

**Innovative Pharmaceuticals Association of South Africa (IPASA)
Submission**

on the

**Draft Regulations
relating to the
Protection of Personal Information Act**

**Submitted to:
The Information Regulator
Ms M Mphelo**

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1 Introduction

- 1.1 The Innovative Pharmaceutical association of South Africa (**IPASA**) was established in 2013 as a voluntary association of leading international and local pharmaceutical companies dedicated to researching and developing novel medications, medical devices and diagnostic tools. IPASA supports initiatives in both the public and private healthcare sectors to help develop practical solutions to address the country's most pressing healthcare challenges.
- 1.2 IPASA wishes to contribute to the development of a privacy regulatory environment in South Africa that aligns with global best practices and which facilitates, in a practical way, the work it does for the benefit of South Africans.
- 1.3 IPASA is supportive of the Protection of Personal Information Act and would like to affirm our continued support to working with the South African Government to enhance the ethos and values of our society, as enshrined in our democratic Constitution.
- 1.4 IPASA values constructive engagement with government in a consultative process such as commenting on the Draft Regulations relating to the Protection of Personal Information Act.
- 1.5 IPASA submits the following comments on the draft Regulations Relating to the Protection of Personal Information, 2017.
- 1.6 IPASA wishes to note the intent to actively participate in the process with respect to applying for a Code of Conduct for the industry it represents, noting the need to fulfil the criteria as detailed within the Regulations.

2 Regulation 2 and Form 1

- 2.1 Whilst section 11(3) of POPIA requires responsible parties to deal with data subject objections to the processing of their personal information, it does not require the responsible party to assist a data subject to make that objection. Regulation 2(2) is therefore *ultra vires* POPIA.
- 2.2 Form 1 requires a data subject to fill in detailed information about the responsible party to which the objection is being made. The data subject may not know that information, and in any event, is it necessary to provide information about the responsible party to the responsible party which it already knows? We believe that the details of the data subject, the name of the responsible party, the personal information to which objection is being made and the grounds of objection are sufficient.

3 **Regulation 3 and Form 2**

The same comments in respect of Regulation 2(2) and Form 1 apply to Regulation 3(2) and Form 2.

4 **Regulation 4**

4.1 Regulation 4 places a number of obligations on an information officer which are, with respect, not permissible.

4.2 The scope of the duties and activities of an information officer are clearly set out in s 55(1). The power in s 112(2)(d) to deal with things in the regulations “as may be prescribed” is not an open-ended power. The duties prescribed by regulation must be connected to the duties prescribed by POPIA.

4.3 Regulations can never go further than POPIA itself and the information officer cannot be burdened with responsibilities which are not envisaged by POPIA.

4.4 For this reason, and because regulation is subsidiary legislation it is beyond the powers of regulation to oblige and provide an information officer the role to:

4.4.1 develop, implement and monitor a compliance framework. (That is not the job of an information officer);

4.4.2 have responsibility for ensuring that adequate measures and standards exist in order to comply with the requirements of POPIA. (That would elevate an information officer who is not an executive to executive functions which is impermissible, and it goes beyond the scope of POPIA itself);

4.4.3 ensure that preliminary assessments are conducted. (It is unclear what assessments are being referred to. POPIA does not prescribe such obligations);

4.4.4 develop a manual. (Whilst this is an obligation of the responsible party, it is not the obligation of an information officer. In our experience, the manuals produced under the Promotion of Access to Information Act have not lent themselves to practical implementation, particularly those published by government departments in the gazette.

4.5 In other words, the proposed Regulations 4(1)(a), (b), (c), (d) and (e) are *ultra vires* and beyond the powers of regulation. We would like to implore the Government to assess the section of these regulations as in our view they are possibly subject to court review and, with respect, would be set aside if taken on review when published or when attempts are made to enforce those regulations. The duties of the information officer must be confined to those set out in s55 of POPIA itself.

5 **Regulation 5 and Form 3**

5.1 A public or private body which in the opinion of the Regulator sufficiently represents a class of bodies, industry, profession or vocation may apply to the Regulator for the issue of a code of conduct in a form substantially in accordance with Form 3. This suggests that the public or private body must first apply to the Regulator for confirmation that it is sufficiently representative and only once that approval is given, may it proceed to apply for the issuing of a code of conduct. Further, both Regulation 5 and Form 3 are silent as to who prepares the code of conduct.

5.2 IPASA submits that:

5.2.1 the body seeking approval of the code of conduct must do so and that Form 3 should cater for the inclusion or attachment of a draft code of conduct.

5.2.2 the application should require the body to demonstrate that it is sufficiently representative class of bodies, industry, profession or vocation it claims to represent to avoid a two-step process of first seeking approval and then considering the draft code.

5.2.3 the application should contain the grounds as to why the public or private body seeking approval for a code of conduct believes that it is sufficiently representative.

6 **Regulation 6**

6.1 Section 69(2)(b) of POPIA states that the data subject's consent to direct marketing "must be requested in the prescribed manner and form". Regulation 6 states that "a responsible party may request a data subject's consent in writing on a form which corresponds substantially with Form 4..." The requirement in POPIA is mandatory, whereas the requirement in Regulation 6 is discretionary.

6.2 Furthermore, it is not possible for a responsible party who is doing direct marketing to get a form filled in, in the nature of Form 4. We believe this may provide unreasonable and an impractical requirement and will make direct marketing impossible which cannot be the purpose of POPIA. Where s 69(2)(b) provides for the consent to be obtained in the prescribed manner and form, the manner and form has to be rational and reasonable in relation to the purposes of POPIA. The proposal for filling in a form such as Form 4 does not pass this test. In our opinion, the regulation would be set aside on review.