Annex G – Response sheet

Instructions

- If possible, please send responses electronically to medicines.consolidation@mhra.gsi.gov.uk using the following table. Even if you reply in hard copy, please use this table.
- If any of your answers refer to specific regulations in the draft consolidated regulations, please provide the regulation number and corresponding 'j-number' (this is shown in square brackets after the regulation number) in the relevant columns.
- Please provide any other observations in the second table below. Use one row per comment, and add more rows if necessary.
- Please also complete and return the confidentiality template at Annex H.

Respondent details

Please provide your details as requested below. The second and third pieces of information would assist us in delivering the Government's commitment to engage with small, medium and micro businesses.

- Please provide your name and (if relevant) the organisation or body you represent: Jo Mullin, College of Optometrists. Submitted in partnership with the Optical Confederation.
- Please tick this box if you or the body you represent are in the NHS or public sector: ☐ *Please see further comments section*.
- If you represent a private sector company, please indicate the number of employees in the company by ticking the relevant box below:

9 or less ☐ 10-49 ☐ 50-249 ☐ 250 or more ☐

	Question Number	Question	Response	Regulation number (if relevant)	J-number (if relevar
	1	Are there any benefits and costs of consolidation other than those outlined in the impact assessment? If so, what are they?			
	2	What other evidence is there of the benefits and costs of consolidation for you or your organisation?			
	3	Please review the sections relevant to your industry and/or body and provide comments on the accuracy of our assumptions. In particular, we would like to know the following:			
	3a	Approximately how much time does your firm or body currently spend every year understanding the regulations as they are currently drafted?			
	3b	What change in this annual amount of time would you expect as a result of the consolidated regulations?			
	3c	Roughly how much time			

		do you think your firm or body will take in familiarising itself with them?			
	3d	Where relevant, how much time do you estimate your firm or body will require to alter your own guidance material in response to the consolidated regulations?			
	3e	What is the approximate wage rate of the staff who will engage in understanding regulations and revising guidance?			
	3f	Is our assumption that small and micro businesses generally rely on their trade and professional bodies for regulatory information correct?			
	4	Do you agree with the structure of the draft regulations? Why, or why not?			
	5	Do the draft regulations introduce any changes other than those outlined in this document?			
	6	Are there any drafting errors in the draft			

		regulations?			
	7	Are there any provisions in the draft regulations that could be made clearer?			
	8	What should we do to help users prepare for the entry into force of the consolidated regulations?			
	9a	Should we add more requirements to Reg 3 [j002B] for medicinal products that fall outside the scope of the consolidated regulations? If so, what?			
	9b	We have replaced the term “prepared” that was used in a few of the exemptions in the Medicines Act 1968 with “manufactured”, as we believe that term covers the making of any product. Do you see any difficulties with this?			
	9c	Is the provision too narrow or too broad in any respect?			
	10	Is the new definition of advertisement sufficient to cover all relevant forms of advertising?			
	11	Do you agree with the proposals for the two			

		simplifications in relation to herbal medicines? Why, or why not?			
	12	Do you agree with the proposal to remove the requirement to dispense certain medicinal products in fluted bottles? Why, or why not?			
	13	Do you agree with the proposal to remove statutory warnings, including for paracetamol? Why, or why not?			
	14	Do you agree with the proposals to change the persons appointed process? Why, or why not?			
	15	Do you agree with our proposals to remove exemptions that are obsolete or no longer relevant? If not, why?			
	16a	Do you agree with our proposal to extend to other organisations concerned with research the provisions allowing sale or supply of medicines to universities and institutions concerned with research or higher			

		education. Why, or why not?			
	16b	If such a change were introduced, should it be subject to the exclusion of any classes of medicines in addition to controlled drugs? Why, or why not?			
	17	Should the limit on the size of ampoule in which water for injection can be supplied be extended to 5ml? Why, or why not?			
	18a	Should the existing exemption allowing the administration of Adrenaline by injection by any person for the purpose of saving life in an emergency be amended to allow injection up to and including 1 in 1000?			
	18b	Should an increased range of Adrenaline preparations be subject to any limitations on the route of administration. Why, or why not?			
	19	Should Paracetamol and Ondansetron be added to the list of medicines that can be			

		administered parentally by registered ambulance paramedics on their own initiative? Why, or why not?			
	20	Should people be allowed to obtain water for injection for purposes other than parenteral administration without a prescription? Why, or why not?			
	21	Should pharmacists be allowed to sell or supply water for injection without a prescription for purposes other than parenteral administration or for use as a dilutent where no dilutent has been specified by the prescriber? Why, or why not?			
	22	Should holders of the Council's Advanced Life Support (ALS) certificate be allowed to administer Adrenaline and Amiodorone in emergencies involving cardiac arrest? Why, or why not?			
	23	Do you agree with the proposal to retain the	Yes.		

		general structure and requirements of PGDs in their current form, and to retain the principle that only registered health professionals should be able to use PGDs?			
	24	Should NHS bodies be able to supply medicines in accordance with the written directions of an independent nurse, pharmacist or optometrist prescriber? Why, or why not?	Yes. There is no merit in preventing NHS bodies from supplying medicines prescribed by optometrist independent prescribers since it complicates care for eye care patients by creating a regulatory barrier that in no way adds to patient safety. The proposed change would speed up patients' access to medicine. It would also achieve the MHRA's objectives of simplifying regulation, removing obsolete provisions and cutting worthless red tape.		
	25	Should independent hospitals, clinics etc. in England continue to be allowed to use PGDs but by reference to them being registered for the following regulated activities in England? • treatment of disease, disorder or injury • assessment of persons under the Mental Health Act 1983 •surgical procedures •diagnostic and screening procedures •midwifery services. Why, or why not?	Yes. This would improve the coherence of regulation and we cannot see any negative consequences for the care of eye care patients as long asPGD's are only used when alternative mechanisms to provide medicines to patients are not available.		
	26	Should dental practices	Yes. To forbid clinicians from using the same medicines to treat public and private		

		and dental clinics registered with the CQC or private dentists registered with its equivalent in Wales be able to sell, supply or administer medicines under PGDs? Why, or why not?	patients is confusing for patients and clinicians and detrimental to patient care. Furthermore, we would strongly urge the MHRA to extend the scope of this regulation though to enable optometrists to sell, supply or administer medicines under PGDs as well when treating patients outside the NHS. The logic of the case is identical to the MHRA's argument for enabling dentists to sell medicines under PGDs. Optometrists see a mix of private and NHS patients, in the same premises, adhering the same statutory General Optical Council regulatory framework. It makes no sense to treat a patient differently depending whether or not they are currently eligible for an NHS sight test and to do so is a wholly unhelpful regulatory barrier that diminishes optometrists' ability to care for their patients. We would be very happy to work with MHRA to implement this change.		
	27	Do you agree with the proposal to facilitate the optimisation of medicines use? Why, or why not?			
	28	Do you agree with our proposal for keeping the consolidated regulations up to date? Why, or why not?			

Further comments (please use a separate row for each comment and insert more rows if necessary)

Number	Further comment	Regulation number (if relevant)	J-number (if relevant)
	The College of Optometrists is the Professional, Scientific and Examining Body for Optometry in the UK. With around 13,000 members, it is a registered charity working for the public benefit. The College has prepared this response in partnership with the Optical Confederation. The optical represents the 12,000 optometrists, the 6,000 dispensing opticians and 7,000 optical businesses in the UK. The Confederation is a coalition of the five optical representative bodies: the Association of British Dispensing		

	Opticians (ABDO); the Association of Contact Lens Manufacturers (ACLM); the Association of Optometrists (AOP); the Federation of Manufacturing Opticians (FMO) and the Federation of Ophthalmic and Dispensing Opticians (FODO).		