ECOO EUROM I and EUROMCONTACT Response to 'measures for improving the recognition of prescriptions issued in another Member State'

Introduction

1. The European Council of Optometry and Optics (ECOO), EUROM I and EUROMCONTACT are delighted to have the opportunity to respond to the consultation on 'Measures for Improving the Recognition of Medical Prescriptions issued in Another Member State'. Overall we support the initiative which we feel is in European patients' and consumers' interests.

2. ECOO represents optometrists and opticians in 31 European countries. ECOO members are principally prescribers and dispensers of ophthalmic and optical medical devices including spectacles, contact lenses, contact lens solutions and low vision aids from primary eye care optical practices.[1]

3. EUROMCONTACT represents the national associations and the international manufacturers of contact lenses and contact lens care products – therefore suppliers of medical devices.[2]

4. EUROM I represents the national associations of manufacturers of corrective lenses, frames, and instruments for opticians (totalling 700 companies) – also suppliers of medical devices.[3]

5. Having reviewed the consultation documents and EC Directives we are not convinced that the unique characteristics of our sector have been considered. We would like to take this opportunity to set out some of the unique characteristics of optometry and optics, which will feel should not be overlooked and require careful consideration. We are ready to assist DG Sanco in this task, to deliver seamless yet safe care and access to vision correction for our patients when moving across borders.

6. As DG Sanco will doubtless be aware, optometrists and opticians have not historically been included in the automatic recognition framework of the Recognition

[1] http://www.ecoo.info/
[2] http://euromcontact.org/
[3] http://www.eurom1.org/

of Professional Qualifications (RPQ) Directive due to the broad and varied landscape of these professions across the EU. ECOO is working to harmonise the education of optometrists and opticians across Europe and our medium term goal is for these professions to be included in the automatic recognition framework of the RPQ.

7. In the vast majority of Member States, a prescription can only be issued for spectacles or a specification for contact lenses after visiting an eye care professional or medical doctor. Performing eye examinations or sight tests and fitting contact lens are therefore protected functions under national laws. As DG Sanco will also be aware, under the Cross Border Healthcare Directive (CBHC) 2011/24/EU the definition of prescription is linked to the RPQ Directive. We would like to add for clarity that for reasons of the protection of the public health we believe that the prescribing, fitting and dispensing of ophthalmic medical devices should be included under the provisions of the CBHC.

8. While dispensing is in the main a protected function, in some cases dispensers of optical appliances include corporate groups that may be may not necessarily employ a healthcare professional. We have concerns that by specifying only healthcare professionals, those corporate groups or businesses that do not employ healthcare professionals will not be subject to the same verification and identification requirements, creating a risk to the public's health and distorting the market.

9. ECOO, EUROM I and EUROMCONTACT would be happy to assist in the implementation of the CBHC for our sector, and we would welcome a meeting to discuss cross border healthcare in our sector at the earliest possible opportunity.

Prescriptions from Eye Care Professionals

10. The CBHC Directive and consultation papers specify that a non-exhaustive list of elements should be clearly identifiable on a prescription to facilitate dispensing (ref: CBHC Article 11 (2) (a-d)). We would urge DG Sanco to exercise caution in this regard as a prescription is also issued after a sight test or eye examination (prior to fitting or dispensing an ophthalmic medical device), the content of which differs markedly from other medical prescriptions.

11. If legislating for or specifying the content of an eye examination or sight test prescription, further consultation within the eye care professions would be essential to ensure that any proposed 'exhaustive list of elements' fits our patients' needs. Otherwise we fear that the list would include elements which are not at all relevant to spectacle prescriptions for example dosage or active substance. On the other hand, necessary information like replacement frequency of contact lenses may be

missing. We would be more than happy to work with DG Sanco to ensure that a system can be devised that works for eye care professionals.

Prescription for Ophthalmic Medical Devices

12. In most EU Members States, under national laws, on completion of an eye examination or sight test, the patient must be given a copy of his or her prescription, or a statement that the current prescription has not changed or that none is required.

13. A prescription following an eye examination or sight test should include:
    - Patient name, address and date of birth
    - Power of vision correction if required (including spherical, cylindrical components and axis as required
    - Date of prescription and time limit
    - Contact details of the prescribing eye care professional (including email?)
    - Signature of the prescribing eye care professional
    - The registration number of the prescribing eye care professional (and country of registration)
    - In some countries whether the eye examination or sight test was state funded or private (as appropriate under national laws).

14. In our view the national authorities should provide an online register of their registered healthcare professionals. We feel this is the most appropriate solution to allow the supplier of the devices to check (as appropriate) that the prescribing professional is in fact registered.

Supplementary and Independent Prescribing

15. We would also like to echo the comment made by our colleagues in pharmacy (PGEU – Pharmaceutical Group of the European Union) that relates to supplementary and independent prescribers of certain medicines. Prescriptions issued by a supplementary or independent prescriber, for example a pharmacist or accredited optometrist in the UK, should be valid in other Member States.

Dispensing of Ophthalmic Medical Devices

16. When dispensing an ophthalmic medical device (appliance) there are service aspects to the dispense that are integral to the supply, for example a discussion of the most appropriate appliance for that patient's needs, measurements necessary to ensure appropriate fitting of the appliance, and adjustments to the appliance to ensure appropriate wear. The dispenser should also check what is being ordered against a verified original prescription.

Specification for Contact Lenses

17. As noted above, the fitting of contact lenses is a regulated medical function which results in the issuance of a specification of the appropriate contact lens and wearing modality. A specification allows the patient to choose where he or she might have their contact lenses dispensed.

18. A contact lens specification should include:
    - Patient name, address and date of birth
    - Lens specifications (manufacturer and type of lens (brand and material name) base curve, peripheral curve, total diameter, power)
    - Wearing schedule
    - Replacement frequency
    - Recommended care system (if required)
    - Date of next aftercare
    - Time limit of specification
    - Name and contact details of the prescribing eye care professional
    - Signature of the prescribing eye care professional
    - In some countries registration number of the prescribing eye care professional.

Time Limits on Prescriptions and Specifications

19. For reasons of public safety, the majority of EU Member States have statutory legislation that includes a time limit on an ophthalmic prescription or specification, as appropriate for the patient's needs. We believe that regular eye tests and refitting of contact lenses are important to detect changes to the eye and systemic health (for example conditions such as diabetes or hypertension can be uncovered at an eye examination or sight test). Regular eye examinations or sight tests are also key to detecting avoidable sight loss, 50% of which is estimated to be preventable if detected and referred promptly.

Verification System

20. The United States operates a verification system for contact lens prescriptions (known as specifications in some Member States) which requires the dispensing party to verify the specification with the original prescriber under the Fairness to Contact Lens Consumers Act 2003. The dispensing party must allow the original prescriber eight working hours to respond to the request.

21. The supplier in the US must provide the prescribing party with
    - Patient's full name and address
    - Contact lens brand, material, power, manufacturer, base curve or appropriate designation, and diameter when appropriate

- Quantity of lenses ordered
- Date of patient order
- Date and time of verification request
- Name and contact details of contact person at seller's company

Records of communications relating to the proof of verification must be kept for three years.

22. We believe that since DG Sanco is considering verification of prescriptions, the US system provides an interesting model that could apply to the EU, subject to not conflicting with national laws. As above, we would be pleased to assist DG Sanco on this initiative.

Language Barrier

23. Prescriptions and specifications issued by eye care professionals should be relatively easy to interpret given that the key information is recorded in digits.

24. However, some misunderstandings or errors could arise from working between languages. To assist the verification of a prescription or specification for ophthalmic medical devices, it would be helpful if there were an online resource (possibly held and updated by the EMA) with sample optical prescriptions and specifications in the 23 official languages of the EU available to download. We would be happy to work with DG Sanco and the EMA to ensure these are appropriate for eye care professionals and ophthalmic medical devices, and in accordance with national requirements.

25. Practical difficulties could also result when checking the validity of the prescriber. As stated above the national authorities should provide an online register of their registered healthcare professionals in a clear format.

26. We appreciate that there is a difficult balance to strike and that supply to the patient should not be delayed if at all possible, however as stated above there should be a requirement on the healthcare professional or supplying corporate group that ensures that the prescription or specification be checked, and records kept of the communications, as a safeguard to minimise the risk of error and protect patients.

Substitution of Ophthalmic Medical Devices

27. As DG Sanco has indicated, substitution of medical devices is in some instances in a patient's best interest, but this should only be done following careful consideration of patient safety. While not relevant to prescriptions following an eye examination or sight test, the issue of substitution does arises in contact lens wear. As noted above, a specification is issued which the patient can use to purchase contact lenses,

usually up to a specified time limit. In our view in limited circumstances substitution of contact lenses can be in the patients' best interests and therefore appropriate.

28. Appropriate substitution would be where the fitting optometrist/CLO/provider substitutes a near identical contact lens for instance because
    - a private label version of the exact same lens is supplied
    - a better (upgraded) version of the lens has come on the market, and it does not require a re-fit i.e. the fit is equivalent
    - there has been an interruption of supply for some reason and, rather than putting the patient at risk either of wearing old lenses or of going without vision correction, the provider substitutes for a short time with a very similar lens and recalls the patient for an aftercare/further fitting to verify the suitability of the chosen lens.

    We strongly believe that substitution of contact lenses should only be permitted under these circumstances.

29. In all other circumstances, the patient should see an appropriately qualified and registered practitioner to be properly refitted with the proposed other contact lens.

30. For example, inappropriate substitution would mean that a contact lens which is not identical or near identical to the original is substituted for instance
    - without a proper fitting, verification, or follow-up aftercare
    - by operating on the basis that "one size fits all"
    - without fully informed consent of the patient (inform about the differences between the lenses (especially the material and geometrical (design) ones) and the reasons, as well as the risk for the proposed substitution
    - on the basis of simple cost benefit to the provider whether or not this is in the patient's best interests.

31. For ophthalmic medicines and drug prescriptions, our view is that substitution should only be permitted in limited circumstances where it is in the patients' best interest, for example where a registered practitioner or pharmacist opts for a generic substitute because the prescribed drug is not available in another Member State.

Roadmap Proposal (Version 2) for Implementation of Recognition of Precriptions under Article 11 para 2 (CBHC)

32. As above we believe that to ensure a level playing field, corporate groups should also verify prescriptions/specifications and be required to keep a record of related communications.

33. We support the policy objectives outlined in the Roadmap, although we feel that the unique characteristics of optometry and optics require further careful consideration.

34. We favour Option 2 for a 'core set' – a non-exhaustive list of elements for cross border prescriptions, which for our sector should facilitate checking authenticity of the prescription, safe supply and substitution, while providing comprehensive information to patients. We strongly oppose the imposition of prescriber database applications at Member State or EU (Options 3 and 4) level as being overly bureaucratic, costly and disproportionate to the numbers of patients that access healthcare across borders.

35. We feel that as prescribers, dispensers, manufacturers and suppliers of medical devices we should be involved in the targeted consultations with key stakeholders. We would welcome a meeting with the implementation team in early 2012.

This has been submitted by Mr Mark Nevin mark@fodo.com on behalf of ECOO, EUROM I and EUROMCONTACT.

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