi-factor authentication;

- implementing an effective incident response plan;
- checking that backups and restore mechanisms are working;
- ensuring that online defences are working as expected, and;
- keeping up to date with the latest threat and mitigation information.

Links:

- Ukraine specific information is here.
- Cyber security guidance actions are available here. :
- NCSC query line is here.

High-tech manufacturing warned of heightened cyber threat

THE CENTRE for the Protection of National Infrastructure (CPNI) and the National Cyber Security Centre (NCSC) have released a document on Threats to the UK Advanced Materials Sector, as well as guidance on the risks businesses may face and how to manage them.

Innovative manufacturing companies make a significant contributor to future UK economic growth and offer considerable benefits to the safety and security of the UK. However, some state actors are taking advantage of UK advanced materials companies' strengths in innovation to advance their own political, economic, technology and military programmes.

Even if you do not consider your technology to be dual-use or sensitive, it may be used by state actors to support their military and technology programmes. According to CPNI and NCSC, state-backed organisations are looking for vulnerabilities in companies of every size and at every technology readiness level. They may use a variety of means, including insiders, cyber targeting and the exploitation of standard business engagement to obtain confidential information about your business, such as intellectual property (IP), research data, financial information, organisation mapping, information on your customers or suppliers and commercially sensitive material.

View the full document here.

Public Accounts Committee report on Brexit

THE HOUSE OF COMMONS' Public Accounts Committee (PAC) has warned of further delays in moving goods between Britain and the EU. In a new report , the PAC says that says government's plans to create 'the most effective border in the world' by 2025 is: 'optimistic, given where things stand today' and is not convinced that it's underpinned by the plan to deliver it. Government has a poor record on digital-dependent projects it says, and it requests that it be updated on progress every six months from now on.

The report says that in 2019, HMRC estimated that complying just with the new customs rules could cost UK and EU firms £15 billion a year. It has not updated its estimate but there are indications that costs to businesses will be less than that estimate.

Due to tightly defined criteria, less than £7 million was spent under the Brexit Support Fund.

Committee chair Dame Meg Hillier said: "One of the great promises of Brexit was freeing British businesses to give them the headroom to maximise their productivity and contribution to the economy – even more desperately needed now on the long road to recovery from the pandemic. Yet the only detectable impact so far is increased costs, paperwork and border delays.

"The PAC has repeatedly reported on Brexit preparedness and at every step there have been delays to promised deadlines. It's time the government was honest about the problems rather than overpromising.

"In our view, there is much more work that Government should be doing in the short term to understand and minimise the current burden on those trading with the EU, to address the immediate delivery and readiness risks in introducing import controls, and to have a border in place which is operating effectively without further delays or temporary measures."

The report was published within hours of Jacob Rees-Mogg's appointment as Cabinet Office minister for Brexit opportunities. To read the report click here.

Chips Act aims to make Europe a semiconductor powerhouse

MEASURES DESIGNED to address the current shortage of semiconductors and develop Europe into a powerhouse for semiconductors production by the end of the decade, have been set out by EU policymakers.

European Commission president, Ursula von der Leyen, said: "The European Chips Act will be a game changer for the global competitiveness of Europe's single market. In the short term, it will increase our resilience to future crises, by enabling us to anticipate and avoid supply chain disruptions. And in the mid-term, it will help make Europe an industrial leader in this strategic branch."

The draft Act is aimed at bolstering European capacity to make semiconductors with the ambition that 20% of worldwide production of semiconductors will stem from Europe by 2030. In part the policy responds to the recent US 'Chips for America Act' and plans by the Chinese government to provide massive support of China's semiconductor industry.

If implemented, the draft Chips Act would provide a framework through which public funds could be channelled to new semiconductor manufacturing facilities and fast-track processes to enable them to clear administrative hurdles in relation to planning and construction.

The Commission, plans to commit €3.3 billion of EU funds to the initiative. But

Florian von Baum, (left) Munich-based expert in technology, science and industry who specialises in semiconductor issues at Pinsent Masons, said: "Building one chip manufacturing factory may require an investment of €20 billion or so, so it is a high capital expenditure. The real impact of the new EU program is therefore in question."

Questions&Answers

The plastic packaging tax

Q: IF WE buy plastic packaging from a supplier in the UK, they will have paid the tax when they converted the plastic and sold it to us. They will be looking to cover any additional cost by passing the tax on in the form of a price rise to us! When we use the packaging to send out products onto the UK market, are we liable to pay the tax again if we exceed the yearly tonnage and it is not 30% recycled content? The reason I ask is that HMRC would get a double benefit in this scenario.

A: No - the tax should only be paid once by either the UK manufacturer of finished plastic packaging (after that piece of packaging's 'last substantial modification' before pack/filling), or the importer if produced overseas. As you have found, most manufacturers in the UK are increasing their prices to recoup funds from paying the tax.

It's worth noting that there is a possibility that there is confusion along the supply chain and tax gets paid twice on a piece of packaging, so it is important to clarify with your suppliers that they are paying the tax on in-scope items.

Q: WE IMPORT plastic packaging including point of sale boxes from outside the UK, so it is clear that we could become liable for tax if the criteria for recycled content is not met. We would get certified evidence that the material contains more than 30% recycled material in order to prove exemption from the tax.

If we import semi-finished goods for example PCBs, metal or polymer parts that are wrapped in plastic packaging but that packaging does not get transferred to the final goods that we ship, do we have to include this in our calculation?

A: In terms of liability for PPT for importers – you will be liable for any filled or unfilled finished plastic packaging, but there is a narrow exemption for transit packaging used around imports. Also known as 'tertiary' packaging it must be used to group a number of sales units together, and be used only to protect the goods during shipment into the UK. If the packaging you mention that doesn't get transferred to the final goods, and doesn't enter the UK, it won't be subject to PPT. It doesn't sound like the bags will be liable for the transit exemption as they are primary packaging.

Q: IF WE import semi-finished goods for example test leads that are packed in plastic bags that do end up in the final goods that we ship I assume we will have to include in our PPT calculation (unless we prove exempt)?

A: Yes, the plastic bags will have to be included in your calculations.

Updating to comply with latest version of the standard

Q: WE ARE currently updating our manuals to cover a couple of extra additions to the BSEN: 61010 - 2019 edition. While I understand that we cannot update anything once it is in the distribution chain, what is the distribution chain? We also sell products to OEM partners who have also updated their manuals. Does the distribution chain start when they leave our site, ie all complete items still in stock should have the manuals replaced?

What about OEM? Does the distribution chain start when the products leave our site or the OEM partners site?

A: The distribution chain is usually defined as once the product has left the manufacturer or importer as a finished product, until it reaches the end user.

If an OEM manufacturer is placing a product on the market under their own name/brand then they take on the role of 'manufacturer' and are therefore responsible for the compliance of the product.

Upcoming GAMBICA Webinars

The Changing Workplace: legal updates & the impact of COVID | 2 March 2022

A ONE-HOUR HR review.

Government guidance on Covid including vaccinations, returning to work and sick pay has changed frequently over the last two years. This webinar will provide a short but complete review of current best practice so that you can be sure you have updated all your policies and wound up in the right place. The webinar will be delivered by HR experts Quest, who are the providers of your free HR, Law, Health and Safety and tax helplines and document libraries.

The content may be amended to include new topical issues, but will cover the following:

~ Latest government guidance
~ Varying sick pay
~ Testing & vaccinations
~ Lone workers
~ Holiday issues
~ Reducing company sick pay
~ Returning to work
~ Hybrid working
~ Long covid
~ Returning to school

To reserve your place, click here.

GAMBICA Annual Conference | 21 - 22 March 2022

IN AN exciting development, a new speaker has been added to the GAMBICA conference in March. Matt Wherry, Chief Engineer at Waters for Instrument Control Systems has agreed to present the first information released to industry about a co-operative initiative being taken by Waters, Agilent, Thermo and Shimadzu to develop a common interface for their LC-MS products.

As well as leading the Waters work on the Common Analytical Instruments Standard Interface (CAISI) Matt also leads the Waters delegation to the Laboratory Analytical Device Standard work being done with German federal funding and will be able to comment on progress on that too.

If you work in chromatography or spectroscopy you will find this an invaluable insight to the way the industry is heading.

The conference will also feature information on the implication of developments in nano-technologies for lab companies, take away actions on how to make improvements to your sustainability and boost your bottom line, and a chance to hear from important customers about what they want from you.

Book now to attend the conference, and if you would like to come to the very convivial dinner the night before you will get a chance to meet other members and the speakers in advance.

The conference will take place at Stapleford Park in Melton Mowbray on the 22 March, with the dinner on the evening of the 21st. We are offering a special 'second delegate' rate so that you can bring your key staff along to the conference and make sure that ideas can be disseminated and acted on in your company without you having to do all the work yourself. To book your place, please click here.

Plastic Packaging Tax Update | 1 April 2022

MEMBERS HAVE been asking what's happening about the plastic packaging tax which comes into force this year. Louisa Goodfellow from Ecosurety will be giving us an update on 1st April at 10.30am.

To reserve your place, click here.

Working effectively with distribution partners | 14 April 2022

MANY SALES leads have responsibility for selling both direct and through distributors. This model does present some challenges and in this webinar, Steve Vaughan, senior trainer and coach for George James Ltd will give tips for those in this position.

The webinar will cover:

- Using influencing skills rather than telling
- How to build trust
- Don't be afraid to say no!
- Effective joint visits and
- Managing expectations

To reserve your place click here.

Events

Hydrogen Tech Expo UK 2022 | International Centre | Telford March 31

THE INAUGURAL Hydrogen Tech Expo will provide an opportunity to connect with technology and service leaders and discover advanced concepts technologies and partners. For more information click here.

Future Labs Live | Basel, Switzerland | June 2022

FUTURE LABS LIVE is intended to be a stimulating and exciting event for the future of all R&D labs. The event, which is planning to take place in person, will bring together hundreds of expert speakers and attendees from Europe and North America and has issued a call for expressions of interest in presenting at the event.
More than 50 speakers have already been confirmed including:

- **Simon McSharry** | Senior Director, R&D Tech, GSK
- **Vladislav Zarayskiy** | Director of Automation and Screening Technologies, Monte Rosa TX
- **Nessa Carson** | Principal Automation Scientists, Syngenta
- **Saritha Kuriakose** | Director - Data Integration & Ontologies, Novo Nordisk
- **Eva Aparicio** | Senior Associate, Roche
- **Lesley Shirley** | Senior Staff Scientist, Sanger Institute
- **Jeremy Frey** | Head of Computational Systems Chemistry, University of Southampton
- **Dana Caulder** | Director of Software Engineering, Genentech

If you would like to speak at the event, please register your interest here.

Surfex | Coventry Building Society Arena | 7-8 June 2022

THIS FACE-to-face UK event for the surface and coatings technology industry also offers scientific papers, webinars and a video hub. For more information click here.

Big Science Business Forum | Granada, Spain | 4-7 October 2022

BSBF2022 will be held at the Granada Congress Centre. All registered attendees, sponsors, exhibitors, and participants of BSBF2021 have been automatically transferred to 2022 and do not need to follow any special procedure regarding registration or participation. Further information, the updated programme, and the new calendar is available here.

Lab Innovations South | London | 21 April 2022

EASYFAIRS THE organisers of Lab Innovations have launched a new one-day event based in London. With 30 suppliers and a conference, the event is designed to bring together 500 UK life sciences researchers and laboratory decision-makers for a full day of knowledge-sharing, discovery, and networking.

The conference programme will offer panel discussions, masterclasses, case study presentations, and roundtable debates. The full conference agenda can be found here.

To contact the organisers email: Mauricio.Montes@easyfairs.com

Engage with... LIVE | London | 29 March 2022

A FIRST face-to-face event about the electric revolution for over two years will take place at the Octagon, Sheffield, in March. Designed for people from the Power Electronics, Machines and Drives community (PEMD) the event will allow them to network, collaborate, and attend engaging sessions focused on the electrification processes, improving supply chains, and moving towards a clean technologies future. To see the full agenda and speaker details **click here**.

bioSASH#3 – Faster and safer labs hackathon | Online | 29 March 2022

ALL LABORATORY users, robotics companies, pharmaceutical companies, start-ups & SMEs, students and coders are invited to join SILA's next three online lab automation hackathons.
The three hackathons will bring together laboratory users with a platform of top European experts in the field of automation and IT development to formulate innovative ideas and approaches to solutions for automation in the laboratory.
The target audience for the upcoming hackathons are both experienced and inexperienced coders as well as lab users who wish to exchange with European automation experts in the field of automation and IT development.

Date and topics

- **3 March 2022:** Devices in the local lab and LIMS in the cloud – how to build a smart data integration
- **10 March 2022**: Mobile Robotics/Laboratory Automation Plug & Play with SiLA/ ROS - SiLA bridge
- **17 March 2022**: Processes that require complex information in execution while the hands are busy – (approaches to solutions in the fields of microbiology, chemical analysis and packaging examination.)

Times: 10:00 am – 06:00 pm (CET)
For any questions and more info please contact Jamin Bouras Project Manager BioSASH jamin.bouras@biolago.org

CHEMSPEC EUROPE | FRANKFURT | 31 MAY – 1 JUNE 2022

ChemSpec Europe is Europe's premier sourcing and networking event for the fine and speciality chemicals industry. The Chemical Industries Association (CIA) has co-ordinated the UK group attendance at this event for many years and, for 2022, are

partnering with DIT to host the UK Pavilion. For more details contact Ian Cranshaw at Cranshawl@cia.org.uk or 07951 387048.

This is one of the very few events for which DIT grants are available. UK based SME's wishing to exhibit at this event could possibly receive grants of between £2,000-£4,000, but interested members will need to act quickly! The deadline for applications is 15 March 2022 and applications for grants must be submitted online here.

Further information about ChemSpecEurope available here.

Contamination and Geotech Expo | NEC, Birmingham | 14-15 September 2022

THE EXPO is expected to welcome 3000+ visitors and 100 speakers and offer 60 CPD sessions and free networking events, with an on-site pub, street food market and live music.

Topics covered will include land remediation, brownfield regeneration, air quality, waste and contaminated water and hazardous materials.

The broad programme is split across four theatres, and runs alongside the Flood Expo, Resource and Waste Management and Letsrecycle Live events, which combine to form the UK's largest event for the environmental sector.

In September, the co-located events will welcome more than 12,000 environmental professionals and over 800 exhibitors.

To find out more and register your interest visit the website here.

Export News

Medlab conference predicts increasingly equipment-heavy labs & the migration of routine testing from hospitals to pharmacies

IT WAS a smaller and more intrepid group than usual who joined the GAMBICA pavilion at MedLab in Dubai in January. The more cautious had decided to leave it a year before venturing back, but those who did go were not disappointed. The weather was lovely and co-locating the show with Arab Health (for one year only) improved visitor numbers and as always there was an accompanying conference to ensure that plenty of health and lab staff were there too. With a whole day devoted to 'Lab empowerment through sustainability, and innovation', and frequent papers of interest to lab staff throughout the four days, there was quite a lot to choose from for conference delegates at Medlab Dubai.

One of the major themes of the conference sessions was how advances in equipment could be used to compensate for the shortage of skilled pathologists worldwide. The unceasing growth in path services is not being met by an equal growth in trained and

skilled pathologists with only 3% of UK histopathology departments being fully staffed and 25% of current staff being over 55 years of age. The work of path labs has become more complex, not least because of the growth of cancer cases, the number of medical students becoming pathologists cannot keep pace with the losses.

While there is a growth in the use of university-trained pathologists' assistants, it is improved IT solutions and additional capital investment to implement digital pathology which will make the difference delegates were told.

A doctor from Spain explained how the Catalan region is moving wholesale to digital pathologies. His hospital group had got European funding to provide 24 scanners, and to digitalise 1,200,000 slides per annum with 170 pathologists moving to working on screen and via the internet. With 183 two screen workstations in place the system will eventually be the largest digital pathology network in the world.

Santiago Ramon y Cajal, Professor of Pathology in UAE, presented a paper on precision medicine which compared the costs of different methods of analysis.

Next generation sequencing (NGS), he said, can reduce the time taken to get together all the necessary results for a cancer patient from two to three weeks to less than seven days. The application of NGS can also reduce the amount of tissue required and be cost positive if more than three genes are being sequenced with a cost of between £400 and £2000 depending on how many patients are being tested per week.

He acknowledged the need for technical and diagnostic quality controls but went into some detail on the different applications of gel electrophoresis and Mass Fix. Mass Fix or miRAMM was said to have higher resolution but be harder to read and interpret than MALDI-TOF but to be able to pick up evidence of disease not seen by use of MALDI-TOF.

The rise of instrumentation

Dr James Donnelly, who is currently based in Abu Dhabi, looked at what's coming next in clinical chemistry and mass spectrometry. He set out this history of biochemistry…

- 1920s – Biochemistry adopted
- 1940s-50s – Assay menu grew
- 1960s and 70s - Scalability through automation
- 1970s to 90s - Democratisation of techniques
- 1980s onwards- Improvements in quality management
- 1980s onwards – New uses for established assays for example, Point of Care Tests

He described the current era as the time of the 'rise of instrumentation'

In the early days, manual assays were used and spectrophotometer reagents were prepared in labs. Early industrial scale labs were very labour intensive and chaotic and to try to improve quality, labs implemented six sigma, "but humans can only be efficient up to a point" he said.

He pointed out that over time equipment costs tend to stay stable or reduce and generally quality and productivity improves, whereas the cost of labour, particularly

skilled labour always goes up. Therefore technological advancements are key to keeping costs down in a lab.

Because of increasing demand for lab services it is inevitable, Dr Donnelly thinks, that labs will consolidate to achieve economies of scale and scope and that the hub and spoke model of labs will grow quickly.

“Because of the shortage of skilled staff, there will be big pushes in the future to use pharmacists and physicians collaboratively to manage patients. Physicians can now view test results and adjust medication without ever seeing the patient.”

He expects to see a move to high co-pay health plans, which will be cheaper to buy but will require the patient themselves to pay for a proportion of their treatment. This, he felt, has beneficial effects in encouraging patients to better self-manage their conditions.

Pointing to the growing inequalities in health based on race, religion, income and region he predicted a lack of access to primary care will be likely to affect a growing proportion of the population, even the wealthy.

By 2026 there will be a shortage of between 15,000 and 135,000 primary care physicians in the US so upwards of 30,000,000 patients will not have access to a physician, irrespective of insurance. There is also a corresponding decrease in brick and mortar hospitals and beds.

“People don’t like going to the doctors but they do like going to the shops,” James said. “Pharmacies are shops and they offer a natural solution to the shortage. Pharmacists already do tests and collect specimens in the USA and could be used to provide remote lab services.” He noted that pharmacists felt they had missed out on the Nurse Practitioner revolution and wanted to ensure they got the benefit of the new wave in medicine.

“With the increase in chronic illness, all this means a need for empowerment of patients to take more responsibility for their own care. The new need is to get them in front of someone who can do a test and give them a result – the pharmacist. Some of the major chains are already showing that they are keen to step up and serve patients in this way.”

He sounded a note of warning however, reminding delegates of the case of Elizabeth Holmes who was recently found guilty of conspiracy to commit fraud for stating that her company Theranos had low cost tests available which had minimal specimen requirements. While her claims were found to be false, she very effectively demonstrated the size of the potential market and a number of other companies are now rushing to produce what she claimed she had.

One example of which is ‘Tasso’, a collection device for blood samples which can be used without skilled staff and is said to be ‘relatively painless’. A capillary collection device is also being developed which can apparently obtain sufficient specimen to do 35 assays in less than one minute. The intention is to draw, spin and test at a pharmacy by professional staff with minimal training. James felt sure that dispersed collections and testing will come but that there will remain a need for large central laboratories.

“Labs will continue to grow in size and scope of testing, provided that the costs of testing are better than more distant referral centres. Clients and patients will need convenient fast testing in order to take on empowerment and responsibility.”

Medlab is just one of the overseas exhibitions at which GAMBICA manages a UK pavilion. If you would like to come with us on a future trip, get in touch.

Licensing delays likely to get worse before they get better says ECJU

THE EXPORT Control Joint Unit has admitted that decision-making delays have now reached such a level that it is missing both its 60 day and 20 day processing targets and that the situation is likely to get worse before it gets better.

Focussing on delays and refusals of licenses for exports to China, the China Britain Business Council recently invited representatives of the Export Control Joint Unit to a meeting of some of the affected exporting companies which was attended by GAMBICA.

The targets for the unit are to process 70% of applications within 20 days and 99% within 60 days. In the most recent reporting period the unit actually achieved 62% within 20 days and 58% within 60 days. Refusal rates for China in the last four quarters have been 8.7%, 7.6%, 10% and 12.9%. China represents one of the highest export destinations, the largest by both volume and value. 36-44% of all applications to export to China are refused. The refusal rate for Russia is 17-23.3%. Russia and China jointly account for 58% of all refusals. Refusal rates are overall are 2.2% of applications.

China is now subject to enhanced military end use controls to which makes it likely that many more exports to China, Hong Kong or Macao could need a license. One example given was of wooden batons. These are not military equipment or weapons of mass destruction and would not previously have required an export license but they are used by police in Hong Kong, so now they would. Those in the queue for export licenses have been concerned at the potential for a huge growth in applications, but the ECJU is not worried. “We have decided it is likely to be about 100 additional licenses per year, based on what we know. But it is a guess,” the ECJU team said.

The team pointed out that ‘quite a lot’ of license applications are submitted for items which are not controlled and that this causes delay. They hope to re-institute their outreach to help exporting companies to better understand which items do and which don’t require licenses.

Iain Everett, who heads up the operational team at the licensing unit, explained that the ECJU team work closely with joint advisors in the MOD and other bodies in order to assess applications. Overall he has 115 staff to process 16,000 applications per annum.

Asked about the reason for the increased delays, he denied that application numbers were increasing or that more poor quality applications are being received saying that there was no evidence that Brexit is to blame. “Resources are the challenge” he said, “highly qualified specialists in technical assessment and enforcement are in short supply and we are not able to over-resource. We have to wait until someone leaves before we can replace them and they have to be security cleared which can take up to

six months. We are also moving from the SPIRE to the LITE IT systems which is a drain on resources. In addition, emerging technologies and the geopolitical situation are impacting on our work."

In response the Unit has engaged in an 'organisational redesign'. A new management layer is to be added to give better support to technical staff and carry out line management responsibilities. "We are improving our learning and development packages for staff and looking at our recruitment strategy and career progression.

"We want more interaction with academia and industry to ensure that we understand the new technologies. And for our long-standing cases we want to have a stronger grip on transparency."

Applicants have been particularly critical of the lack of information on applications in progress and on the appeals process. There are plans underway to introduce a Service Level Agreement (SLA) for this process. However, no such SLA exists between the other departments and the ECJU, which must have an impact on the Unit's ability to meet its throughput targets.

One of those at the meeting, Dan Aldridge from Zeiss said that historically, processing speeds in the UK for export licenses have been significantly slower than by their counterparts in Germany.

Iain Everett responded: "Changing an operation is rocky and performance will be negatively impacted before we start to see significant improvements in the medium term in terms of greater visibility and transparency."

CBBC's Andrew Seaton noted: "There is an export competitiveness issue here and DIT's remit is to get the UK to a global trading role. Government's own machinery should operate in such a way that it does not hamper competitiveness. The UK Government needs to do all it can to ensure UK companies can compete on a level playing field."

Evidence submitted on EU trading relationship

GAMBICA HAS submitted evidence to the International Trade Committee for its inquiry into the EU trading relationship via its sister body EAMA the Engineering And Machinery Alliance.

EAMA's six-page submission sets out an objective overview of member firms' experiences so far and views for the future, mindful that the impact of Brexit will vary according to circumstances and opinions. The submission does not attempt to be comprehensive but aims to highlight the most important issues and areas where there is a need for improved government processes.

To read the submission, click here.

Analysis of business risk of trading in the Lebanon

AN EXPLORATION of key security and political risks which UK businesses may face when operating in Lebanon since the Beirut port explosion has been published by the Government here.

Lebanon has a precariously balanced power-sharing arrangement between eighteen sectarian groups and significant inter-communal tensions. In the absence of job-creation or basic state services, most citizens rely on non-state groups with sectarian bases, dominated by a small elite. This creates an environment where corruption is pervasive.

October 2021 saw the worst armed clashes in Beirut since 2008, and security risks are rising due to the deteriorating economic situation, which is manifesting itself in increased crime and conflict over resources, as well as increasing pressures on poorly-paid security forces.

Economics

Lebanon's GDP dropped from 52 billion USD in 2019 to an estimated 21.8 billion USD in 2021. This was the highest contraction of any country. In addition, inequality is very high, with 82% of the population in multidimensional poverty, and 34% in extreme multidimensional poverty.Unemployment is on a rise and exceeded 50% during 2021. Inflation is very high, averaging 423% for food and non-alcoholic beverages, 522% for transportation, 425% for water, gas and electricity, and 405% for healthcare (in December 2021).

Lebanon has multiple exchange rates. Since August 2019, the parallel market exchange rate has diverged from the official exchange rate (1500 LBP/USD), and has depreciated by over 95%. By January 2022, the value of the Lebanese Lira reached an all-time low of 33,000 LBP/USD on the parallel market. The parallel market rate fluctuates on a daily basis. Since January 2022, the Lebanese Central Bank has attempted (with some success) to stabilize the exchange rate by injecting foreign currency into the parallel market, but it is unclear for how long this practice can be sustained, given the pressure that it is placing on the Central Bank's dwindling foreign currency reserves.

Lebanon's banking sector is in a precarious position, with banks having introduced informal capital controls, limiting customer withdrawals and transfers since October 2019. In March 2021, several international banks cut ties with the Lebanese financial system. This led to a loss of confidence in the bank system and a sudden drop in capital inflows, which coupled with a continued large current account deficit (9.8% of GDP in 2021), has led to a gradual depletion in foreign exchange reserves at the Central Bank.

Business

With a long history as a trading hub, Lebanon has historically boasted huge potential from its well-educated population, enterprising youth and innovative tech sector. The private sector, particularly SMEs, forms the cornerstone of the Lebanese economy.

Total trade in goods and services (exports plus imports) between the UK and Lebanon was £565 million in the four quarters to the end of Q3 2021, a decrease of 12.3% or £79 million from the four quarters to the end of Q3 2020.

The top five goods exported from the UK to Lebanon in the four quarters to the end of Q3 2021 were:

- Mechanical power generators (capital) (£29.0 million);
- Medicinal & pharmaceutical products (£15.4 million);
- Beverages (£14.3 million);

- Cars (£11.4 million); and
- Dairy products & eggs (£8.3 million).

Importers wishing to transfer payments overseas have faced challenges due to capital controls imposed by Lebanese banks, but have generally been able to identify other means of payment in order to overcome this issue.

Lebanon imports 80% of its products - most of the country's oil, meat, grain and other supplies come from abroad. Lebanon receives US dollar inflows through tourism, foreign aid, remittances and loans. In turn, the country spends these dollars to purchase supplies across borders. Volatile exchange rates have led to skyrocketing retail prices.

In 2020 Lebanon ranked 143 out of 189 in the World Bank's ease of doing business index (down ten places from 2017). Long-standing infrastructure problems have been exacerbated by the influx of Syrian refugees since 2017 – at 1.5 million Lebanon hosts the highest number of refugees per capita. In the 2018 Global Competitive Index Lebanon ranks 105 out of 137, with government instability, corruption and inadequate supply of infrastructure put as the most problematic factors for doing business.

UK companies should seek professional legal advice should they have, or be considering, entering into agreements in Lebanon. The British Embassy is ready to support UK companies seeking to invest or operate in Lebanon.

Contact the DIT team in Lebanon for more information and advice on opportunities for doing business in Lebanon.

Only 10% of successful applicants receive full grant for overseas tradeshows

ACCORDING TO a report in *The Times* by Richard Tyler, only 10 per cent of the two to three thousand successful applicants to the government's overseas tradeshow support programme will receive a full £4,000 grant.

Another 30 per cent of businesses that meet the Department for International Trade's (DIT) criteria will receive £2,000 towards the cost of preparing for and attending overseas exhibitions. The remaining successful applicants will be offered four hour-long online training modules delivered by the government's Export Academy on how to make use of trade fairs, as well as some advice on the specific one selected. In addition, some applicants will be offered £200 to cover travel to European shows or £500 for shows outside Europe.

The £7.9 million support scheme started as a pilot last November with the aim of 'educating UK-based small and medium-sized enterprises about the benefits of exhibiting at overseas trade shows'. It replaced the longstanding Tradeshow Access Programme, which provided grants of between £500 and £2,500, largely administered by industry trade bodies.

In guidance to the new scheme the DIT stated that its support for trade show exhibitors was open to businesses with between £250,000 and £5 million in sales. Businesses looking for support to send sales reps to attend events have to be smaller, between £85,000 and £250,000 in revenues.

As GAMBICA members are only too well aware, the government support is only available once and applicants found to be planning to 'offshore jobs', which some exporters to Europe have done to avoid the higher cost of servicing European customers from Britain post-Brexit, will be unsuccessful. The choice of trade shows is limited to only those approved by the DIT.

At the time of writing there were six approved trade fairs for exhibitors and 24 for delegates on the great.gov.uk website.

Trade bodies had called on the government to create 'truly world class' trade show support. The Federation of Small Businesses pointed to a Canadian government scheme, which offers C$75,000 (£44,000) in grant funding for a broad range of export-readiness related costs.

The FSB has said that the need for the DIT to make the trade show programme as comprehensive and accessible as possible was pressing: "Even more so now we've left the EU and are striking new trade deals around the world. We're in a global race, and we want UK firms, products, and services at the forefront."

A DIT spokesman said the new programme was ambitious and would: "Help our brilliant exporters in every part of the UK take full advantage of the trade deals we negotiate", adding: "We are supporting a range of tradeshows to help businesses exhibit their first-class products overseas, but this is just the start and we are adding more and more events to our programme to help businesses kickstart their export journey."

Company News

New GAMBICA member's biotech range includes pipette cleaning equipment

GC BIOTECH, a company which started in the Netherlands in 2004 as a distributor for Agencourt (subsequently acquired by Beckmann Coulter) has found a particular niche in the UK in providing cleaning solutions for research labs.

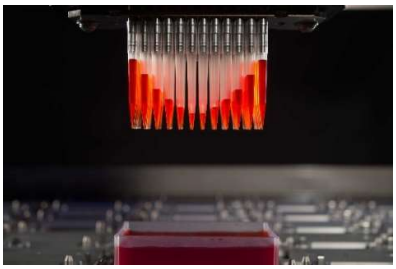
The company, which is the sole EU distributor for key a wide range of lab equipment including automation equipment and manufacturing kits for DNA and RNA isolation, decided that after Brexit, a UK centre was essential to be able to properly serve its clients in Great Britain and has now taken up GAMBICA membership to signal its commitment to the UK market.

Since arriving, the company has found that Tip Wash products from US company Grenova, are particularly popular with high-throughput labs in the UK. The Tip Novus and Tip Novus Mini wash and dry, used pipette tips using a chemical solution and water. The washing process involves air pressure, UV sterilisation and ultrasonic cleaning for smaller

contaminates. These systems are already very commonly used in the US. However, washing pipette tips obviously offers enormous reduction of plastic waste and so has proved popular with the sustainably-minded biotech and pharma markets.

The company also provides a range known as CleanNA offering RNA and DNA and isolation kits and NGS clean up kits using paramagnetic beads. The kits remove salts, primers, primer-dimers, dNTPs, and binds DNA fragments to the magnetic beads particles. Their use can be adapted to most liquid handling workstations used for Down-stream applications such as:

- Next-Generation Sequencing (NGS)
- PCR
- Genomic DNA clean up
- RNA clean up
- Fragment analysis
- Microarrays
- Restriction Enzyme clean up
- Cloning



GC Biotech also distributes Dynamic Devices' Lynx liquid handler which can carry out Volume Verified Pipetting in which each of the 96 heads can be programmed to pipette a different volume. The unique 96 VVP head which delivers 96 individually verified volumes also has 96 sensors that monitor every single tip and the volume entering it. These can be programmed to repeat pipetting until any bubbles or clogs are eliminated, thus significantly cutting waste.

Obviously complex programming is required which can need specialist skills, something with which GC Biotech is very happy to help. This is in line with their aspiration to provide full service for their clients and not to just distribute equipment. They are looking to grow their UK operation quickly and will shortly be appointing a support engineer and further sales staff.

The company is being headed up in the UK by Debora Marchese, (left) a globetrotting Italian with a degree in pharmacy who studied languages and ended up with a masters in Global Marketing. She worked in Taiwan for seven years, as a sales rep and then as head of sales for a biotech company. She moved to the UK to set up the UK branch of the Taiwanese company in 2020, moved for a short while to Inivos the hospital decontamination company before taking the plunge to head up GC Biotech UK.

Debora, and Glenn Nohar, CEO of GC Biotech BV and UK, will be joining us at the GAMBICA conference in March so do take the opportunity to say hello to them there.

My Green Lab, the United Nations' favoured Lab certification company, joins GAMBICA

LABS CONSUME five to ten times the energy per square foot of a typical office space and with the biotechnology market predicted to grow by 15% per year, the United Nations has set out specific, near-term targets for laboratories as part of the UN Race to Zero Campaign called breakthrough outcomes.

Race to Zero is the UN-backed global campaign rallying companies, cities and institutions to take action to halve global emissions by 2030. It has been widely taken up by blue-chip companies, including those in the pharma sector.

AstraZeneca signed up as an early supporter of the Race to Zero Campaign and has set ambitious targets to be net zero across its global operations by 2025 and carbon negative across its entire value chain by 2030.

The UN has highlighted new GAMBICA member, My Green Lab, as a key player to help pharmaceutical and medical tech companies achieve the goal of a zero carbon world by 2050. The United Nations Framework Convention on Climate Change (UNFCCC) Breakthrough Outcome for the Pharma Sector sets out a requirement that **"95% of labs across major pharma and med-tech companies are My Green Lab certified at the green-level by 2030."**

COO of Biopharmaceuticals R&D, at AstraZeneca, Penny James has been quoted as saying: "So far, we've adopted My Green Lab Certification in over 65 labs around the world. This is a key way in which we are accelerating carbon reduction in healthcare R&D and instilling a culture of sustainability at AstraZeneca."

My Green Lab, which is the organisation behind the ACT label for laboratory equipment already used by a number of GAMBICA members, is a not-for-profit environmental organisation with a mission to build a global culture of sustainability in science.

Chief Executive James Connelly, sees a key part of the organisation's remit as inspiring scientists and lab professionals to make a positive change in their labs by reducing the environmental impact of their work and is focused on the marketing and outreach needed to make that happen.

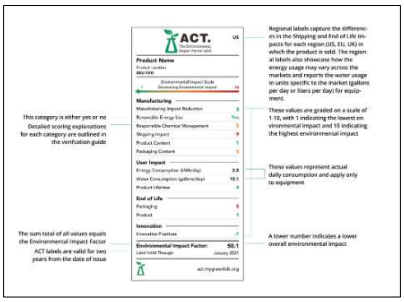
"The High Level Climate Champions' 2030 Breakthroughs outline a bold, ambitious vision, but these goals must be followed up by concerted action with real impact. My Green Lab Certification is a critical tool to drive action on the ground in the industry, and we firmly believe it is possible for all labs globally to go green by 2030 and absolutely necessary if we are going to achieve a long term zero carbon target for the industry."

An architect and economist by training, James Connelly first became involved in sustainability via a Fulbright Scholarship which took him to China to work on their green building system. He then went to work at the Living Future Institute creating a raft of sustainability standards called the Living Building Challenge and the Living Product Challenge, as well as Zero Carbon Building Certification. The Living Building Challenge

has excellent operational energy efficiency as its baseline, but also requires offsetting of a building's embodied carbon. Offsetting is only allowed if it is via certified or verified emissions reduction such as wind power or methane gas recovery, the largely discredited RECs (Renewable Energy Credits) are not allowed.

James was recruited to join the My Green Lab team five years ago by founder Alison Paradise, a neuroscientist. Alison stepped down and James took on the CEO role in June 2020. The organisation has grown quickly since then and has now certified 800 labs in 29 countries and created 1400 Green Lab ambassadors in 40 countries. 14 prominent companies have signed up to have their products certified with an ACT label.

"Building awareness is a core part of our mission, we have presented in-person at 10 conferences all over the world in the last year and at dozens of on-line events every week. We are planning a summit in May which will bring together more than 750 people to discuss the future of labs.



"Our aspiration is that every lab is green and that every lab product is designed with the environment in mind. Science should lead the world in mitigating climate change, but we have been laggards. Not anymore. We think that My Green Lab certification is a key leverage point and that it will drive green procurement.

"The My Green Lab certification is a proven process for driving down energy use in a lab, and it's independently verified. It's the only programme currently in use by biotech and pharma laboratories.

"Green labs are here to stay, and sustainability is going to become a core aspiration and goal for all clients in this industry. We are still at the early adopter phase, so companies still have an opportunity to get ahead and distinguish their products by getting an ACT label. That first mover advantage is not going to last forever, however, given our current and expected growth rate. We think ACT will quickly become ubiquitous. When it is, the program should inspire a race to the top where companies compete to have the best score through a consistently applied framework and level playing field. The cost of ACT is significantly less than other eco-labels in other industries and provides great value to companies in improving their own operations as well as connecting with customers."

Raj Patey and Jack O'Grady from My Green Lab will be at the GAMBICA's Lab conference in March so that you can ask them more about certification of both labs and equipment then.

HR News

Sheetmetal fabrication company in court after worker's finger crushed

A COMPANY specialising in manufacturing canopies and ventilation ducting has been fined after an employee's hand was drawn into the rotating parts of a machine, resulting

in serious injury.
Manchester Magistrates' Court heard how on 14 October 2019, an apprentice of R Briggs Sheetmetal Fabrication Ltd, was instructed by another apprentice and a trainee on how to operate a swaging machine. This consisted of two rotating wheels controlled by a foot pedal, used to put a groove around a ducting tube. After carrying this process out on approximately four pieces of tubing, the apprentice was left to proceed on their own, unsupervised. Whilst continuing the task a the fabric safety glove worn by the apprentice caught in the rotating wheels of the machine. On releasing the foot pedal, the wheels took a few seconds to stop, drawing the apprentice's hand between them. The employee suffered from a crushed fingertip and a fracture. As a result of the incident the worker was unable to work for two months.
An investigation by the Health and Safety Executive (HSE) found that the company had not performed a risk assessment for using the machine or implemented any safe systems of work including recognising that the gloves presented a drawing-in and entanglement hazard on that machine. They did not provide staff with adequate training or assess the additional risks presented by a young, inexperienced person working with machinery and being unaware of existing or potential risks.
R.Briggs Sheetmetal Fabrication Ltd of Bond Street, Colne, Lancashire, pleaded guilty to breaching Section 2 (1) of the Health and Safety at Work etc. Act 1974. The company was fined £13,000 and ordered to pay costs of £2,682.
Speaking after the hearing, HSE inspector Leanne Ratcliffe said: "This incident could so easily have been avoided. Employers should ensure they carry out an assessment of the risks and put in safe system of works for the operation of all machinery. Companies should be aware of their responsibility to recognise the way in which their employees are working. Employers should also be aware of the use of gloves when operating machinery where there is a risk of entanglement."

Employers set to award record pay rises in 2022, CIPD poll finds

FIRMS ARE anticipating a record increase in pay awards this year, a poll of employers has revealed, but experts say a wage hike alone will not solve staff shortages.

The latest **Labour Market Outlook** from the Chartered Institute of Personnel and Development (CIPD) found employers are anticipating a median pay increase of 3 per cent in 2022, the highest figure since the professional body started collecting comparable data in 2012/13.

The survey, which polled more than 1,000 employers, revealed that the majority (84 per cent) are planning a pay review between January and December 2022 – of which four in 10 (40 per cent) say they expect to increase basic pay. Another 7 per cent said they expect a pay freeze, while just 1 per cent said they expect a decrease. The remaining 52 per cent were unsure as to whether pay will increase or decrease.

The CIPD data found that in the three months to January, nearly half (46 per cent) of employers reported having vacancies that were hard-to-fill. Of the firms that had hard-to-fill vacancies over the last six months, 48 per cent increased wages to attract new hires, while 46 per cent advertised more jobs as being flexible.

The Labour Market Outlook also found that over the last six months, 41 per cent of employers reported increased employee turnover or difficulty retaining people. In response, almost half of these firms raised the pay of their current workforce, while 40 per cent said they plan to raise pay in the future.

Initial assessments of substances added to the EU REACH Candidate list in 2021 published

HSE, WITH the Environment Agency, has assessed 11 substances and substance groups that were submitted for identification as Substances of Very High Concern (SVHCs) in EU REACH.

The assessments consider if formal identification as SVHCs is an appropriate action for these substances under UK REACH.

The assessments have been published on HSE's website, along with supporting information on SVHCs in UK REACH:

- Assessments of substances added to the EU Candidate List in 2021
- UK REACH substances of very high concern (SVHC)

As a result of these assessments, HSE and the Environment Agency have identified 4 priority substances or substance groups requiring regulatory management options analysis (RMOA).