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PROPOSED PRIORITIES FOR THE COMING THREE YEARS

Paper prepared by the Presidium

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Proposed priorities for the coming three years

Purpose and scope of this document: focus points for the three coming years

This document provides information on the proposed Presidium's priorities for the next three years. It is an outcome of a discussion between the Chair, the two Vice-Chairs and the Ph.Eur. secretariat. Of course there may be developments that will require an update of the priorities defined in November 2013. These priorities will therefore be periodically reviewed by the Presidium.

The following topics do not represent an exhaustive list, but highlight issues and activities which, for the Presidium, require further follow-up in order to ensure the Ph.Eur. remains a leading pharmacopoeia, recognised throughout the world.

1. Taking account of scientific/technical developments

We need to make sure that the Ph. Eur. continues to fulfil the need of its stakeholders: NCAs, industry etc...The 2010 conference “The European Pharmacopoeia. Is it prepared for the future?” collected feedback from stakeholders on their needs and identified a number of topics that should be addressed.

One of the most important topics relates to **biologicals**, an area in which there clearly is a need to further improve acceptance of biological monographs by assessors (and industry) and assure that future new molecules, e.g. modified proteins and monoclonal antibodies, are covered adequately in the Ph.Eur.. While the Presidium is happy that a number of steps have already been taken to promote the work in the field after the Prague conference, e.g. a closed workshop with representatives of competent authorities to discuss how best to proceed that took place in February 2011, followed by a number of smaller meetings with regulators, this topic needs further follow-up and action.

Finished product monographs in the Ph.Eur. were identified at the Prague conference as crucial to ensure the required quality level of finished products in Europe and to maintain the essential role of the Ph. Eur. in the global protection of public health. This need should be balanced with the need of not stifling innovation. A pilot-project on finished product monographs has been initiated since; its outcome will hopefully be presented to the Commission in its March 2014 session to enable it to take a decision on future action.

In the context of the **control of impurities**, use of **Fast-LC** has been identified as an issue – and taken up by the CST working party. The use of **NMR** in the control of impurities and **more flexibility** in the use of LC-MS techniques are further topics that need to be followed-up.

As regards combating **counterfeit medicines**, the COM has so far taken the position that the Ph.Eur is a single reference work for the quality control of medicines which does not provide methods to detect counterfeited or adulterated products as adding such texts in monographs may give the wrong impression that by applying the Ph.Eur., adulteration of the product can be detected. However, some exceptions to this rule have already been decided by the COM on a case by case basis, e.g. in the case of heparin. In the context of globalisation, the Presidium considers that this topic merits further discussion and the position may need to be revised in the future. Possibilities would be to contribute advice (e.g. General Chapter/s) and/or tools (e.g. methods) that allow a screening of products with the target to detect unexpected and undesired components.

As regards the evolving **new quality paradigm** – the application of e.g. **Quality by Design** and **RTRt**, the COM has adopted a number of new or revised texts that facilitate and encourage the application of innovative approaches. However, work is still on-going with the revision of general chapters. In addition, the Presidium feels it is important to further follow developments, e.g. in the field of application of QbD principles to analytical methods, and to continue these activities.

In an international comparison, the implementation of the **3 Rs**, another topic of the Prague conference, is most developed in Europe. For the Ph.Eur., a good initiative to further move ahead would be to review the current monographs in order to list the tests using animals to provide transparency and, if possible, define further actions, in parallel and complementary to the activities of the EDQM's Department for Biological Standardisation, OMCL Network and Healthcare (DBO) in the field.

These are just the major high-lights from the Prague conference. The Presidium will closely follow-up their development and propose further actions, if appropriate.

1 In addition, the Conference foreseen for the 50th Ph. Eur. Anniversary will be an excellent opportunity to
2 collect further and updated feed-back from stakeholders.

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4 **2. Status/role/influence of the Ph. Eur. short term, medium term, long term**

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6 The Presidium fully supports the activities of the Ph.Eur. at an international level – the **Pharmacopoeial**
7 **Discussion Group**, contributions to the drafting of **Good Pharmacopoeial Practices** under the auspices
8 of the WHO, and the **collaboration with sister pharmacopoeias**, e.g. the prospective API harmonisation
9 run with the USP – which the Japanese Pharmacopoeia now has joined for some substances.

10 However, the Presidium is convinced that we need to reflect further on how to strengthen the position of the
11 Ph. Eur. worldwide. Some elements have already been high-lighted in the summary on the outcome/follow-
12 up of the Prague conference. In addition, the Presidium plans to draft a **Ph.Eur. strategy paper** how a
13 “modern, fit for purpose” monograph should look like, acknowledging that different solutions might be
14 necessary depending on the type of the monograph. First discussions have already taken place in the
15 context of biologicals.

16 A certain number of **observers** participate in different activities of the Ph. Eur.: - this is a potential unique to
17 the Ph.Eur. and it is considered worth to reflect on how to involve them more actively in order to promote
18 the Ph.Eur. worldwide and benefit from their experience and expertise. The Presidium was already pleased
19 to see the number of experts to the groups of experts and working parties, proposed by observer countries,
20 but it would good to have even more countries become actively involved in the elaboration of the Ph.Eur.

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22 **3. “User friendly” information on the Ph. Eur.**

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24 Members of the COM are very familiar with the Ph.Eur. However, stakeholders not that intimately involved
25 in our activities may find the “Blue Book” not that evident and self-explanatory, in addition they may lack
26 background information. Therefore, the Presidium will reflect on how to improve further the user-friendly
27 availability of information on the Ph. Eur. to further strengthen the position of the Ph. Eur. within their
28 members and within the international context.

29 As an example: in addition to the information on revised texts that is supplied via the Pharmeuropa
30 platform, also new texts, and if novelties – particularly concerning General Chapters, General Monographs
31 and Monographs on Dosage Forms – could be presented in an easily available and “pre-digested” way.

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33 **4. Review of current working processes and procedures**

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35 The environment in which the European Pharmacopoeia operates evolves with time: e.g. Secretariats (at
36 NPAs and EDQM) have more and more limited resources, and are faced with difficulties to find Experts,
37 Specialists and Chair.

38 This development makes it worth reflecting on if and how to adapt current practice to the changed
39 environment.

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41 **5. Paediatric formulary**

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43 The Presidium fully supports the development of a pan-European paediatric formulary – outside the
44 European Pharmacopoeia, and in close collaboration with the Committee for Pharmaceuticals and
45 Pharmaceutical Care (CD-P-PH).

46 Presidium

47 Dr Jean-Louis Robert, Chair

48 Dr Tobias Gossdschan, Vice-Chair

49 Mr Erik Wolthers, Vice-Chair

50 Dr Susanne Keitel, Director, EDQM

51 Mrs Cathie Vielle, Secretary to the Ph. Eur. Commission