

## PSNC Agenda

For the meeting to be held on 9th & 10th May 2017

at Melia White House, Albany Street, London, NW1 3UP

Commencing at 1pm on 9th May

**Members:** David Broome, Mark Burdon, Peter Cattee, Ian Cubbin, Mark Donovan, David Evans, Samantha Fisher, Peter Fulford, Kathryn Goodfellow, Mark Griffiths, David Hamilton, Jas Heer, Mike Hewitson, Tricia Kennerley, Clare Kerr, Sunil Kochhar, Andrew Lane, Margaret MacRury, Fin McCaul, Garry Myers, Bharat Patel, Indrajit Patel, Prakash Patel, Umesh Patel, Jay Patel, Janice Perkins, Adrian Price, Anil Sharma, Stephen Thomas, Faisal Tuddy, Gary Warner

**Chairman:** Sir Mike Pitt

### 1. Apologies for absence

Apologies for absence have been received from Mike Hewitson.

### 2. Matters arising from the minutes

To consider matters arising from the minutes of the March meeting which are not dealt with elsewhere within the agenda.

### 3. Chairman's Report and Chief Executive's Report

## ACTION

### 4. Election of a member of RAP

An additional member of the Review and Audit Panel must be elected. Chairs of subcommittees and the vice chair are ineligible for election.

### 5. Election strategy

A paper is attached at [Appendix 01/05/2017](#) for consideration.

### 6. Formation of a joint Community Pharmacy IT Group

At the January 2017 meeting, the Committee agreed, in principle, to form a joint Community Pharmacy IT Group, which would replace the Pharmacy Voice IT group and PSNC's IT working group. The NPA agreed to host the PV IT group until a new joint group could be formed, and at the time of setting the agenda, drafting of the Terms of Reference (ToR) for the new joint group is nearly concluded.

Based on the discussions so far, it is proposed that the group will meet quarterly and it will be constituted with three members from each of the following bodies: CCA, NPA, AIMP, PSNC and RPS. It is also expected that the NPA and PSNC will jointly provide a secretariat for the group. If the draft ToR are finalised prior to the Committee meeting, they will be circulated by email to the Committee.

To be effective, it is important that the group works closely with pharmacy system suppliers, so they would generally be invited to attend most parts of the meetings of the group.

If agreement is reached on the ToR, it is hoped the first meeting of the group will be at 11am, Tuesday 6th June at the NPA. The Committee is asked to approve the formation of the group, with three members nominated by PSNC sitting on the group.

## **7. Falsified Medicines Directive (FMD)**

PSNC is working on FMD with the other community pharmacy bodies via the UK FMD Working Group. Several PSNC members are members of the working group, having been appointed via other pharmacy bodies (Sam Fisher, Adrian Price and Stephen Thomas).

In February, the working group launched a micro-site which provides basic information on FMD to community pharmacy teams - [www.fmdsource.co.uk](http://www.fmdsource.co.uk); this will be updated as further information becomes available.

The development of systems and technology to allow community pharmacy teams to implement FMD realistically cannot be undertaken until greater clarity is provided by DH and MHRA on how they expect certain aspects of FMD to be implemented. The Delegated Regulations provide some discretion as to how certain aspects of the policy should be implemented and clarity on these matters is required before the design of a system for community pharmacy can be finalised.

DH and MHRA have been drafting a public consultation on these matters, which will be accompanied by a draft impact assessment. While Brexit has not yet altered the UK Government's view on the need to implement FMD, the general election purdah period has now delayed the publication of the public consultation. DH and MHRA have stated that they will seek to publish the consultation as soon as possible after the new Government commences.

On 9th February 2017 – two years before the date on which FMD must be implemented - the UK FMD Working Group wrote to DH to express its concern over the tight timescales for implementation. That letter and the subsequent response from DH is set out in [Appendix 02/05/2017](#).

PSNC will need to respond to the DH public consultation and as further clarity becomes available on how FMD will need to be implemented, we will need to consider the practical and financial implications of this for contractors. The UK FMD Working Group will continue to act as a forum for joint work by the pharmacy bodies on FMD, but there will be specific issues, particularly around funding, upon which PSNC specifically will need to take action.

In order to support the work PSNC will need to undertake on FMD, it is proposed that a limited-life working group should be formed to support PSNC's work on FMD. The work of this group is largely likely to be undertaken via email discussion and teleconference. The Committee is asked to approve the proposal to form a working group.

## **RATIFICATION**

### **8. Resource Development & Finance subcommittee**

A meeting of the Resource Development and Finance subcommittee is scheduled to take place on Tuesday 9th May 2017. The subcommittee chairman will provide a report on the meeting.

### **9. Health Policy and Regulations subcommittee**

A meeting of the Health Policy subcommittee is scheduled to take place on Tuesday 9th May 2017. The subcommittee chairman will provide a report on the meeting.

#### **10. LPC & Implementation Support subcommittee**

A meeting of the LPC & Implementation Support subcommittee is scheduled to take place on Tuesday 9th May 2017. The subcommittee chairman will provide a report on the meeting.

#### **11. Funding & Contract subcommittee**

A meeting of the Funding and Contract subcommittee is scheduled to take place on Tuesday 9th May 2017. The subcommittee chairman will provide a report on the meeting.

#### **12. Service Development subcommittee**

A meeting of the Service Development subcommittee is scheduled to take place on Tuesday 9th May 2017. The subcommittee chairman will provide a report on the meeting.

### **REPORT**

#### **13. PSNC Plans**

The PSNC Plans can be found at the front of the agenda papers.

#### **14. Next PSNC Meeting**

The next PSNC meeting will be held on Tuesday 11th July at the PSNC office (14 Hosier Lane, London, EC1A 9LQ) and Wednesday 12th July 2017 at CCT Venues Barbican, Aldersgate House, 135-137 Aldersgate Street, London, EC1A 4JA.

#### **15. Challenge to Confidentiality**

#### **16. Any Other Business**

## Election Strategy

### Introduction and Community Pharmacy Tactics

On Tuesday April 18th, Prime Minister Theresa May announced that there would be a general election on June 8th.

PSNC's priority remains to build a more constructive relationship with the Government and policy makers in order to develop the community pharmacy service. Key considerations in its election and post-election strategy are therefore:

- There are greater challenges ahead as NHS funding is squeezed and options such as remote dispensing continue to be explored. We must prepare for these.
- There is a need to continue building on the success of the campaign last year – we have built a huge amount of public and Parliamentary support and we must maintain that momentum. That support gives us leverage and a stronger position for the future.
- The election offers an opportunity for community pharmacy to reset relationships, seeking a new and constructive relationship with the new Government after the election.
- There are likely to be a number of new MPs following the election; the earlier we can engage with them to get them interested in healthcare and pharmacy, the better.

In the days following the announcement the Head of Communications and Public Affairs convened a teleconference and then a meeting of the public affairs leads of all the national pharmacy organisations, and the CEO and Head of Communications and Public Affairs met with Luther Pendragon to discuss strategy. PSNC issued a press statement which has been included on the campaign webpage and newsletters, and we have issued an alert to LPCs. The text of the statements and email to LPCs are included in [Appendix 1](#).

### Pre-Election Campaigning

#### Local campaigning tactics

In order to meet PSNC's objectives as set out above, there is a need to engage with as many MPs as possible immediately following the election. That is made easier if they have already been approached and have pledged their support for community pharmacy as Parliamentary candidates before the election. Candidates will be interested in appealing to constituents through the election period, so the advice from Luther Pendragon is that this engagement will best be done locally. The priority will be to engage positively with candidates with a very simple message – community pharmacy is extremely valuable; please make use of it. The advice from Luther is that pharmacy visit photo calls are a good opportunity for any general election candidate, being easy to set up and giving them access to constituents. They also allow us to ask candidates to sign up to a simple pledge to support community pharmacy. Candidates will be asked to pledge their support for community pharmacy, if elected.

We will therefore be encouraging LPCs to set up such opportunities and providing resources to help them to do so. We will offer advice on key messages where candidates already have a good working knowledge of community pharmacy, and background briefings for those who want them, but the priority will be to keep things positive and simple for the very many candidates who will be too busy to have time to get involved in any detail at this stage.

#### Working with other pharmacy organisations

On April 25th representatives from the Royal Pharmaceutical Society, National Pharmacy Association, PSNC and the CCA joined a meeting convened by PSNC. The objective was to align any pre-election campaigning work as far as is possible.

As ever, there is a need to ensure that all messages, both to community pharmacists and to election candidates, are aligned as far as is possible, and at the meeting it was agreed that:

- The objective is to get all candidates to visit pharmacies, sign up to a simple pledge and have their photos taken for press/twitter. The pledge will be to back community pharmacies.
- Engagement will primarily be done locally ie through LPCs and pharmacists. Pharmacy organisations were not planning to meet with candidates directly themselves, but will share information if that changes.
- Messaging should be kept simple, and engagement should be positive.
- We will use the hashtag #pharmacy17 for all visits and promotion.
- We will aim to have a single detailed pharmacy visit guide, which all organisations can endorse.

The RPS will publish guidance for members wanting to get involved in the election and the NPA are producing flyers and resources for their members to write to candidates, hand out to patients, etc. PSNC will produce guidance and resources for LPCs to help them plan pharmacy visits and talk to candidates positively. All organisations agreed to share their resources as they develop them, and we will make them all available via the pharmacymanifesto website which is currently being updated by PSNC (see below). PSNC asked that where organisations talk about pharmacy visits, they ask that these are coordinated via LPCs.

PSNC has set up a further teleconference to discuss this work on Tuesday May 2<sup>nd</sup>, and on a weekly basis from then onwards, to ensure that the pharmacy organisations are sharing intelligence and resources with one another.

#### **PharmacyManifesto website and resources**

In December 2014, PSNC and Pharmacy Voice produced a pharmacy manifesto and associated website: [www.pharmacymanifesto.com](http://www.pharmacymanifesto.com)

Although it was agreed by the communications group that a pharmacy manifesto will be too detailed for candidates in a fast-moving election such as this one, we feel that the website could be a useful resource for the pharmacy sector. PSNC is therefore updating it for use as an internal pharmacy website, hosting all our resources on the 2017 election. There will be a page for any candidates who do end up on the website.

Resources for the website will include:

- A guide to hosting a candidate visit (PSNC);
- Template tweets for pharmacies and candidates;
- A set of proposed questions for pharmacists to ask candidates at any hustings/radio phone ins;
- Flyers and handouts (NPA);
- A guide to getting involved in the election (RPS); and
- Messaging and resources including infographics (PSNC).

The PSNC resources will be available in time for the official start of the election campaign. We expect all of the Parliamentary Candidates to be agreed before the 11th May deadline, and will encourage LPCs to contact them after that point. We intend to launch the website in the week before the 11<sup>th</sup>.

#### **Messaging**

The key messages throughout the election campaign will be:

- Community pharmacy is a trusted and valuable resource, helping people to stay healthy and avoid the need to see their GP or go to hospital. The PwC data can be used to support this.

- The current crisis in social care and the role we can play in helping to alleviate it. Examples to include falls reduction service and domiciliary MURs. We can also cover current support such as compliance aids and delivery which would add to pressures if not provided.
- The current crisis in primary care and the role we can play in helping to alleviate it. Background briefing resources will include an updated briefing on minor ailments, and a briefing on pharmacy's potential long-term conditions role.

Resources for LPCs to use on messaging, both initially and where candidates seek more detail, will include:

- PwC infographics and summary
- The HSJ/LGC article on local community pharmacy services
- Community Pharmacy Forward View resources
- Background briefings as outlined above
- PSNC service prospectuses for the various services being highlighted

### Target candidates

Throughout the campaign for community pharmacy last year, PSNC, LPCs and the other pharmacy organisations were able to build a network of supportive MPs. While these MPs may not all be elected again, we agreed with the other pharmacy organisations that where strong relationships exist, it would be good to ensure that those candidates are approached in the run up to the election. We are therefore producing a list of target MPs, and will call the relevant LPCs to discuss election campaigning with them over the next week or so. The initial list of MPs is included as [Appendix 2](#).

Throughout the election campaign we will encourage LPCs and contractors to tell us about any contact they have made with candidates, most likely using the [team@pharmacymanifesto.com](mailto:team@pharmacymanifesto.com) email address. The Communications Group have agreed to log that information on a shared database so that we have a single record of all MPs engaged with; this is similar to the contact grid maintained through the campaign for community pharmacy last year.

### Influencing manifestos

We have had discussions with Luther Pendragon about how best to influence the main party manifestos and ensure that community pharmacy gets a mention in them. At time of writing, Luther had been in contact with Labour, and we understand that the following paragraph is under consideration for the Labour manifesto:

*Tory cuts to local pharmacies threaten at least 3,000 pharmacy closures across England. Labour has campaigned to save community pharmacies from closing and withdrawing their free NHS services. A Labour government would stop the cuts and protect community pharmacies. Community pharmacies provide valuable services helping people to stay healthy and to manage long-term conditions like asthma and diabetes. This also helps to take the pressure off GP practices and A&E departments, which suffered the worst winter crisis in the history of the NHS this year.*

For the Liberal Democrats and Conservatives, the communications group is going to work to try to secure an inclusion along the following lines:

*Faced with congestion in A&E departments, busy GP surgeries and rising demand for social care, it is more important than ever that we use the valuable network of community pharmacies on our high streets to keep people healthy and out of hospitals.*

## Post-Election Strategy

We expect large numbers of new MPs and through the programme outlined above, we will have a database of those we want to persuade to take an interest in pharmacy for follow-up. Returning MPs will also receive follow-up.

We do not know how likely it is that Jeremy Hunt and David Mowat will retain their briefs. Despite the revelation in the course of the Judicial Review of the misinformation given to the Prime Minister by the Secretary of State and the Chancellor, we plan to focus on constructive relationships, not attack, if possible. Messaging for MPs will include the PwC Value study and subsequent study if agreed. LPCs will be briefed to support local integration initiatives and undertake local follow-up and engagement events.

Key messages for MPs will be:

- Government policy in December 2015 was formed without an understanding of the social and community role of pharmacy and the value revealed by the PwC Value report.
- Public support for community pharmacy services is strong, and it plays a particularly important role in deprived communities.
- We want to build a strong and collaborative relationship again with government, characterised by open, evidence-based dialogue.
- Pharmacy is committed to building closer integration with GPs and is already working to do so at local level.
- It is essential that community pharmacy's role as a social and community resource is understood and evaluated in local government and we want to move forward in this area.
- Remote supply services cannot provide the full value of locally based community pharmacies and large scale closures that would follow pushing greater use of remote supply will add large costs to NHS and social care bills.
- Pharmacy commits to ensuring that the benefits of digital technology identified by the NHS: online ordering of prescriptions and 'click and collect', are available to all patients.
- Developing the value community pharmacies already offer can be key to alleviating the crisis in general practice and we are asking for an opportunity to demonstrate this.

The All-Party Pharmacy Group report will be used to seek to ensure that the Murray review is adopted as policy and implemented. The proposed seminar on Long Term Conditions will be arranged, now most likely to be early autumn.

We expect that a Conservative government may move swiftly to legitimise de-prescribing of a range of OTC medicines and this will affect policy and prioritisation of minor ailments. PSNC's proposals for a national service were for a Minor Ailments Advisory Service, and we will need to ensure that the distinction is understood in developing support for this policy.

A programme of targeted briefings of MPs and peers will be arranged through the summer and Party Conference season, to ensure that the profile of community pharmacy as a popular and valued resource is maintained, and to dissuade the government from damaging the sector.

## Appendix 1

PSNC Statement following the announcement of the general election:

Prime Minister Theresa May has announced that there will be a general election on June 8th 2017. Although the election is likely to be dominated by important and emotive topics beyond healthcare, community pharmacy can also use it to ensure that as many Parliamentary Candidates as possible are made aware of the value that community pharmacy teams provide to the NHS, patients and wider society, as well as the potential they have for creating significant savings and providing additional care if commissioners better utilised their skills.

Following the announcement, PSNC has been in contact with the other national pharmacy organisations and our communications teams are working to coordinate efforts. Joint work will include a programme to brief candidates on community pharmacy and to seek commitments from them and their national parties about the future of the sector.

We will work together to issue guidance on how LPCs and pharmacy teams can help in the run up to the election, with our key focus continuing to be the development of the community pharmacy service for the benefit of patients, the NHS and pharmacy. To ensure that you have all the latest updates on the campaign, sign up to our email newsletters at: [psnc.org.uk/email](https://psnc.org.uk/email)

Email from the Head of Communications and Public Affairs to LPCs following the announcement of the general election:

Following last week's announcement that there is to be a General Election, PSNC has been developing its election strategy. As part of that, yesterday I convened a meeting of the cross-sector communications group. The election offers us a significant opportunity to come together as a sector and engage with candidates across the political spectrum. The priority is to make contact with all candidates locally and to host pharmacy visits for them. Candidates will be asked to pledge their support for community pharmacy, if elected. I know that LPCs have plenty of experience in hosting visits like these, but to facilitate them further we are updating the PSNC guidance on hosting pharmacy visits, and pulling together a range of key messages and resources that can be used with interested candidates.

The priority will be to engage positively with candidates with a very simple message – community pharmacy is extremely valuable; please make use of it. Candidates are going to be very busy indeed, so most will not have time to get involved in any detail. We will have background briefings for those who want it, but the priority is to keep things simple. We must build a constructive working relationship with whatever new Government is formed, so we should keep things positive when talking to candidates during the election campaign. That was agreed by all those attending the communications group meeting yesterday.

We expect the updated PSNC resources to be available next week, in time for the official start of the election campaign. We expect all of the Parliamentary Candidates to be agreed before the 11th May deadline. After 11th May, a full list of candidates will be available here: <https://www.yourvotematters.co.uk/register-to-vote/find-your-local-authority>

We suggest that you might like to contact candidates immediately after 11th May. In our guidance on hosting visits, we will include some draft text that you can use to contact candidates, as well as a press release to promote the visit afterwards.

At the communications group meeting yesterday we agreed that social media should form an important part of the campaign, and that all pharmacy visits should be recorded on twitter and discussed using a shared hashtag – #pharmacy17. We are also agreeing wording of a very simple pledge which we can ask all candidates to sign up to – we can then tweet photographs of that happening.

The NPA, Royal Pharmaceutical Society and other organisations will be producing resources specifically for their members, but these will be in line with all our shared messages. I have also asked specifically that where members are asked to invite candidates for pharmacy visits, the resources ask them to contact their LPC to coordinate this activity.

We will bring all of the available resources together in one place on the [pharmacymanifesto.com](http://pharmacymanifesto.com) website. Melinda at PSNC is currently updating that website, but for this election campaign period we will turn it into a website for pharmacists to use to access all the information they need. We will of course include information for any candidates who do end up on the website, but we expect that to be very few as candidates will have plenty to do over the next seven weeks! We expect to launch the website next week and to issue a joint media release about it. I will of course send all the information to LPCs as we have it.

If you have any immediate questions about the election please do contact me directly on [zoe.smeaton@psnc.org.uk](mailto:zoe.smeaton@psnc.org.uk). We will be in touch with more information soon. In the meantime you may like to familiarise yourselves with some of our most useful resources, including:

PWC Infographic and Report: available in the 'LPC resources' section of [psnc.org.uk/valueofpharmacy](http://psnc.org.uk/valueofpharmacy)  
[CPFV Infographic](#)  
[Potential of community pharmacy infographic](#)

## Appendix 2

Craig Mackinlay	South Thanet	Conservative	Has tabled multiple PQs on community pharmacy.
Alex Chalk	Cheltenham	Conservative	Spoke in support during October pharmacy debate and has tabled PQs.
Derek Thomas	St Ives	Conservative	Has met with PSNC and tabled Westminster Hall Debate and PQs. Spoke in November pharmacy debate. Very supportive.
Jason McCartney	Colne Valley	Conservative	Has met with PSNC. Spoke in support during pharmacy debate. Defied whip to vote for the Opposition Day Motion.
Oliver Dowden	Hertsmere	Conservative	Wrote to Jeremy Hunt in the summer. Spoke in support during November pharmacy debate.
Rebecca Harris	Castle Point	Conservative	Has met with PSNC. Attended APPG Round Table
Sarah Wollaston	Totness	Conservative	Chair, Health Select Committee. Shown good recent engagement with PSNC.
Sir Henry Bellingham	North West Norfolk	Conservative	Is meeting with Mowat on behalf of LPC
Steve Double	St Austell and Newquay	Conservative	Has met with PSNC. Spoke in support during November pharmacy debate.
Victoria Borwick	Kensington	Conservative	Spoke in support during November pharmacy debate.
Yasmin Qureshi	Bolton South East	Conservative	Spoke in support during November pharmacy debate.
Paul Scully	Sutton and Cheam	Conservative	Spoke in support during November pharmacy debate.
Grant Shapps	Welwyn Hatfield	Conservative	Tabled PQs on community pharmacy.
Anne Main	St Albans	Conservative	Spoke in support during November pharmacy debate. Tabled Westminster Hall debate for January.
Tom Brake	Carshalton and Wallington	Liberal-Democrat	Attended party conference event. Has tabled multiple PQs on community pharmacy.
Tim Farron	Westmorland and Lonsdale	Liberal-Democrat	Leader of the Lib-Dems. Has tabled a number of supportive PQs. Spoke in support during November pharmacy debate.
Norman Lamb	North Norfolk	Liberal-Democrat	Attended party conference event. Has tabled multiple PQs on community pharmacy.
Julie Cooper	Burnley	Labour	Shadow Minister of Community Health. Very supportive.
Karin Smyth	Bristol South	Labour	Has met with PSNC. Spoke in support during pharmacy debate. Attended party conference roundtable.
Kate Green	Stretford and Urmston	Labour	Spoke in support during October and November pharmacy debates. Attended APPG meeting.
Rosie Winterton	Doncaster Central	Labour	Has met with local pharmacy to discuss cuts. Spoke in support during November pharmacy debate. Has asked to be kept updated.
Sue Hayman	Workington	Labour	Tabled multiple PQs on community pharmacy funding changes

## Correspondence regarding FMD



*Liz Woodeson CBE*  
 Director, Medicines, Pharmacy and Industry  
 Department of Health  
 Wellington House  
 133-155 Waterloo Rd  
 London  
 SE1 8UG

9<sup>th</sup> February 2017

Dear Ms Woodeson,

I am writing to you today, two years before the serialisation and authentication requirements of the EU Falsified Medicines Directive are due to come into force, to express significant concerns about the timetable for implementation.

The **UK FMD Working Group for Community Pharmacy** brings together expert representatives from trade associations and negotiating bodies across the UK (AIMp, CCA, CPNI, CPS, CPW, NPA and PSNC). Its primary objective is to work with relevant partners to secure the best possible implementation of this complex directive within community pharmacy. We work closely with the stakeholder-led repository organisation SecurMed UK, and representatives from the Department of Health and MHRA regularly attend our meetings. The group has come to the conclusion that the time available to implement the Directive is now insufficient.

The work required to prepare over 14,000 community pharmacies to implement FMD should not be under-estimated. This project represents a significant business change in community pharmacy, and requires IT upgrades in addition to process changes and training, all of which will incur a significant financial cost. We would also raise concerns that a rushed implementation may contribute to patient safety issues that could be mitigated with a more measured implementation period.

In November 2016 the UK FMD Working Group provided the Department of Health with a paper on FMD process mapping and costings. This paper sought to highlight the issues arising with implementing the FMD Directive as it currently stands. The paper described options for implementation, including those that would facilitate change with optimal efficiency and at the lowest cost. In our paper, we highlighted several key matters that needed clarification in order for operational processes to be developed.

The UK FMD Working Group has developed strategies for implementation of the Directive within community pharmacy, but we have now taken the development of these as far forward as possible. The further work required to support implementation of the Directive cannot be

undertaken without the timely provision of guidance from the competent authorities on the key matters identified in our paper. Based on our understanding of the current timelines for the provision of this further guidance, we do not believe that a fully operational system can be delivered by February 2019. Community pharmacy owners cannot make significant financial investments in FMD based on possible implementation approaches.

As it stands, full enforcement of this Directive is due to commence in February 2019, which potentially puts us, and those we represent, in a difficult position. We believe that rigorous discussions should now take place to set a clear and realistic plan of enforcement, with progressive timelines which allow us to move forward together so that we ultimately achieve the objectives of the Directive, but in a planned and efficient manner. Our concern is that without vigour being applied now we could be left in a position where your forthcoming consultation concludes that we are given an impractical workload to achieve in the remaining year before the deadline for implementation. You may also wish to note that there are other sectors that must implement the Directive which are not as advanced as the community pharmacy sector and will require even more time to make their operational decisions. Pharmacy IT systems suppliers have already developed their work programmes for 2017. By November 2017 the work streams for 2018 will undoubtedly have been finalised so the opportunity of having a Patient Medication Record based solution will prove extremely challenging.

We wish to make clear that the UK FMD Working Group seeks to work collaboratively with Government to achieve the common goal of an efficient and cost effective solution which protects the integrity of the supply chain.

I will conclude by saying that the level of engagement from your team, and from staff at the MHRA led by Andy Gregory and Jan MacDonald, has been significant and very helpful. We have had open conversations with MHRA and DH staff, and they have been very accommodating in agreeing to attend many of our meetings to contribute to discussions. Their contributions to this unique project should be commended.

Yours sincerely,



Rajesh Patel MBE  
Working group chairman  
On behalf of the members of the UK FMD Community Pharmacy Working Group

cc:  
Dr Ian Hudson, Chief Executive, MHRA



Department  
of Health

Wellington House  
133-155 Waterloo Road  
London SE1 8UG

Tel: 020 7 972 2000

7<sup>th</sup> March 2017

Rajesh Patel MBE – by email  
Working Group Chairman  
UK FMD

*Dear Mr Patel,*

Thank you for your letter of 9 February alerting me to concerns raised by the UK FMD Working Group for Community Pharmacy about the timetable for implementation of the Falsified Medicines Directive. I am glad you shared this with me as it is very important I should be aware of views like this. It also gives me a chance to – hopefully – offer you some reassurance.

Until exit negotiations are concluded, the UK remains a full member of the EU and all the rights and obligations of EU membership remain in force. During this period the government will continue to negotiate, implement and apply EU legislation. The outcome of the exit negotiations will determine what arrangements will apply in relation to EU legislation in future once the UK has left the EU. However the UK remains committed to putting in place measures to protect against the public health threat posed by falsified medicines.

I can assure you that we do not underestimate the challenge of implementation. This is a complex project being delivered to a tight timetable. However I believe the UK is in a good position. We know from previous experience that the strong relationships we have in place, including with the pharmacy sector, can help deliver critical public health projects on time. Whilst we recognise there has been a hiatus whilst we have consolidated our implementation plans and developed positions on key issues, over the next few months significant steps forward will be made:

- SecurMed are expected to complete the tender process for the software provider which will allow pharmacy IT systems the contact point to progress work on connectivity;
- The UK government will be publishing a draft impact assessment as part of a formal public consultation which will invite views on proposed steps we will be taking to implement the Directive; and

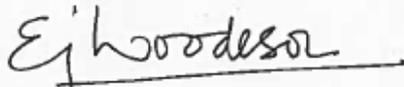
- Further guidance addressing key implementation questions will be released through the newsletter, stakeholder engagement and our website.

I would like to thank the UK FMD Working Group for the paper on process mapping and costings. This was analysed as part of our work on the draft impact assessment and has also been helpful in identifying other issues where we need to publish guidance. When considering implementation issues, it is important to be clear that there is a distinction between where we do and do not have the legal scope to make alternative arrangements for the UK. The public consultation will focus on a small number of areas where there is discretion to consider different implementation options. However, it will not consider additional proposals beyond the current scope of legal flexibility; this includes a number of issues raised by the Working Group. From a positive perspective, issues of this nature are not tied to the consultation timetable and we will be seeking to address these in parallel. As a first step, please see the attached annex which addresses a number of the key concerns raised in your paper from November.

We do understand that stakeholders need the UK's approach to implementation finalised as soon as possible. We want to continue to work constructively with you and others in different sectors to deliver implementation on time and to the right standard, to help to protect patients from harm.

I am extremely grateful for all your hard work and commitment thus far. I do not underestimate the size and complexity of the task ahead. But I hope very much we can continue to rely on your help and support so that together we can deliver on a system that will bring very positive benefits for patients.

Yours sincerely,



Liz Woodeson

Director of Medicines and Pharmacy

cc: Dr Ian Hudson, Chief Executive, MHRA  
Claymore Richardson, MHRA

## Annex 1 – Response to FMD process mapping and costing paper, November 2016

The Delegated Regulation (EU) 2016/161 published in February 2016 sets out the rules and obligations that legally stakeholder and member states are required to meet. EU Regulations apply automatically in all EU member countries and is therefore part of UK law; as a general rule we do not need to transpose a Regulation separately unless there are areas where there is specific discretion (as we have for 'Safety Features'). We do need to make UK specific legal changes to ensure that non-compliance can be enforced through sanctions (this will be part of the public consultation). Separate guidance is issued by European Commission and member states to help with implementation and compliance. The Commission's latest Q&A is available on their website: [https://ec.europa.eu/health/sites/health/files/files/falsified\\_medicines/qa\\_safetyfeature\\_v5\\_0.pdf](https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/qa_safetyfeature_v5_0.pdf).

As noted, some of issues raised are beyond the scope where we have legal flexibility to make changes. Please see the responses below which address a number of the key points raised in the Working Group's paper (November 2016):

- **Article 22 inhibiting implementation post Brexit:** Whilst it is not possible to predict exactly what relationship the UK will end up having once we have left the EU, there is nothing explicit within Article 22 from a legal perspective which would suggest that that the UK would be prevented from entering into its own agreements with the EU. This would enable the UK to be part of a wider European FMD verification system.
- **10 day rule:** The Delegated Regulation sets out in Article 13(1)(b) that reverting the status must not take place more than 10 days after the unique identifier was decommissioned. This is a legal obligation over which we do not have that scope to make changes.
- **Definition of supply needs to be broad:** We have always recognised that the UK has a more complex supply chain than much of Europe. As you know some concessions were secured in the Delegated Regulation to take account of particular characteristics of supply chains. This includes flexibility for member states to enable wholesalers to decommission in certain circumstances and recognising split packs. Further there is also an understanding that aggregated codes may be used. However, the EU Commission were clear that the effectiveness of the system in preventing falsified medicines as well as other benefits such as those which have expired, been recalled or withdrawn reaching patients rely on decommissioning happening at the point of supply to the patient. As you know, the legislation to

enable hub and spoke across different legal entities has not been progressed; this will be one of the aspects that would need to be addressed.

- **Standalone or integrated system**: This is a decision for the pharmacy sector to explore with their system suppliers. Both options could possibly fulfil the minimum obligations to verify and decommission products under the conditions set out in the Delegated Regulation.
- **Definition of 'time of supply'**: The Delegated Regulation sets out in Article 25 (1) that the decommissioning should happen at the time the product is supplied to the public. As outlined above, the EU Commission has been clear that they envisage this happening at the point of handing to the patient.